PERÚ Ministerio de Salud | Dirección General de Medicamentos, Insumos y Drogas

CenadIM
Centro Nacional de Documentación e Información de Medicamentos

Fuentes de Información en Farmacovigilancia

Q.F. Karina Gutiérrez

kgutierrez@digemid.minsa.gob.pe

DECRETO SUPREMO N° 016-2011-SA

Art. 150.- La información sobre los riesgos asociados al uso de los productos farmacéuticos y dispositivos médicos puede proceder de las siguientes fuentes:

a) Información publicada en documentos oficiales de la Organización Mundial de la Salud y autoridades reguladoras de alta vigilancia sanitaria y en la literatura científica;

b) Notificación espontánea de casos individuales de sospechas de reacciones adversas e incidentes adversos;

c) Estudios post autorización;

d) Bases de datos sobre seguridad de productos farmacéuticos y dispositivos médicos;

e) Información de los ensayos clínicos;

f) Informaciones relacionadas con la fabricación, conservación, comercialización, distribución, dispensación, prescripción y uso de productos farmacéuticos y dispositivos médicos;

g) Publicaciones científicas;

h) Otras fuentes de información, como las relativas al uso incorrecto y abuso de los productos farmacéuticos y dispositivos médicos, o las correspondientes a errores de medicación, que puedan aportar datos relevantes para la evaluación de los beneficios y riesgos de los productos farmacéuticos y dispositivos médicos.

Documentos oficiales de la OMS, OPS, The Uppsala Monitoring Centre.

World Health Organization

dia centre | Publications | Countries | Programmes | About WHO | Search

Medicines

WHO Pharmaceuticals Newsletter

The aim of this Newsletter is to disseminate information on the safety and e
of pharmaceutical products, based on information received from our networ
"drug information officers" and other sources such as specialized bulletins a
journals. The information is produced in the form of résumés in English.

To receive the newsletter by e-mail

Please use our e-posting system for receiving PDF
pharmaceuticals newsletter via e-mail. To automati
version of every new issue of the WHO Pharmaceu
message to listserv@who.int containing the followi
WHO-PHN."

To unsubscribe from the service, please send a me
containing the following message text: "SIGNOFF

2014

Newsletter No. 3
Newsletter No. 2
Newsletter No. 1

WHO Pharmaceuticals Newsletter proporciona la información más reciente sobre la seguridad de los medicamentos y las acciones legales emprendidas por las autoridades reguladoras en todo el mundo.


WHO PHARMACEUTICALS NEWSLETTER

World Health Organization

prepared in collaboration with the WHO Collaborating Centre for International Drug Monitoring, Uppsala, Sweden

No. 3, 2014

The WHO Pharmaceuticals Newsletter provides you with the latest information on the safety of medicines and legal actions taken by regulatory authorities across the world. It also provides signals from the Uppsala Monitoring Centre's SIGNAL document

The feature article in this issue gives you an overview of the WHO programme for the monitoring and surveillance of Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) medical products.

Contents

Regulatory matters
Safety of medicines
Signal
Feature

al Medicines and Health Products
on Portal"

Just published"

gle database of training activities

ction and Use of Essential
s (TRS 985)

