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CONGRESSO NACIONAL
DE PEDIATRIA
25 — 27 OUT 2017
Centro de Congressos
Alfândega do Porto



MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO



Alexandra Vasconcelos



“A DIFERENÇA ENTRE O REMÉDIO E O VENENO
ESTÁ NA CIRCUNSTÂNCIA E NA DOSE”

Anthony Wong



Medicamentos Não Sujeitos a Receita Médica _ MNSRM

NÃO REQUER “PRESCRIÇÃO MÉDICA”



Segundo a Diretiva 92/26 CEE - artigo 3

o MNSRM tem que apresentar um **perfil de segurança aceitável** que permita a sua administração sem supervisão médica proporcionando ao consumidor poupar tempo e custos de tratamento no alívio de situações ligeiras de doença

MNSRM-EF



Desde 2005 estão acessíveis em supermercados e outros pontos de venda sem a supervisão de um farmacêutico



preocupação ao nível da
exequibilidade da monitorização
da segurança dos MNSRM

MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

Despacho nº 2245/2003, de 16 de Janeiro (que revoga o anterior Despacho nº 8637/2002, de 20 de Março)		Despacho nº 17690/2007, de 10 de Agosto	
Sistema	Situações passíveis de automedicação (termos técnicos)		
Digestivo	a) Diarreia. b) Hemorróidas (diagnóstico confirmado). c) Pirose, enfartamento, flatulência. d) Obstipação. e) Vômitos, enjoo do movimento. f) Higiene oral e da orofaringe. g) Endoparasitoses intestinais. h) Estomatites (excluindo graves) e gengivites. i) Odontalgias.	a) Diarreia. b) Hemorróidas (diagnóstico confirmado). c) Pirose, enfartamento, flatulência. d) Obstipação. e) Vômitos, enjoo do movimento. f) Higiene oral e da orofaringe. g) Endoparasitoses intestinais. h) Estomatites (excluindo graves) e gengivites. i) Odontalgias. <i>j) Profilaxia da cárie dentária.</i> <i>k) Candidíase oral recorrente com diagnóstico médico prévio.</i> <i>l) Modificação dos termos de higiene oral por desinfecção oral.</i> <i>m) Estomatite aftosa.</i>	
Respiratório	a) Sintomatologia associada a estados gripais e constipações. b) Odinofagia, faringite (excluindo amigdalite). c) Rinorreia e congestão nasal. d) Tosse e rouquidão	a) Sintomatologia associada a estados gripais e constipações. b) Odinofagia, faringite (excluindo amigdalite). c) Rinorreia e congestão nasal. d) Tosse e rouquidão <i>e) Tratamento sintomático da rinite alérgica perene ou sazonal com diagnóstico médico prévio.</i> <i>f) Adjuvante mucolítico do tratamento antibacteriano das infecções respiratórias em presença de hipersecreção brônquica</i> <i>g) Prevenção e tratamento da rinite alérgica perene ou sazonal com diagnóstico médico prévio (corticóide em inalador nasal)</i>	
Cutâneo	a) Queimaduras de 1.º grau, incluindo solares. b) Verrugas. c) Acne ligeiro a moderado. d) Desinfecção e higiene da pele e mucosas. e) Micoses interdigitais. f) Ectoparasitoses. g) Picadas de insectos. h) <i>Pitiríase capitis</i> (caspa). i) Herpes labial. j) Feridas superficiais. l) Dermatite das fraldas. m) Seborreia. n) Alopecia. o) Calos e calosidades.	a) Queimaduras de 1.º grau, incluindo solares. b) Verrugas. c) Acne ligeiro a moderado. d) Desinfecção e higiene da pele e mucosas. e) Micoses interdigitais. f) Ectoparasitoses. g) Picadas de insectos. h) <i>Pitiríase capitis</i> (caspa). i) Herpes labial. j) Feridas superficiais. l) Dermatite das fraldas. m) Seborreia. n) Alopecia. o) Calos e calosidades.	

MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

	p) Frieiras.	p) Frieiras. q) Tratamento da pitíriase versicolor. r) Candidíase balânica. s) Anestesia tópica em mucosas e pele nomeadamente mucosa oral e rectal. t) Tratamento sintomático localizado de eczema e dermatite com diagnóstico médico prévio.
Nervoso/psique	a) Cefaleias ligeiras a moderadas	a) Cefaleias ligeiras a moderadas b) Tratamento da dependência da nicotina para alívio dos sintomas de privação desta substância em pessoas que desejem deixar de fumar. c) Enxaqueca com diagnóstico médico prévio. d) Ansiedade ligeira temporária. e) Dificuldade temporária em adormecer
Muscular/ósseo	a) Dores musculares ligeiras a moderadas. b) Contusões. c) Dores pós-traumáticas	a) Dores musculares ligeiras a moderadas. b) Contusões. c) Dores pós-traumáticas d) Dores reumáticas ligeiras moderadas (osteartrose/osteoartrite). e) Dores articulares ligeiras a moderadas. f) Tratamento tópico de sinovites, artrites (não infecciosa), bursites, tendinites. g) Inflamação moderada de origem músculo esquelética nomeadamente pós-traumática ou de origem reumática.
Geral	a) Febre (< três dias). b) Estados de astenia de causa identificada. c) Prevenção de avitaminoses.	a) Febre (< três dias). b) Estados de astenia de causa identificada. c) Prevenção de avitaminoses.
Ocular	a) Hipossecção conjuntival, irritação ocular de duração inferior a três dias	a) Hipossecção conjuntival, irritação ocular de duração inferior a três dias b) Tratamento preventivo da conjuntivite alérgica perene ou sazonal com diagnóstico médico prévio. c) Tratamento sintomático da conjuntivite alérgica perene ou sazonal com diagnóstico médico prévio
Ginecológico	a) Dismenorreia primária. b) Contraceção de emergência. c) Métodos contraceptivos de barreira e químicos. d) Higiene vaginal.	a) Dismenorreia primária. b) Contraceção de emergência. c) Métodos contraceptivos de barreira e químicos. d) Higiene vaginal. e) Modificação dos termos de higiene vaginal por desinfeção vaginal. f) Candidíase vaginal recorrente com diagnóstico médico prévio. Situação clínica caracterizada por corrimento vaginal esbranquiçado, acompanhado de prurido vaginal e habitualmente com exacerbação pré-menstrual. g) Terapêutica tópica nas alterações tróficas do tracto génito-urinário inferior acompanhadas de queixas vaginais como disparêunia, secura e prurido
Vascular	a) Síndrome varicosa — terapêutica tópica adjuvante	a) Síndrome varicosa — terapêutica tópica adjuvante b) Tratamento sintomático por via oral da insuficiência venosa crónica (com descrição de sintomatologia).

Medicamentos não sujeitos a receita médica - razões mais frequentes de seu uso

Most frequent reasons for the consumption of Non-prescription Medicines

Ana Fernandes¹, Lídia Palma^{1,2}, Fátima Frazão^{2,3} Carla Monteiro^{1,2}

Recebido em 11/11/2009

Aceite em 25/01/2010

Rev. Lusófona de Ciências e Tecnologias da Saúde, 2010; (7) 1: 47-55

Versão electrónica: <http://revistas.ulusofona.pt/index.php/revistasauda>

“Tradição e confiança são os motivos que movem 90% dos portugueses a comprar Medicamentos Não Sujeitos a Receita Médica (MNSRM) numa farmácia.”^[2]

O estudo nacional de Ana Fernandes refere que a aquisição de um MNSRM destinou-se ao alívio de diversos sintomas:

45,2%	dor/febre
14,4%	problemas respiratórios
2,8%	dificuldade em dormir
8,5%	obstipação/diarreia
2,3%	problemas de estômago
4,6%	fadiga
22,2%	outros sintomas

61,7% não dava conhecimento ao seu médico desse consumo de MNSRM

CAUTION
EMPOWERMENT
ZONE
AHEAD!

POPULAÇÃO PEDIÁTRICA

Esta tipologia de dispensa de medicamento ao público de **MNSRM** fundamenta-se, no entanto, no princípio que os pais

- ➡ tenham um bom nível de literacia para a saúde
- ➡ detenham a capacidade em realizar um correto diagnóstico da situação clínica da sua criança
- ➡ consigam respeitar doses e número de dias de tratamento

**A AUTOMEDICAÇÃO DÁ O CONHECIDO EMPOWERMENT
(AUTONOMIA E CAPACITAÇÃO)**

Downloaded from <http://pediatrics.aappublications.org/> by guest on October 4, 2017

COMMENTARIES (CONTINUED)

Safety and effectiveness of over-the-counter drugs: The FDA's OTC drug review

In this issue there is a report of twin infants ingesting, "sweet spirits of nitre" (p. 000). This tragic example of an over-the-counter drug used for decades prompted us to ask the Food and Drug Administration to comment upon their current activities regarding review of this category of agents. Their investigation of this particular agent reveals no other deaths, but it illustrates the hazards from this large group of drugs which were approved for use under a "grandfather" ruling. We are pleased that action is being taken to review and eliminate from pharmacies those drugs which are useless and hazardous.

R. J. H.

Nonprescription (over-the-counter or OTC) drugs permit patients to treat a wide range of minor, usually self-limiting, problems and may be helpful before professional medical assistance is sought or when it is not immediately available. While their misuse may at times create or compound medical problems, most people perceive OTC drugs as safe and effective in their limited role. In fact, however, the evidence supporting safety and effectiveness of most OTC products has never been subjected to critical review. The principal reason for this is that most

OTC products are made of ingredients marketed long before the modern requirements of the Food, Drug and Cosmetic Act were promulgated.

The predecessor to our contemporary Food, Drug and Cosmetic Act was the Pure Food and Drugs Act of 1906, which provided that drugs marketed in interstate commerce had to meet minimal standards of strength, quality, and purity. Until the Act was amended in 1912, the law did not address the claims made for drugs. Even then, those early requirements were

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The basic we know tragic death of elixir of diethylene glycol antifreeze Drug and that a ma drug not that the c in its label the "gra marketed was per providing their "gra meet the retain the

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these grandfather products, unlike manufacturers of newer drugs, have no obligation to prove them safe or effective. Rather, the burden of proving them unsafe or ineffective in a court of law rests with FDA.