http://www.who.int/medicines/publications/newsletter/en/

World Health Organization

a centre | Publications | Countries | Programmes | About WHO | Search

Medicines

PHARMACEUTICALS: RESTRICTIONS IN USE AND AVAILABILITY, 2008

Authors:
Quality assurance and Safety: Medicines

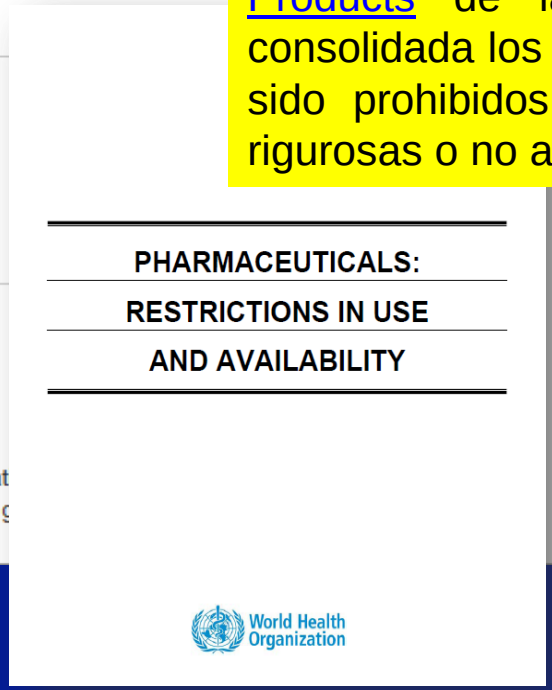
Publication details

Number of pages: 57
Publication date: 2008
Languages: English
WHO reference number: WHO/EMP/QSM/2008.3

Downloads

– Full document
pdf, 503kb

This volume presents information on new nat
withdrawal of products by manufacturers on g
to October 2008.



Es una actualización de la Consolidated List of Products de las Naciones Unidas en donde se consolidada los productos cuyo consumo y/o venta han sido prohibidos, retirados, sometidos a restricciones rigurosas o no aprobados por los gobiernos.

http://www.who.int/medicines/publications/restrictions/en/

World Health Organization

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Medicines

Drug Alerts

OMS emite un alertas de medicamentos rápidas cada vez surge un problema grave en la seguridad de cualquier medicamento.

On receiving information, on a **'potential'** alert, a rapid, ad hoc meeting of the Alert Committee is arranged to validate the information for its source and authenticity, to check for any causality relationship that might have been established, to assess the extent of distribution of the product etc. If the material warrants rapid and worldwide distribution, a Drug alert is composed and mailed to the regulatory authorities and nominated National Information Officers in the Member States.

List of released DRUG ALERTS

Drug Alert 131: Falsified antimalarial medicines
pdf, 667kb
In west and central Africa

Drug Alert 130: Falsified batches of Coartem
pdf, 215kb
Recently circulating in Cameroon

Drug Alert 129: Contaminated

Drug Alert 116: Veralipride
pdf, 104kb
(The European Medicines Agency (EMEA) has issued a Press Release recommending the withdrawal of the marketing authorization for all medicinal products containing veralipride).

Drug Alert 115: Vincristine
pdf, 164kb

Knowledge centre

Search
"Essential Medicines and Health Products Information Portal"

Browse "Just published"

http://www.who.int/medicines/publications/drugalerts/en/

Disponible en:

http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf

Disponible en:

http://new.paho.org/hq/

Disponible en:

http://www.who-umc.org/graphics/24751.pdf

Autoridades reguladoras de países de alta vigilancia sanitaria

Agencias Reguladoras de Medicamentos

- Dirección General de Medicamentos, Insumos y Drogas (DIGEMID).
- Food and Drug Administration (FDA) de los Estados Unidos.
- Agencia Europea de Medicamentos (EMA)
- Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)
- Medicines and Healthcare Products Regulatory Agency (MHRA)

Gobierno del Perú

PERÚ | Ministerio de Salud | Dirección General de Medicamentos, Insumos y Drogas.