In 1966, the FDA arranged for a review of these 4,000 drugs by the National Academy of Sciences-National Research Council (NAS-NRC). The review, referred to as the Drug Efficacy Study, was conducted by 30 panels of expert physicians who, depending on the available evidence, rated the drugs as effective, probably effective, possibly effective, or lacking evidence

The basic Food, Drug and Cosmetic Act that we know today was established in 1938 after the tragic death of over 100 persons who had taken an elixir of sulfanilamide preparation containing diethylene glycol, a toxic solvent used in automobile antifreeze products. The 1938 Federal Food, Drug and Cosmetic Act required for the first time that a manufacturer show, before marketing any drug not generally recognized by experts as safe, that the drug was safe under the conditions of use in its labeling. Under a provision of the Act called

the "grandfather" clause

COMMENTARIES (CONTINUED)

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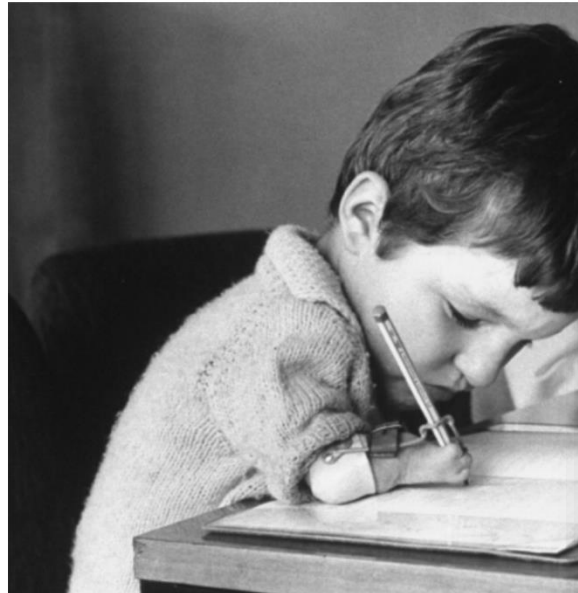
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Following the thalidomide tragedy of the early 1960's, Congress passed the Drug Amendments of 1962, amending the old 1938 Federal Food, Drug and Cosmetic Act to require that all new drugs, prescription and OTC, be proved effective as well as safe before marketing. This Amendment applied to the 4,000 prescription and OTC new drug products that had been approved for safety only between 1938 and 1962, but did not apply to the "grandfather" drugs. The manufacturers of

THE THALIDOMIDE TRAGEDY: LESSONS FOR DRUG SAFETY AND REGULATION

By: Bara Fintel, Athena T. Samaras, Edson Carias

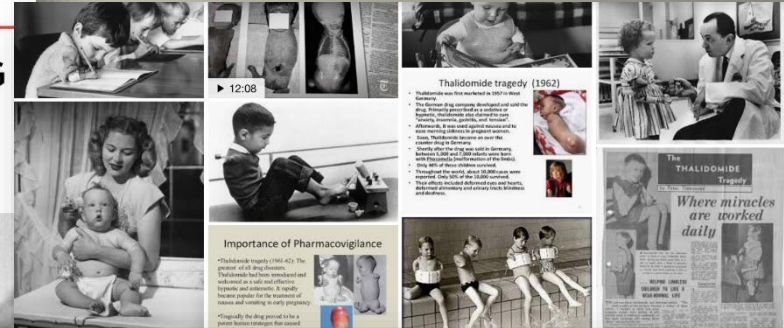
Jul 28, 2009



Many children in the 1960's, like the kindergartner pictured above, wore thalidomide, resulting in the shortening or absence of limbs. (Photo Images)

In a post-war era when sleeplessness was prevalent, thalidomide was a sleeping pill. At the time, one out of seven Americans took them in some European markets, and the presumed safety of thalidomide, gave the drug massive appeal. Sadly, tragedy followed its release, approval and monitoring systems in place at the **United States Food**

Thalidomide first entered the German market in 1957 as an over-the-counter drug. They advertised their product as "completely safe" for everyone, in its developers "could not find a dose high enough to kill a rat." By 1961, sales nearly matching those of aspirin.

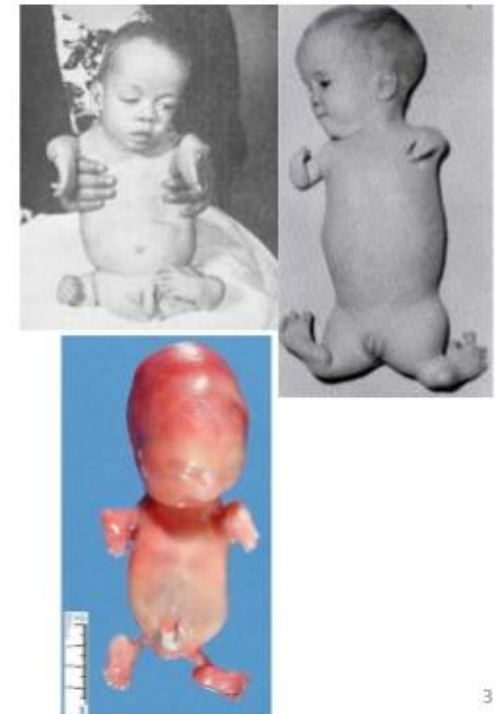


History of Thalidomide Disaster

•Thalidomide tragedy (1961-62): The greatest of all drug disasters. Thalidomide had been introduced and welcomed as a safe and effective hypnotic and antiemetic. It rapidly became popular for the treatment of nausea and vomiting in early pregnancy.

•Tragically the drug proved to be a potent human teratogen that caused major birth defects in an estimated 10,000 children

•Phocomelia was a characteristic feature



MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

Os pais preocupam-se em ter uma solução imediata para o alívio sintomático e cura de qualquer doença dos seus filhos, principalmente na época do inverno com o primeiro ranho no nariz, tosse e noites mal dormidas e basta pesquisar a internet ou as redes sociais para compreender a diversidade de fontes de “autoajuda” à automedicação oriunda de conselhos de outros pais.



A indústria farmacêutica promove eficazmente *nos media* publicidade atrativa aos MNSRM oferecendo **soluções** “**instantâneas**” que vão de encontro à necessidade dos pais incentivando o uso dos MNSRM na população pediátrica.



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Colic Kids

INDICAS DA KEL

FUNCHICÓNEA:

PARA O BEM OU PARA O MAL?



marketing materials and does not require that advertisements show a “fair balance” between risks and benefits. Direct-to-consumer advertisements assert that preparations are safe and effective, and many state that ingredients are “pediatrician-recommended.” A frequent theme is that giving children these products allows parents to relax. In fiscal year 2007, accord-



n engl j med 357;23 www.nejm.org december 6, 2007

A PERCEÇÃO DOS PAIS EM RELAÇÃO

À SEGURANÇA DOS MNSRM

É QUE SÃO MUITO SEGUROS,

COMO QUE INOFENSIVOS

E INTRINSECAMENTE APROVADOS

OU

RECOMENDADOS PELOS PEDIATRAS

~~~~~ Tidings of Joy, ~~~~~ NOT SNIFFLES & SICKNESS

With the holidays come parties, guests, family, travel, road trips and sometimes coughs, runny noses, sore throats and other seasonal symptoms. When given as directed, over-the-counter (OTC) medicines can help treat your child's symptoms.



General Medicine Safety Tips for Parents

**AGE
MATTERS!**



Never give OTC oral cough and cold medicines to children under 4 years.

Safely store medicines up and away and out of sight.
Hide them like you hide their gifts!



Always read the directions carefully and use the measuring device that comes with the medicine.

Never give two medicines with any of the same active ingredients.



Make a list (and check it twice!) of the medicines you give your child.

Pay attention to active ingredients.
Just like when baking holiday cookies!



Talk to a doctor, pharmacist, or other healthcare professional if you have any questions at all.



Never use an OTC medicine for the purpose of making your child sleepy.

Helping parents treat with care through the holiday season and all year long!
Visit OTCsafety.org to learn more.

OTCsafety.org

@OTCSafety

/OTCSafety

Share this with your friends to help spread the information and don't forget to use the hashtag **#OTCSafety**.

A PERCEÇÃO DOS PAIS EM RELAÇÃO À SEGURANÇA DOS MNSRM É QUE SÃO MUITO SEGUROS, COMO QUE INOFENSIVOS E INTRINSECAMENTE APROVADOS OU RECOMENDADOS PELOS PEDIATRAS.

Esta noção potencializa o risco da sua má utilização

- 1) uso indevido (utilização durante um período prolongado de tempo ou de uma dose superior à recomendada)
- 2) utilização em idades contraindicadas (especialmente em crianças <2 anos)
- 3) ocultação dos sintomas
- 4) atraso potencial no correto tratamento de uma doença grave
- 5) risco de aparecimento de reações adversas
- 6) aumento da polimedicação e de interações com outros medicamentos usados regularmente

**DO NOT USE IN CHILDREN
UNDER 5 YEARS**

Parental Misinterpretations of Over-the-Counter Pediatric Cough and Cold Medication Labels

Nicole Lokker, PharmD^a, Lee Sanders, MD, MPH^b, Eliana M. Perrin, MD, MPH^c, Disha Kumar, BA^d, Joanne Finkle, RN, JD^c, Vivian Franco, BS^d, Leena Choi, PhD^e, Philip E. Johnston, PharmD^f, and Russell L. Rothman, MD, MPP^d

Many parents may have difficulty understanding the indications and appropriate dosing of OTC medications. In 2003, the National Assessment of Adult Literacy found that ~90 million Americans have basic or below basic literacy skills, and >110 million people have basic or poor quantitative skills.²² Low-literacy skills are associated with worse understanding of medication labels, worse knowledge of one's disease, and worse clinical outcomes.^{23–33} The role of quantitative skills, or numeracy, has been less studied,^{34,35} but one recent study found that low numeracy was associated with poorer understanding of food labels.³⁶ Little is known about caregivers' ability to choose and dose medications appropriately for their infants and young children.³⁷

RESULTS—A total of 182 caregivers were recruited; 87% were the infants' mothers. Mean education level was 12.5 years, and 99% had adequate literacy skills, but only 17% had >9th-grade numeracy skills. When examining the front of the product label, 86% of the time parents thought these products were appropriate for use in children <2 years of age. More than 50% of the time, parents stated they would give these over-the-counter products to a 13-month-old child with cold symptoms. Common factors that influenced parental decisions included label saying "infant," graphics (eg, infants, teddy bears, droppers), and dosing directions. Caregivers were influenced by the dosing directions only 47% of the time. Caregivers with lower numeracy skills were more likely to provide inappropriate reasons for giving an over-the-counter medication.

MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO



U.S. Food and Drug Administration

3 h · 🌐

SAFETY ADVISORY: Directions for administering Baby Organic Liquid, a dietary supplement for infants, might make it difficult for babies to swallow, possibly causing them to choke. Therefore, Garden of Life asks anyone who's bought this product to return it for a full refund. The company will relabel the product with new directions: **DON'T** put the product directly into the baby's mouth. **DO** mix the product with breast milk or formula **BEFORE** giving it to babies. Baby Organic Liquid, expiration 12/2018, was sold in natural grocers, health food stores, and online. For more information and who to contact if you have any questions: <https://go.usa.gov/xRFmn>.



BENZOCAÍNA DENTISPRAY TOPIGEL

Solução gengival 50 mg/ml
Gel 200 mg/g

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Benzocaine and Babies: Not a Good Mix

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When a baby is teething, many a mom or dad reaches for a pain remedy containing benzocaine to help soothe sore gums. Benzocaine is a local anesthetic and can be found in such over-the-counter (OTC) products as Anbesol, Hurricaine, Orajel, Baby Orajel, and Orabase.

But the use of benzocaine gels and liquids for mouth and gum pain can lead to **rare but serious**—and sometimes fatal—condition called **methemoglobinemia**, a disorder in which the amount of oxygen carried through the blood stream is greatly reduced. In the most severe cases, says FDA pharmacist Mary Ghods, R.Ph., methemoglobinemia can result in death.

And children under 2 years old appear to be at particular risk.



Since the Food and Drug Administration (FDA) first warned about potential dangers in 2006, the agency has received 29 reports of benzocaine gel-related cases of methemoglobinemia. Nineteen of those cases occurred in children, and 15 of the 19 cases occurred in children under 2 years of age, says FDA pharmacist Kellie Taylor, Pharm.D., MPH.

The agency repeated the warning in April 2011 and remains particularly concerned about the use of OTC benzocaine products in children for relief of pain from teething, says Taylor. This concern is fueled by the serious potential outcomes and the difficulty parents may have recognizing the signs and symptoms of methemoglobinemia when using these products at home. These symptoms may not always be evident or attributed to the condition.

For these reasons, FDA recommends that parents and caregivers not use benzocaine products for children younger than 2 years, except under the advice and supervision of a health care professional.

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Danger Signs

Symptoms of methemoglobinemia include:

- pale, gray, or blue-colored skin, lips and nail beds
- shortness of breath
- fatigue
- confusion
- headache
- light-headedness
- rapid heart rate

"Symptoms can occur within minutes to hours after benzocaine use," Ghods says. "They can occur after using the drug for the first time, as well as after several uses."

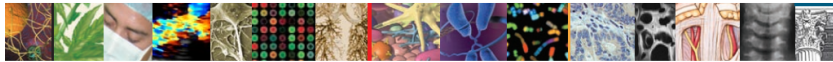
If your child has any of these symptoms after using benzocaine, she adds, stop using the product and seek medical help immediately by calling 911.

Methemoglobinemia caused by benzocaine may require treatment with medications and admission to a hospital. Serious cases should be treated right away. If left untreated or if treatment is delayed, methemoglobinemia may cause permanent injury to the brain and body tissues, and even death, from the insufficient amount of oxygen in the blood.

Tabela 5 – Percentagem de mercado de MNSRM de acordo com a classe terapêutica

	Portugal	Europa
Analgésicos e antipiréticos	19,4	16,5
Antitússicos e expectorantes (Cough and cold)	31,5	20,0
Digestivos e outros fármacos GI	16,2	14,3
Dermatologia	14,3	8,7
Vitaminas, minerais e Suplementos nutricionais	3,1	14,0
Outros MNSRM	15,5	26,5

Dados: A Indústria em Números, ed.2010 (APIFARMA)



The NEW ENGLAND JOURNAL of MEDICINE

Perspective

DECEMBER 6, 2007

Over the Counter but No Longer under the Radar — Pediatric Cough and Cold Medications

Joshua M. Sharfstein, M.D., Marisa North, B.A., and Janet R. Serwint, M.D.

In recent weeks, over-the-counter cough and cold medications for children have received unprecedented attention from regulators, physicians, the media, and parents. This scrutiny represents a