ATENCIÓN DE EQUIPOS – DIRECCION DE AUTORIZACIONES SANITARIAS (DAS)

Inicio | Institucional | Normatividad | Transparencia |

Alertas
- Calidad
- Productos falsificados
- Seguridad

Buscador Alertas

Año
Mes
Contenido
Buscar

< Septiembre 2014 >

D	L	M	X	J	V	S
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14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				

Enlaces de Interés

Inicio > Alertas > Seguridad

ALERTA DIGEMID Nº 48 - 2014
LOTE DE DISPOSITIVO MEDICO
01-09-2014

ALERTA DIGEMID Nº 46 - 2014
RISPERIDONA, PALIPERIDONA
FLÁCIDO INTRAOPERATORIO
01-09-2014

ALERTA DIGEMID Nº 45 - 2014
ESZOPICLONA: RIESGO DE ME
01-09-2014

MINISTERIO DE SALUD
Dirección General de Medicamentos, Insumos y Drogas

ALERTA DIGEMID N° 46 - 2014

RISPERIDONA, PALIPERIDONA O PALMITATO DE PALIPERIDONA: RIESGO DE SÍNDROME DE IRIS FLÁCIDO INTRAOPERATORIO

La Dirección General de Medicamentos, Insumos y Drogas (DIGEMID) del Ministerio de Salud, comunica a los profesionales de salud, instituciones, establecimientos farmacéuticos y al público en general que se ha dispuesto la modificación del inserto en los apartados de **advertencias y precauciones y reacciones adversas** de los medicamentos que contienen Risperidona, Paliperidona o Palmitato de Paliperidona, antipsicóticos indicados en el tratamiento de la esquizofrenia, los episodios maniacos asociados a los trastornos bipolares y la agresión relacionada con trastornos psiquiátricos.

Esta decisión se basa en la información de seguridad proveniente de la Agencia Canadiense de Medicamentos[1] la que comunica a los profesionales de salud y pacientes:

En personas que toman medicamentos que contienen Risperidona, Paliperidona o Palmitato de Paliperidona existe el riesgo de desarrollar síndrome de iris flácido intraoperatorio (SIFI) durante y después de la cirugía de cataratas.

El SIFI es una complicación intraoperatoria que ha sido observada durante la cirugía de cataratas. Se caracteriza por una triada de signos intraoperatorios que pueden aparecer en distintos estadios de gravedad y que son los siguientes: ondulación del estroma del iris flácido, constricción progresiva intraoperatoria de la pupila, propensión al prolapso del iris hacia el facoemulsificador y las incisiones.

En ese sentido se informa a los profesionales de la salud:

- El beneficio potencial de interrumpir el tratamiento con Risperidona, Paliperidona o Palmitato de Paliperidona, antes de la cirugía de cataratas, no se ha establecido; y debe ser sopesado contra el riesgo de detener la terapia antipsicótica.
- A los cirujanos que realicen la intervención de cataratas, tener especial precaución en pacientes que hayan tomado este tipo de medicamentos. Si existe la sospecha de que puede llegar a desarrollarse un SIFI, puede ser preciso adoptar las medidas necesarias para evitar el prolapso del iris durante la cirugía de cataratas.

A los pacientes, se les recomienda:

- Si está planificando someterse a una operación oftálmica, asegúrese de indicarle a su médico que está tomando o ha tomado la Risperidona, Paliperidona o Palmitato de Paliperidona.
- No dejar de tomar Risperidona, Paliperidona o Palmitato de Paliperidona sin consultar con su médico.
- Si tiene cualquier pregunta o inquietud sobre su tratamiento con Risperidona, Paliperidona o Palmitato de Paliperidona consulte con su médico.

Finalmente se recuerda que es necesario y obligatorio reportar al Sistema Peruano de Farmacovigilancia, las sospechas de reacciones adversas que se observen por la utilización de los productos farmacéuticos que se comercializan en nuestro país, al correo electrónico: farmacovigilancia@digemid.minsa.gob.pe

Lima, 29 de Agosto del 2014

1.Health Canada: Risperidone- or paliperidone-containing products - Intraoperative Floppy Iris Syndrome (IFIS) - For Health Professionals. Disponible en: http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/36719e-eng.php

http://www.digemid.minsa.gob.pe/Main.asp?Seccion=371

http://www.fda.gov/Safety/MedWatch/default.htm

MedWatch The FDA Safety Information and Adverse Event Reporting Program

- Safety Information

Safety Alerts for Human Medical Products

Drug Safety Labeling Changes

Resources for You

- Report a Serious Medical Product Problem Online
- Subscribe to MedWatch Safety Alerts
- Medication Guides
- An FDA Guide to Drug Safety Terms [ARCHIVED]
- Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)