long-overdue reassessment of products that were purchased by 39% of U.S. households during the past 3 years.¹ It also reflects an important evolution in the standard of evidence for medications used in children.

Over-the-counter cough and cold preparations include various combinations of antihistamines, decongestants, antitussives, and expectorants. There is no standard for describing these products; two products marketed similarly may have different types of ingredients (see table). Consumers purchase about 95 million packages of such medication for use in children each year.¹ Within the pediatric com-

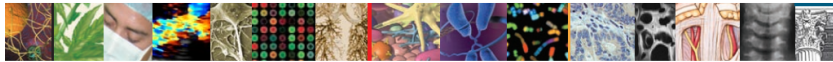
munity, however, concern over the effectiveness and safety of such drugs has been growing for more than two decades.

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Meanwhile, poison-control centers have reported more than 750,000 calls of concern related to cough and cold products since January 2000.² A recent report from the Centers for Disease Control and Prevention identified more than 1500 emergency room visits in 2004 and 2005 for children under 2 years of age who had been given cough or cold products.³ Among other concerns are findings in children under six linking decongestants to cardiac arrhythmias and other cardiovascular events, antihistamines to hallucinations, and antitussives to depressed levels of consciousness and encephalopathy. A review by the Food and Drug Administration (FDA) identified 123 deaths related to the use of such prod-

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The NEW ENGLAND JOURNAL of MEDICINE

Perspective

DECEMBER 6, 2007

Over the Counter but No Longer under the Radar — Pediatric Cough and Cold Medications

Joshua M. Sharfstein, M.D., Marisa North, B.A., and Janet R. Serwint, M.D.

In recent weeks, over-the-counter cough and cold medications for children have received unprecedented attention from regulators, physicians, the media, and parents. This scrutiny represents a

long-overdue reassessment of products that were purchased by 39% of U.S. households during the past 3 years.¹ It also reflects an important evolution in the standard of evidence for medications used in children.

Over-the-counter cough and cold preparations include various combinations of antihistamines, decongestants, antitussives, and expectorants. There is no standard for describing these products; two products marketed similarly may have different types of ingredients (see table). Consumers purchase about 95 million packages of such medication for use in children each year.¹ Within the pediatric com-

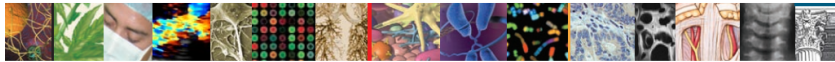
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ucts in children under six during the past several decades.⁴ Serious adverse effects have been associated with accidental overdose, inadvertent misuse, and drug-drug or drug-host interactions in children given standard doses.



MUCOLITICOS, EXPECTORANTES, ANTITÚSSICOS, DECONGESTIONANTES E ANTI-HISTAMÍNICOS - USO EM CRIANÇAS NA TOSSE E ALIVIO SINTOMÁTICO DA CONSTIPAÇÃO -

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Most Young Children With a Cough or Cold Don't Need Medicines

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What can parents do when their babies and young children have a cough or cold? It depends on the child's age.

Although most colds in children don't have serious complications, they can cause worry to caregivers, and are among the top reasons for visiting a doctor. The U.S. Food and Drug Administration doesn't recommend over-the-counter (OTC) cold and cough medicines for children younger than 2. For infants and children younger than 2, those medicines may have serious and [potentially life-threatening side effects](#).

The FDA also warns that children younger than 12 shouldn't take codeine products to treat pain or cough because of the risk of [developing potentially life-threatening breathing problems](#). The FDA recommends against use of codeine in youths ages 12 through 18 who are obese or have conditions such as obstructive sleep apnea (blocked airflow during sleep) or severe lung disease. These risk factors can increase their chances of developing [serious breathing problems](#) when taking these medications.



MUCOLITICOS, EXPECTORANTES, ANTITÚSSICOS, DECONGESTIONANTES E ANTI-HISTAMÍNICOS - USO EM CRIANÇAS NA TOSSE E ALIVIO SINTOMÁTICO DA CONSTIPAÇÃO -

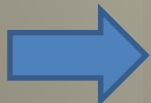
Use Caution When Giving Cough and Cold Products to Kids

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Safety Information for Parents and Caregivers

Children under 2 years of age should not be given any kind of cough and cold product that contains a decongestant or antihistamine because serious and possibly life-threatening side effects could occur. Reported side effects of these products included convulsions, rapid heart rates and death. What about older children? When giving cough and cold medicine to children over 2 years of age, parents and caregivers should use caution.

A meeting about the safety and effectiveness of cough and cold drug product use in children by the U.S. Food and Drug Administration in 2007 revealed that there were many reports of harm, and even death, in children who used these products. During 2004-2005, an estimated 1,519 children less than 2 years of age were treated in U.S. emergency departments for adverse events, including overdoses, associated with cough and cold medications. Manufacturers voluntarily removed over-the-counter (OTC) infant cough and cold products intended for children under 2 years of age due to these safety concerns.



EUROPA

Em Fevereiro de 2008, o **Paediatric Medicines Expert Advisory Group** (PMEAG) e a **Commission on Human Medicines** (CHM) pronunciaram-se sobre o binómio benefício-risco dos medicamentos “cough and cold” OTC em crianças com idade inferior a 2 anos como **não favorável**.

O **Paediatric Medicines Expert Advisory Group** (PMEAG) e a **Commission on Human Medicines** (CHM) aconselharam, igualmente, a implementação das seguintes medidas de segurança para o grupo de medicamentos referidos no que diz respeito à sua utilização em crianças com idades compreendidas entre os 2 – 6 anos:

- a) Introduzir informações sobre a dose máxima diária;
- b) Adicionar o aviso para que não fosse administrado qualquer outro medicamento para a tosse ou alívio sintomático da constipação;
- c) Reforço da instrução para procurar conselho de um farmacêutico ou outro profissional de saúde antes de usar o medicamento.

MUCOLITICOS, EXPECTORANTES, ANTITÚSSICOS, DECONGESTIONANTES E ANTI-HISTAMÍNICOS - USO EM CRIANÇAS NA TOSSE E ALIVIO SINTOMÁTICO DA CONSTIPAÇÃO -

Existem quatro categorias principais de substâncias farmacologicamente activas utilizadas no grupo pediátrico para o alívio sintomático da tosse e rinofaringite/constipação autorizados em Portugal como medicamentos não sujeitos a receita médica (MNSRM):

- **Descongestionantes** (Desloratadina + Sulfato de Pseudoefedrina, Fenilefrina, Cloridrato de Fenilefrina, Oximetazolina, Tonzilamina + Isobenzidrina + Lisozima, Tramazolina, Xilometazolina e Xilometazolina + Brometo de ipratrópio monohidratado)
- **Mucolíticos** (Acetilcisteína, Carbocisteína, Ambroxol, Ambroxol+Clenbuterol e Bromexina) e
Expectorantes (Dornase Alfa, Guaifenesina, Guaifenesina + Paracetamol + Cloridrato de Fenilefrina, Guaifenesina + Salbutamol, Cloperastina, Manitol, Sobrerol e Sobrerol + Carbocisteína),
- **Antitússicos** (dextrometorfano e folcodina) e
- **Anti-histamínicos** (Azelastina, Clemastina, Cromoglicato de sódio, Difenidramina, Difenidramina + Levomentol, Di-hexazina, Dimetindeno, Levocabastina, Mequitazina, Prometazina, Pseudoefedrina + Triprolidina, Pseudoefedrina + Loratadina)

Algumas destas substâncias activas são utilizadas em combinação (muitas associações também contêm analgésicos) para tratar uma variedade de sintomas da rinofaringite/constipação comum.

DESCONGESTIONANTES NASAIS

(Desloratadina + Sulfato de Pseudoefedrina, Fenilefrina, Cloridrato de Fenilefrina, Oximetazolina, Tonzilamina + Isobenzidrina + Lisozima, Tramazolina, Xilometazolina e Xilometazolina + Brometo de ipratrópio mono-hidratado)

Efeito vasoconstritor; diminuem o fluxo sanguíneo na mucosa nasal, ação não seletiva

Efeitos indesejáveis: Hipotensão, náuseas, vômitos, convulsões

Fenilpropanolamina retirada do mercado nos EUA em 2000 por estar associada a hemorragia intracraniana

Descongestionantes tópicos

- Ação direta na mucosa nasal
- Absorção sistêmica é mínima
- Diminui a congestão nasal
- Uso é limitado a poucos dias por risco de *`rebound congestion`* (rinite medicamentosa)
- Não existe informação sobre a eficácia em crianças
- As crianças respiram principalmente pelo nariz, por isto existe preocupação sobre os potenciais perigos associados à sua utilização.

MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

DESCONGESTIONANTES NASAIS

(Desloratadina + Sulfato de Pseudoefedrina, Fenilefrina, Cloridrato de Fenilefrina, Oximetazolina, Tonzilamina + Isobenzidrina + Lisozima, Tramazolina, Xilometazolina e Xilometazolina + Brometo de ipratrópio mono-hidratado)

EFICÁCIA

Há sérias limitações aos estudos de eficácia, dado que muitos dos produtos foram introduzidos há décadas atrás.

Há apenas um estudo cuja conclusão foi inconclusiva sobre a associação de várias substâncias ativas, uma delas sendo a pseudoefedrina usada no alívio sintomático da constipação em crianças com idades compreendidas entre os 2 e os 16 anos.

Não há estudos adequadamente desenhados dos descongestionantes nasais simpatomiméticos nesta população, não sendo portanto possível estabelecer um benefício favorável.



DESCONGESTIONANTES NASAIS

(Desloratadina + Sulfato de Pseudoefedrina, Fenilefrina, Cloridrato de Fenilefrina, Oximetazolina, Tonzilamina + Isobenzidrina + Lisozima, Tramazolina, Xilometazolina e Xilometazolina + Brometo de ipratrópio mono-hidratado)

SEGURANÇA

A partir dos dados relatados pelo Reino Unido:

138 reações graves em crianças com idade inferior a 12 anos, três delas classificadas como sobredosagens.

89 reações graves em crianças com idade igual ou inferior a 6 anos

3 destas relatados como sobredosagem

(ou seja, todas as notificações relacionadas com sobredosagens ocorreram no grupo etário mais jovem)

DESCONGESTIONANTES NASAIS

(Desloratadina + Sulfato de Pseudoefedrina, Fenilefrina, Cloridrato de Fenilefrina, Oximetazolina, Tonzilamina + Isobenzidrina + Lisozima, Tramazolina, Xilometazolina e Xilometazolina + Brometo de ipratrópio mono-hidratado)

POPULAÇÃO PEDIÁTRICA

Descongestionantes tópicos nasais:

As substâncias ativas fenilefrina, efedrina, nafazolina e tramazolina deverão ser **contraindicadas em crianças com menos de 6 anos.**

Os descongestionantes nasais contendo oximetazolina ou xilometazolina com formulações pediátricas específicas (2-6 anos) não apresentam contraindicações relacionadas com a idade.

Todos os descongestionantes nasais tópicos deverão apenas ser utilizados por um período máximo de 5 dias.

Neo-sinefrina – cloridrato de fenilefrina - 2,5 mg/ml não é recomendada para crianças com menos de 6 anos.

Em crianças com idade inferior a 6 anos deverá consultar previamente um médico

Nasorhinathiol - Cloridrato de oximetazolina - 0,25 mg/ ml gotas nasais, solução

MUCOLÍTICOS

(Acetilcisteína, Carbocisteína, Ambroxol, Ambroxol+Clenbuterol e Bromexina)

EFICÁCIA

SEGURANÇA

On 15 February 2008 the French Health Authorities (Afssaps) launched a national pharmacovigilance survey concerning the occurrence of serious adverse drug reactions following oral administration of both mucolytic and expectorant drugs in children under 2 years of age.

According to the French Authorities, the analysis of the results performed in January 2009 shows that recent pharmacovigilance data modify the safety profile of all mucolytic agents and suggest an increased risk associated with the use of these products.

*Therefore, in the absence of new efficacy data on acetylcysteine, the evaluation of positive therapeutic effects of the drug compared to the risks for the patients **is no longer favorable in children below 2 years of age.** The final decision on this survey has been taken by the French National Pharmacovigilance Committee on 24 March 2009.*

MUCOLÍTICOS

(Acetilcisteína, Carbocisteína, Ambroxol, Ambroxol+Clenbuterol e Bromexina)

SEGURANÇA

No registo de dados do MHRA ADR há **78** relatórios de ocorrências graves associadas aos expetorantes em crianças com idade inferior a 12 anos:

55 em crianças menores de 6 anos

23 em crianças dos 6-12 anos

2 casos foram associados com sobredosagem accidental em crianças menores de 6 anos.

Proposta de harmonização para a população pediátrica

Contraindicar os mucolíticos em crianças com idade igual ou inferior a 2 anos.

MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

ANTITÚSSICOS

(dextrometorfano)

DCI / Nome Genérico <i>Active substance / INN</i>	Nome do Medicamento <i>Medicinal product's name:</i>	Forma Farmacêutica <i>Dosage Form</i>	Dosagem <i>Strength</i>	Titular <i>MA holder</i>	Estado de Autorização <i>Authorisation status</i>	Detalhes <i>Details</i>	Genérico <i>Generic</i>
Dextrometorfano	Benflux Tosse Seca	Solução oral	2 mg/ml	Laboratórios Atral, S.A.	Autorizado		Não
Dextrometorfano	Bisoltussin	Pastilha mole	10.5 mg	Sanofi - Produtos Farmacêuticos, Lda.	Autorizado		Não
Dextrometorfano	Bisoltussin Tosse Seca	Solução oral	2 mg/ml	Sanofi - Produtos Farmacêuticos, Lda.	Autorizado		Não
Dextrometorfano	Broncoliber tosse seca	Xarope	2 mg/ml	Tecnimed - Sociedade Técnico-Medicinal, S.A.	Autorizado		Não
Dextrometorfano	Calmarum tosse seca e irritativa	Solução oral	2 mg/ml	Sociedade Farmacêutica Gestafarma, Lda.	Autorizado		Não
Dextrometorfano	Dextrometorfano Azevedos	Solução oral	2 mg/ml	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Autorizado		Não
Dextrometorfano	Dextrometorfano Tussilene	Solução oral	2 mg/ml	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Autorizado		Não
Dextrometorfano	Diacol	Xarope	1.8 mg/ml	Bial - Portela & Cª, S.A.	Autorizado		Não
Dextrometorfano	Drill Tosse Seca	Xarope	1 mg/ml	Pierre Fabre Dermo-Cosmétique Portugal, Lda.	Autorizado		Não
Dextrometorfano	Holsec	Xarope	2 mg/ml	Holon, S.A.	Autorizado		Não
Dextrometorfano	Toceliv	Xarope	2 mg/ml	Laboratórios Basi - Indústria Farmacêutica, S.A	Autorizado		Não
Dextrometorfano	Tussican	Xarope	3 mg/ml	Medinfar Consumer Health - Produtos Farmacêuticos, Lda.	Autorizado		Não
Dextrometorfano	Tussoral	Xarope	1.33 mg/ml	Sanofi - Produtos Farmacêuticos, Lda.	Autorizado		Não
Dextrometorfano	Vicks Xarope Antitussico Mel	Xarope	1.33 mg/ml	Laboratorios Vicks, S.L.	Autorizado		Não
Dextrometorfano + Efedrina	Mebocatuss	Xarope	2 mg/ml + 0.5 mg/ml	GlaxoSmithKline Consumer Healthcare Produtos para a Saúde e Higiene Lda.	Autorizado		Não

Mostrando 15 resultados por página. Está a visualizar a página 1 de 3

ANTITÚSSICOS

(dextrometorfano)



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can help. [CLICK](#)
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Florida Bans Teens From Buying Cough Syrup

By *McCarton Ackerman* 01/10/17

The ban is being praised by Florida health professionals who believe that cough medicine can be a gateway drug.

Florida kicked off 2017 with a new law that bans teens from buying cough medicine in order to prevent them from potentially scoring an easy over-the-counter high. Those who appear to be under 25 years old will be required to show their ID at the register.

Senate Bill 938, which went into effect on Jan. 1, applies to anyone under age 18 and is specifically applied to cough medicines containing dextromethorphan (DXM). The ingredient can be found in numerous over-the-counter products including Robitussin, NyQuil, Alka Seltzer Plus and Tylenol Cough & Cold.



MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

ANTITÚSSICOS

(dextrometorfano)

I realized people were using it in the streets," **said** Dawn Rantinella, a pharmacist in West Palm Beach, to local news outlet WPTV. "We started buying smaller bottles instead of the bigger bottles and regulating ourselves on it so we would see what was going on with the bottles."

The new law was praised by health professionals throughout the state, many of whom believe that cough medicine can be a gateway drug to other substances.

"It's definitely going to be a game changer," said Nita Pettis, a primary therapist with South Ocean Recovery drug rehabilitation in West Palm Beach. "Hopefully it will help to decrease the number of people that become addicted to more harder, life-changing and life-devastating drugs."

A 2009 survey by the Substance Abuse and Mental Health Services Administration (SAMHSA) showed that more than three million young Americans had abused cold or cough medicine, with dextromethorphan being the most widely abused over-the-counter substance. U.S. poison control centers **reported a seven-fold increase** in cases involving 15- and 16-year-olds with DXM between 1999 and 2004.

The trend among American teens has even resorted to gross extremes, with some reportedly **"butt chugging"** cough syrup to get high.

One manufacturer even took matters into its own hands to address abuse of its products. In April 2014, pharmaceutical company Actavis **ceased all sales and production** of its Promethazine Codeine product due to it widely being used in the drug concoction known as "sizzurp," a combination of sugary soft drinks, hard candy and prescription cough syrup. A single serving of sizzurp contains 25 times the recommended dosage of codeine.

ANTITÚSSICOS

(dextrometorfano)

≡ WILLAMETTE WEEK



Oregon Lawmakers Vote to Curb Teenagers' Abuse of Cough Syrup

The Oregon State Senate voted today to limit access to DXM, a common drug found in over-the-counter cough suppressants.



ANTITÚSSICOS

(dextrometorfano)

≡ WILLAMETTE WEEK



By Sophia June | Published March 23 • Updated March 23

The Oregon State Senate voted Wednesday to require teenagers to get a doctor's prescription to purchase DXM, a common drug found in over-the-counter cough suppressants.

The bill makes it illegal to sell DXM, which stands for dextromethorphan, to anyone under 17, without a prescription. The bill also requires that anyone under 25 be asked to prove their age.

"DXM, though safe in small doses, can pose a serious threat that can lead to death, brain damage and several other health problems that can be prevented by keeping this substance out of the hands of unsupervised youth," says Sen. Elizabeth Steiner Hayward (D- NW Portland and Beaverton), who sponsored the bill.

DXM is found in more than a hundred over-the-counter medicines, such as Teraflu and Niquil. When it's induced at 10 to 20 times it's recommended dosage, it produces euphoric effects.

Earlier this month, two members of the U.S. House of Representatives introduced a bill to establish a national age requirement for the purchase of



About Sophia June

Web editor Sophia June has been with Willamette Week since 2015. After graduating from the University of Oregon, where she spent too many nights as a radio DJ, she is happy to be working at her hometown alt weekly.

MOST READ

We Visited Wakonda, A Place That Ken Kesey Invented for a Book, Which Exists Anyway



Two Decades After Author Jim Goad Fell From Grace In Portland, He's Re-emerged As an Icon of the Alt-Right



ANTITÚSSICOS

A supressão da tosse pode ser perigosa especialmente em crianças com asma

Antitússico mais comum: **dextrometorfano (DXM)**

Efeitos Indesejáveis

- ➡ Depressão respiratória
- ➡ Síndrome de serotononérgico
- ➡ Alucinações

Potencial para utilização como droga de abuso em adolescentes

A Academia Americana de Pediatria não recomenda o uso de antitússicos

Outros antitússicos

Codeína – A AAP não recomenda o seu uso

Anti-histamínicos de primeira geração

Proposta de harmonização para a população pediátrica

Contraindicar os antitússicos comercializados como MNSRM (OTC), em **crianças com idade igual ou inferior a 6 anos**.

Os medicamentos para a tosse e constipação contendo codeína ou um dos seus derivados serão sujeitos a prescrição, incluindo para adultos.

EFICÁCIA

Foram identificados dez estudos relacionados com o uso de antitússicos no tratamento de tosse aguda em crianças. Houve 8 estudos de revisão sobre a eficácia de dextrometorfano (DXM) na população pediátrica. Apenas 3 deles relataram um grau variável de efeito positivo sobre os scores de sintomas.

Os outros estudos mais recentes falharam em demonstrar qualquer efeito de DXM no tratamento de tosse aguda, mesmo quando comparado com o mel.

SEGURANÇA

No registo de dados do MHRA ADR DXM:

14 ocorrências sérias em crianças com 12 anos de idade

18 suspeitas de reações graves em crianças com idade inferior a 12 anos.

As reações mais frequentemente relatadas:

distúrbios neuro-psiquiátricos (7/18)

reações cutâneas (5/18)

Não houve nenhum caso fatal no Reino Unido.

ANTI-HISTAMÍNICOS

ANTI-HISTAMÍNICOS

PRIMEIRA GERAÇÃO

Anti-histamínicos H1 sedativos

CINARIZINA
CLEMASTINA
CLOROFENOXAMINA
DI-HEXAZINA
DIFENIDRAMINA
DIMETINDENO
HIDROXIZINA
MEQUITAZINA
PROMETAZINA
PSEUDOEFEEDRINA + TRIPROLIDINA
TRIPROLIDINA

Ingrediente comum nos medicamentos de venda livre
`cough and cold`

Efeitos anticolinérgicos:

- Diminuição da produção de muco
- Boca seca, visão turva
- Retenção urinária, Distúrbios gastrointestinais
- Efeitos cardíacos
- Efeitos no Sistema Nervoso Central

The infographic features a dark red background with white and yellow text. At the top, a white cloud contains the text "A CHEAT SHEET" in red, followed by "FOR PARENTS OF LITTLE ONES WITH ALLERGIES" in brown. Below this, a large white speech bubble asks "CAN I USE OTC ALLERGY MEDICINES TO MAKE MY CHILD SLEEPY?". To the right is a brown bottle of allergy medicine with a white cap. The label on the bottle has a red section with the word "READ" in white, followed by "THE DRUG FACTS LABEL FIRST." in white. Below this, in smaller white text, it says: "Many commonly used allergy medicines including those containing diphenhydramine, cetirizine and chlorpheniramine should not be given to a child under 6 years old." To the right of the bottle, a white speech bubble asks "DO YOU HAVE A CHILD UNDER THE AGE OF 6?". At the bottom left, the word "NO!" is written in large, bold, white letters. At the bottom center, it says "TALK TO A DOCTOR IF YOU HAVE ANY QUESTIONS AND LEARN MORE AT OTCsafety.org". At the very bottom, there are three social media icons: a blue circle with "OTCsafety.org", a blue circle with "@OTCSafety", and a blue circle with "/OTCsafety".

A CHEAT SHEET
FOR PARENTS OF LITTLE ONES WITH ALLERGIES

CAN I USE OTC ALLERGY MEDICINES TO MAKE MY CHILD SLEEPY?

DO YOU HAVE A CHILD UNDER THE AGE OF 6?

READ
THE DRUG FACTS LABEL FIRST.

Many commonly used allergy medicines including those containing diphenhydramine, cetirizine and chlorpheniramine should not be given to a child under 6 years old.

NO!

TALK TO A DOCTOR IF YOU HAVE ANY QUESTIONS
AND LEARN MORE AT OTCsafety.org

OTCsafety.org @OTCSafety /OTCsafety

ANTI-HISTAMÍNICOS

SEGUNDA GERAÇÃO

Não têm efeitos no SNC

Não tem atividade anticolinérgica

Poucos estudos sobre o uso dos anti-histamínicos em crianças nas indicações da rinite/constipação

Vários estudos nos adultos mostraram alívio sintomático com AH de primeira geração



Os anti-histamínicos não sedativos: bilastina, cetirizina, desloratadina (metabolito ativo da loratadina), levocetirizina (isômero da cetirizina), loratadina, mizolastina e rupatadina.



EFICÁCIA

SEGURANÇA

No registo de dados do MHRA ADR há **127 notificações graves** com a utilização dos anti-histamínicos e associações com AH utilizadas para o alívio sintomático da tosse e da constipação em crianças com idade inferior a 12 anos:

92 em crianças menores de 6 anos

35 em crianças de 6-12 anos

Apenas um caso foi associado com sobredosagem accidental

Proposta de harmonização para a população pediátrica

Para os medicamentos com associações de várias substâncias que incluam anti-histamínicos, estes deverão ser contraindicados nas crianças com idade igual ou inferior a 6 anos de idade.

De forma isolada, cada anti-histamínico tem já estudos específicos para cada limite etário e respetiva idade mínima em que podem ser administrados pelo que deverá ser o mesmo autorizado caso-a-caso.

Em relação aos AH comercializados como MNSRM deverá ser introduzida a informação de que o anti-histamínico não deverá ser utilizado se a criança não tem um corrimento nasal e que não deve ser usado para sedar a criança.

Aerius (MSRM)

Taking into account the PRAC Assessment Report on the PSUR(s) for desloratadine, the scientific conclusions of the CHMP are as follows: Two literature reports identified a possible relationship between aggressive reaction/abnormal behaviour and desloratadine use with supportive temporal relationships, positive dechallenges and some with positive rechallenges. Similar cases were reported in Eudravigilance for the reference period. **Considering the potential seriousness of these events in children,** and the number of reported cases with positive dechallenge and rechallenge, the **‘abnormal behaviour’** and **‘aggression’** should be added to the list of adverse drug reactions (ADRs) of desloratadine. A literature article published during the reference period describes **4 cases of epilepsy in children with a family history of epilepsy or relevant medical history.** The causality was assessed as possible for each case, based on temporal association and positive dechallenge. Based on these new data, it could be concluded that desloratadine may aggravate pre-existing seizures in patients (and mainly in children) with medical history of seizures, and that caution should be recommended in treating epileptic patients or those susceptible to convulsions with desloratadine. Based on 4 new publications regarding a possible association between desloratadine and **QT prolongation** were reported in the literature and the fact that ‘QT prolongation’ is already listed as an ADR of desloratadine-containing products, this adverse reaction should be listed as an ADR of any desloratadine-containing product. 4

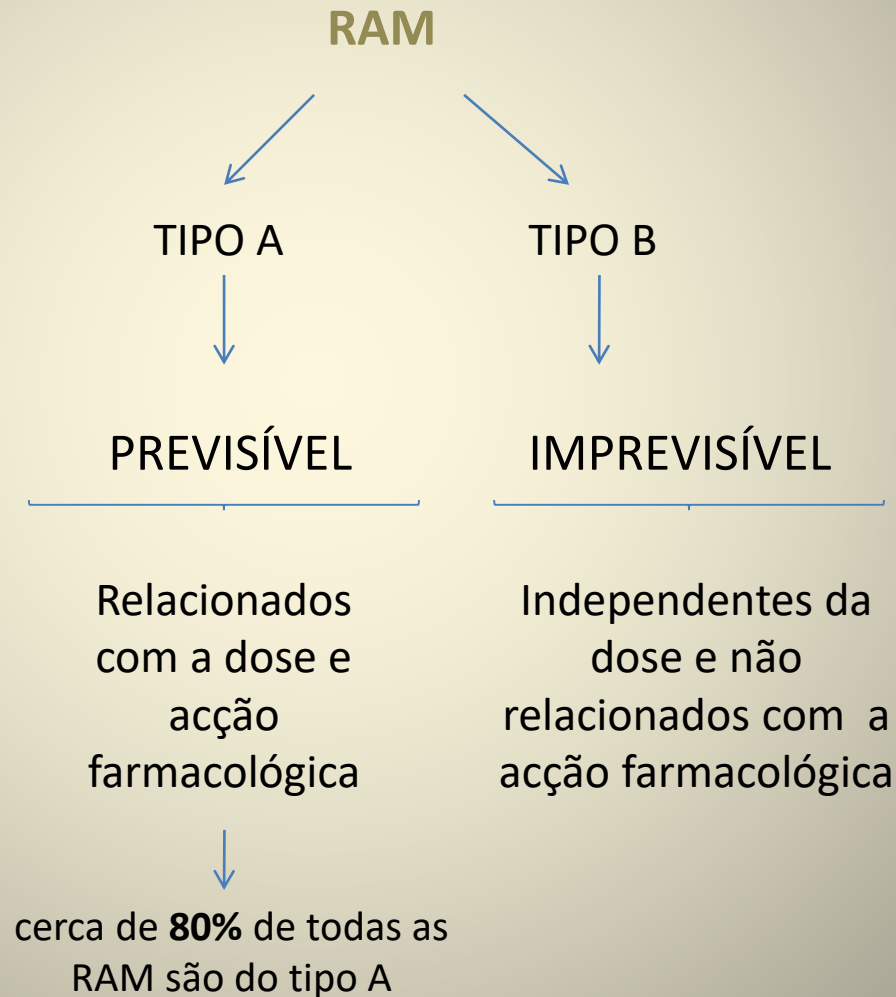
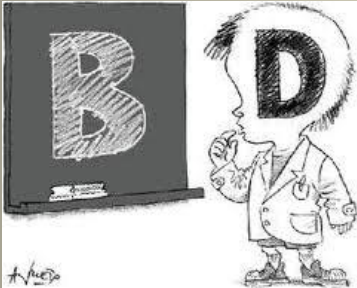
Tabela 5 – Percentagem de mercado de MNSRM de acordo com a classe terapêutica

	Portugal	Europa
Analgésicos e antipiréticos	19,4	16,5
Antitússicos e expectorantes (Cough and cold)	31,5	20,0
Digestivos e outros fármacos GI	16,2	14,3
Dermatologia	14,3	8,7
Vitaminas, minerais e Suplementos nutricionais	3,1	14,0
Outros MNSRM	15,5	26,5

Dados: A Indústria em Números, ed.2010 (APIFARMA)

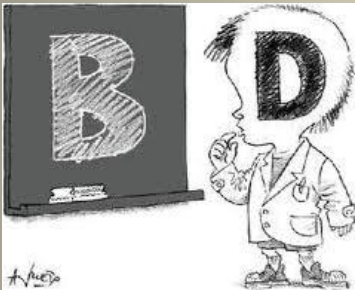
RAM PEDIÁTRICAS

CLASSIFICAÇÃO DE RAM SEGUNDO PATTERSON



RAM PEDIÁTRICAS

CLASSIFICAÇÃO DE RAM SEGUNDO PATTERSON



RAM

TIPO A

PREVISÍVEL

Relacionados
com a dose e
acção
farmacológica



EFEITOS INDESEJÁVEIS



EFEITOS SECUNDÁRIOS



INTERACÇÕES MEDICAMENTOSAS



SOBREDOSAGEM E INTOXICAÇÃO

O estudo de Asseray *et al* constatou que 1% das admissões nas urgências se deve aos efeitos indesejáveis dos MNSRM.

A título de exemplo, os desequilíbrios hidroelectrolíticos nas crianças/jovens pelo uso de laxantes e o uso abusivo do dextrometorfano nos jovens a fim de provocar estados de alteração da consciência e alucinações.



59,000

Number of children in the United States who are treated in emergency departments each year due to unintentional medication poisoning.

4

Number of bus loads of children treated in emergency departments every day due to unintentional medication poisoning.

Agentes frequentes nas intoxicações em crianças

- Paracetamol
- MNSRM: xarope tosse, anti-inflamatórios, vitaminas, ferro
- parafina /querosene
- medicamentos antidepressivos, narcóticos, analgésicos e drogas ilícitas
- pesticidas, insecticidas e herbicidas
- produtos de limpeza (lixívia, detergentes, desinfectantes), cosméticos

PARACETAMOL

Parents:

Acetaminophen in pain relief medicines can cause liver damage.



Drug Facts

Active ingredient	Purpose
Acetaminophen.....	Pain reliever/fever reducer



FDA

U.S. Department of
Health and Human Services
Food and Drug Administration
www.fda.gov/drugs
1-888-INFO-FDA

Background

According to data from the American Association of Poison Control Centers, 11% of children younger than 6 years exposed to pharmaceuticals experience a medication error [1]. Recent findings indicate that most preventable adverse drug events in pediatric outpatients are attributable to errors in medication administration [2].

Errors occur frequently; at least 50% of parents make errors when dosing liquid medications [3,4]. Although acetaminophen is available as a nonprescription over-the-counter (OTC) medication and is generally considered

safe for children, acetaminophen is one of the most frequently implicated pharmaceuticals involved in cases reported to the American Association of Poison Control Center's National Poison Data System [5]. Researchers have demonstrated that acetaminophen-dosing errors occur more than 25% of the time and that this percentage increases to more than 50% of the time if patients are Spanish-speaking, despite caregivers receiving written dosing instructions [6]. This is particularly troubling as acetaminophen has a narrow therapeutic index with overdose linked to hepatotoxicity and death [6,7]. Recently, a US Food and Drug Administration advisory board was convened to focus on strategies to decrease acetaminophen-related toxic exposure [8]

* Correspondence: rdudas@jhmi.edu
Department of pediatrics, Johns Hopkins University School of Medicine,
Baltimore, MD, USA

PARACETAMOL

- antipirético-analgésico mais utilizado
- seguro quando administrado em doses terapêuticas
- overdose provoca toxicidade hepática que pode ser fatal
- 30% das intoxicações ocorrem em crianças com < 6 anos e 22% entre os 6-19 anos

intoxicação accidental

- comportamento exploratório (crianças mais novas); raramente é tóxica
- erro dosagem (dose / frequência); causa maioria das mortes

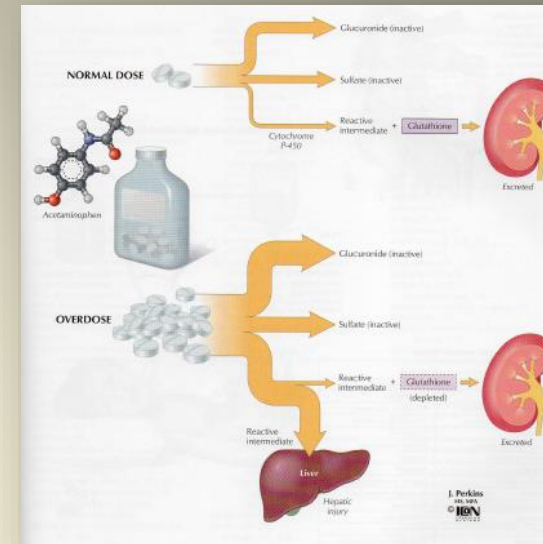
Intencional

- ideação suicida (adolescentes)

PARACETAMOL

Dose tóxica:

- dose tóxica mínima para uma única ingestão é 150 mg/kg
- ou 150 to 175 mg/kg para doses múltiplas (em 2-3d)
- maior risco toxicidade após dose única > 250mg/kg ou ingestões > 12g em 24h
- doses > 350mg/kg levam a toxicidade hepática



Doses repetidas (supraterapêuticas) estão associadas a maior morbidade e mortalidade do que dose única

PARACETAMOL

Toxicidade hepática

- aspartato aminotransferase (AST) ou alanina aminotransferase (ALT) > 1000 IU/L

Factores de risco

- idade (> risco em crianças com < 5a);
- doses múltiplas (supraterapêuticas);
- jejum e malnutrição
- co-morbilidades
- ingestão de múltiplos fármacos

Did You Know?

Before giving your child medicine, make sure you know your abbreviations:

tbsp = tablespoon

tsp = teaspoon

oz = ounce

ml = milliliter

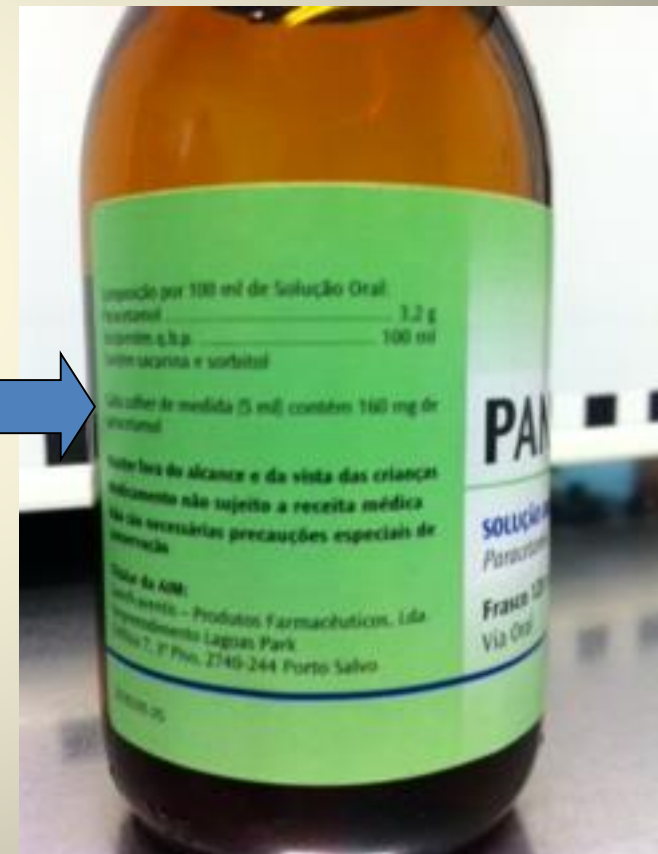
mg = milligram

If the prescribed dose is in a different unit than your measuring syringe, cup, or spoon, don't try to convert it - and don't use a regular spoon because that's not the same as a measuring spoon. Instead, head to your local store or pharmacy for a measuring instrument that will provide an accurate dose.



MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

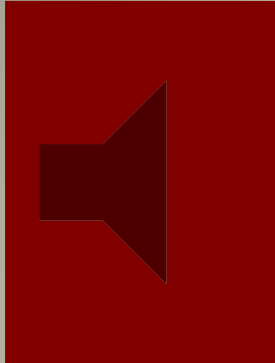
PARACETAMOL



5 mL ----- 160 mg paracetamol

1 mL ----- 32 mg de paracetamol

PARACETAMOL



CUIDADO

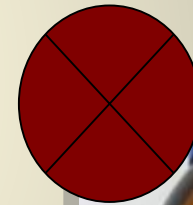
PARACETAMOL

BEN U RON

XAROPE 200 mg/5 ml

5 mL ----- **200 mg**

1 mL ----- 40 mg



MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO

PARACETAMOL

Numa breve análise, há as seguintes discrepâncias nas doses recomendadas nos RCMs e Fis do

TYLENOL®	10 a 15 mg/kg/dose
Ben-U-ron®	15 a 20 mg/kg/dose
Panasorbe®	15 mg/kg/dose

Por vezes a recomendação é indicada por idade outras por peso e esta está expressa ora em ml ora em mg ou em colher (ex. ½ colher).

[illegible]

PARACETAMOL

Odyx	Comprimido prodigioso	350 mg	Tratamento sintomático de situações dolorosas que requerem um analgésico e/ou um anti-inflamatório, tais como: - Sintomatologia associada a estados gripais; - Febre (com duração inferior a 3 dias); - Cefaleias ligeiras a moderadas; - Dor de dente com diagnóstico médico prévio, de intensidade ligeira a moderada; - Dor nas costas, de intensidade ligeira a moderada; - Dor ligas, de intensidade ligeira a moderada; - Dor menomais, de intensidade ligeira a moderada; - Doras traumáticas, musculares e articulares, de intensidade ligeira a moderada.	<table><thead><tr><th>Peso (kg)</th><th>Idade</th><th>Dose individual</th><th>Dose máxima diária (24h)</th></tr></thead><tbody><tr><td>27 - 27 kg</td><td>6-8 anos</td><td>3,2 comprimidos</td><td>6-8 comprimidos (equivalente a 1000 - 1000 mg de paracetamol)</td></tr><tr><td>28 - 40 kg</td><td>9-12 anos</td><td>3,2 comprimidos</td><td>8-8 comprimidos (equivalente a 1000 - 1000 mg de paracetamol)</td></tr><tr><td>> 40 kg</td><td>> 12 anos</td><td>3,2 comprimidos</td><td>9-12 comprimidos (equivalente a 1000 mg - 1000 mg de paracetamol)</td></tr></tbody></table>	Peso (kg)	Idade	Dose individual	Dose máxima diária (24h)	27 - 27 kg	6-8 anos	3,2 comprimidos	6-8 comprimidos (equivalente a 1000 - 1000 mg de paracetamol)	28 - 40 kg	9-12 anos	3,2 comprimidos	8-8 comprimidos (equivalente a 1000 - 1000 mg de paracetamol)	> 40 kg	> 12 anos	3,2 comprimidos	9-12 comprimidos (equivalente a 1000 mg - 1000 mg de paracetamol)	4 anos																																
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Paracetamol Farmalider	Granulado orodispersível	300 mg	Paracetamol Farmalider é utilizado para o tratamento sintomático da dor ligeira a moderada e febre.	6-12 anos 1 a 4 vezes. Dose diária máxima 2 g por dia	Não é adequado para crianças com idade inferior a 6 anos e com menos de 15 kg de peso corporal																																																
Gen-U-Ron	Xarope	40 mg/ml	Tratamento sintomático de situações dolorosas que requerem um analgésico e/ou um anti-inflamatório, tais como: - Sintomatologia associada a estados gripais; - Febre (com duração inferior a 3 dias); - Cefaleias ligeiras a moderadas; - Dor de dente com diagnóstico médico prévio, de intensidade ligeira a moderada; - Dor nas costas, de intensidade ligeira a moderada; - Dor ligas, de intensidade ligeira a moderada; - Dor menomais, de intensidade ligeira a moderada; - Doras traumáticas, musculares e articulares, de intensidade ligeira a moderada.	<table><thead><tr><th>Peso (kg)</th><th>Dose individual (equivalente a paracetamol)</th><th>Dose máxima diária (24 horas) (equivalente a paracetamol)</th></tr></thead><tbody><tr><td>3 kg</td><td>Apesar de 1 mg/kg (até 6 meses por dia) 1,5 ml (60 mg de paracetamol)</td><td>30 mg/kg (até 6 meses por dia) 4,5 ml (180 mg de paracetamol)</td></tr><tr><td>4 kg</td><td>2 mg/kg (até 6 meses por dia) 2,5 ml (100 mg de 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paracetamol)</td><td>420 mg/kg (até 6 meses por dia) 63 ml (2520 mg de paracetamol)</td></tr><tr><td>30 a 32 kg</td><td>15 mg/kg (até 6 meses por dia) 15,5 ml (620 mg de paracetamol)</td><td>450 mg/kg (até 6 meses por dia) 67,5 ml (2700 mg de paracetamol)</td></tr></tbody></table>	Peso (kg)	Dose individual (equivalente a paracetamol)	Dose máxima diária (24 horas) (equivalente a paracetamol)	3 kg	Apesar de 1 mg/kg (até 6 meses por dia) 1,5 ml (60 mg de paracetamol)	30 mg/kg (até 6 meses por dia) 4,5 ml (180 mg de paracetamol)	4 kg	2 mg/kg (até 6 meses por dia) 2,5 ml (100 mg de paracetamol)	60 mg/kg (até 6 meses por dia) 9 ml (360 mg de paracetamol)	5 kg	3 mg/kg (até 6 meses por dia) 3,5 ml (140 mg de paracetamol)	90 mg/kg (até 6 meses por dia) 13,5 ml (540 mg de paracetamol)	6 kg	4 mg/kg (até 6 meses por dia) 4,5 ml (180 mg de paracetamol)	120 mg/kg (até 6 meses por dia) 18 ml (720 mg de paracetamol)	7 kg	5 mg/kg (até 6 meses por dia) 5,5 ml (220 mg de paracetamol)	150 mg/kg (até 6 meses por dia) 22,5 ml (900 mg de paracetamol)	8 kg	6 mg/kg (até 6 meses por dia) 6,5 ml (260 mg de paracetamol)	180 mg/kg (até 6 meses por dia) 27 ml (1080 mg de paracetamol)	9 kg	7 mg/kg (até 6 meses por dia) 7,5 ml (300 mg de paracetamol)	210 mg/kg (até 6 meses por dia) 31,5 ml (1260 mg de paracetamol)	10 kg	8 mg/kg (até 6 meses por dia) 8,5 ml (340 mg de paracetamol)	240 mg/kg (até 6 meses por dia) 36 ml (1440 mg de paracetamol)	11 a 12 kg	9 mg/kg (até 6 meses por dia) 9,5 ml (380 mg de paracetamol)	270 mg/kg (até 6 meses por dia) 40,5 ml (1620 mg de paracetamol)	13 a 15 kg	10 mg/kg (até 6 meses por dia) 10,5 ml (420 mg de paracetamol)	300 mg/kg (até 6 meses por dia) 45 ml (1800 mg de paracetamol)	16 a 18 kg	11 mg/kg (até 6 meses por dia) 11,5 ml (460 mg de paracetamol)	330 mg/kg (até 6 meses por dia) 49,5 ml (1980 mg de paracetamol)	19 a 21 kg	12 mg/kg (até 6 meses por dia) 12,5 ml (500 mg de paracetamol)	360 mg/kg (até 6 meses por dia) 54 ml (2160 mg de paracetamol)	22 a 25 kg	13 mg/kg (até 6 meses por dia) 13,5 ml (540 mg de paracetamol)	390 mg/kg (até 6 meses por dia) 58,5 ml (2340 mg de paracetamol)	26 a 29 kg	14 mg/kg (até 6 meses por dia) 14,5 ml (580 mg de paracetamol)	420 mg/kg (até 6 meses por dia) 63 ml (2520 mg de paracetamol)	30 a 32 kg	15 mg/kg (até 6 meses por dia) 15,5 ml (620 mg de paracetamol)	450 mg/kg (até 6 meses por dia) 67,5 ml (2700 mg de paracetamol)	2 kg
Peso (kg)	Dose individual (equivalente a paracetamol)	Dose máxima diária (24 horas) (equivalente a paracetamol)																																																			
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PARACETAMOL



NO SPOONS!

**EVERY 8 MINUTES, A CHILD UNDER 6
IS GIVEN MEDICINE INCORRECTLY.***

Parents, always read & follow the label & only use
the dosing device that comes with the medicine.



*<http://pediatrics.aappublications.org/content/early/2014/10/15/peds.2014-0309.abstract>

RESEARCH ARTICLE

Open Access

Can medical students identify a potentially serious acetaminophen dosing error in a simulated encounter? a case control study

Robert A Dudas* and Michael A Barone

Abstract

Background: In an effort to assess medical students' abilities to identify a medication administration error in an outpatient setting, we designed and implemented a standardized patient simulation exercise which included a medication overdose.

Methods: Fourth year medical students completed a standardized patient (SP) simulation of a parent bringing a toddler to an outpatient setting. In this case-control study, the majority of students had completed a patient safety curriculum about pediatric medication errors prior to their SP encounter. If asked about medications, the SP portraying a parent was trained to disclose that she was administering acetaminophen and to produce a package with dosing instructions on the label. The administered dose represented an overdose. Upon completion, students were asked to complete an encounter note.

Results: Three hundred forty students completed this simulation. Two hundred ninety-one students previously completed a formal patient safety curriculum while 49 had not. A total of two hundred thirty-four students (69%) ascertained that the parent had been administering acetaminophen to their child. Thirty-seven students (11%) determined that the dosage exceeded recommended dosages. There was no significant difference in the error detection rates of students who completed the patient safety curriculum and those who had not.

Conclusions: Despite a formal patient safety curriculum concerning medication errors, 89% of medical students did not identify an overdose of a commonly used over the counter medication during a standardized patient simulation. Further educational interventions are needed for students to detect medication errors. Additionally, 31% of students did not ask about the administration of over the counter medications suggesting that students may not view such medications as equally important to prescription medications. Simulation may serve as a useful tool to assess students' competency in identifying medication administration errors.



A utilização de MNSRM na população <18 anos de deverá ser encarada como uma responsabilidade partilhada entre famílias, profissionais de saúde, autoridades competentes e a indústria farmacêutica.

Na prática clínica será aconselhável não menosprezar ou esquecer de questionar os pais sobre a administração nas suas crianças/jovens de MNSRM e respetivas doses já que

o “livre não está isento de risco”

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Alexandra Vasconcelos

alexandravasc@gmail.com

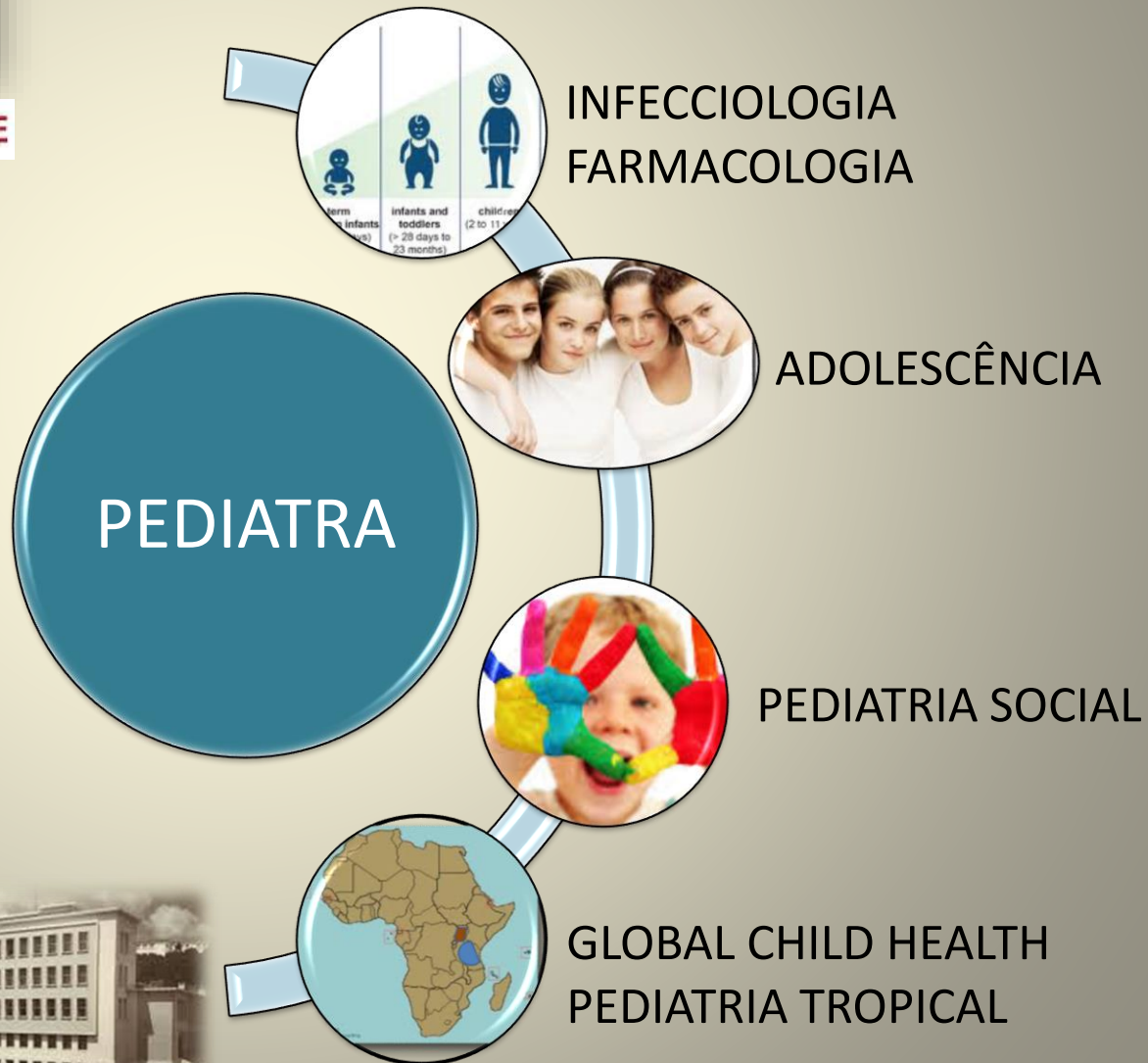
MEDICAMENTOS DE VENDA LIVRE – QUANDO O LIVRE É UM RISCO



Hospital Prof. Doutor **Fernando Fonseca**, EPE



ADOLESCENT UNIT IN THE UCLH



MUCOLITICOS, EXPECTORANTES, ANTITÚSSICOS, DECONGESTIONANTES E ANTI-HISTAMÍNICOS - USO EM CRIANÇAS NA TOSSE E ALIVIO SINTOMÁTICO DA CONSTIPAÇÃO -

Os principais sinais de alerta referentes a estes medicamentos em crianças surgiram nos EUA quando relacionaram a ocorrência de **123 mortes em crianças com menos de 6 anos de idade** nos últimos 20 anos com a toma de medicamentos `cough and cold`.

Discussão sobre a utilização em crianças de medicamentos `cough and cold` como OTC, relacionada com:

- a) Dúvidas sobre o benefício clínico;
- b) Risco de efeitos adversos e ingestão acidental;
- c) Inexistência de guidelines sobre dosagem pediátrica (dados foram inferidos dos estudos realizados na população adulta);
- d) Confusão relacionada com a rotulagem dos produtos;
- e) Existência de vários produtos tipo `multiple-ingredient` com formulações e dosagens variadas, potencializando o risco de sobredosagem;
- f) Multiplicidade de cuidadores de cada criança que pode facilmente conduzir a um aumento do risco de efeitos adversos e sobredosagem.

MUCOLITICOS, EXPECTORANTES, ANTITÚSSICOS, DECONGESTIONANTES E ANTI-HISTAMÍNICOS - USO EM CRIANÇAS NA TOSSE E ALIVIO SINTOMÁTICO DA CONSTIPAÇÃO -

Medidas desencadeadas:

➡ A Agência Norte Americana **Food and Drug Administration (FDA)**:

- Fez recomendações contra a utilização de medicamentos de venda livre `cough and cold` em **crianças com menos de 2 anos**.
- Está a rever a sua utilização em crianças com menos de 6 anos.

➡ A **Academia Americana de Pediatria** é contra o uso de medicamentos de venda livre `cough and cold` em crianças com **menos de 6 anos**.

➡ Embora nenhuma ação regulatória tenha sido adotada - a revisão da FDA ainda está em curso - a maioria dos titulares de AIM nos EUA alterou, de forma voluntária, os avisos declarando "não usar em crianças com menos de 4 anos de idade" e, para os anti-histamínico, acrescentou um aviso de que eles não devem ser utilizados como sedativos.