Medical Product Safety Information

Search the MedWatch Section

MEDWATCH *The FDA Safety Information and Adverse Event Reporting Program*

Safety Alerts for Human Medical Products (Drugs, Biologics, Medical Devices, Special Nutritionals, and Cosmetics)

MedWatch alerts provide timely new safety information on human drugs, medical devices, vaccines and other biologics, dietary supplements, and cosmetics. The alerts contain actionable information that may impact both treatment and diagnostic choices for healthcare professional and patient.

2014 Safety Alerts

2013 | 2012 | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 | 2005 | 2004 | 2003 | 2002 | 2001 | 2000

Drug Safety Labeling Changes

Monthly summaries of drug products with safety labeling changes to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, or PATIENT PACKAGE INSERT/MEDICATION GUIDE sections.

2014: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug

2013: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug|Sep|Oct|Nov|Dec

2012: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug|Sep|Oct|Nov|Dec

2011: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug|Sep|Oct|Nov|Dec

2010: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug|Sep|Oct|Nov|Dec

2009: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug|Sep|Oct|Nov|Dec

2008: Jan|Feb|Mar|Apr|May|Jun|Jul|Aug|Sep|Oct|Nov|Dec

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Safety Alerts for Human Medical Products

2014 Safety Alerts for Human Medical Products

2013 Safety Alerts for Human Medical Products

2012 Safety Alerts for Human Medical Products

2011 Safety Alerts for Human Medical Products

2010 Safety Alerts for Human Medical Products

2009 Safety Alerts for Human Medical Products

2008 Safety Alerts for Human Medical Products

2007 Safety Alerts for Human Medical Products

2006 Safety Alerts for Human Medical Products

2005 Safety Alerts for Human Medical Products

2004 Safety Alerts for Human Medical Products

2003 Safety Alerts for Human Medical Products

2002 Safety Alerts for Human

Acetaminophen Prescription Combination Drug Products with more than 325 mg: FDA Statement - Recommendation to Discontinue Prescribing and Dispensing

[Posted 01/14/2014]

AUDIENCE: Consumer, Dentistry, Emergency Medicine, Internal Medicine, Pharmacy, Pain Management, Surgery

ISSUE: FDA is recommending health care professionals discontinue prescribing and dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule or other dosage unit. There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death.

Cases of severe liver injury with acetaminophen have occurred in patients who:

- took more than the prescribed dose of an acetaminophen-containing product in a 24-hour period;
- took more than one acetaminophen-containing product at the same time; or
- drank alcohol while taking acetaminophen products.

BACKGROUND: In January 2011 FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage which can result from taking too much acetaminophen. This category of prescription drugs combines acetaminophen with another ingredient intended to treat pain (most often an opioid), and these products are commonly prescribed to consumers for pain, such as pain from acute injuries, post-operative pain, or pain following dental procedures.

Acetaminophen is also widely used as an over-the-counter (OTC) pain and fever medication, and is often combined with other ingredients, such as cough and cold ingredients. FDA will address OTC acetaminophen products in another regulatory action. Many consumers are often unaware that many products (both prescription and OTC) contain acetaminophen, making it easy to accidentally take too much.

More than half of manufacturers have voluntarily complied with the FDA request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

RECOMMENDATION: FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that they contact the prescriber to discuss a product with a lower dose of acetaminophen. A two tablet or two capsule dose may still

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm381650.htm

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SCIENCE MEDICINES HEALTH

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Patient safety

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This page lists major changes made to the authorisation of medicines, which have been recommended by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) to improve safety for patients.

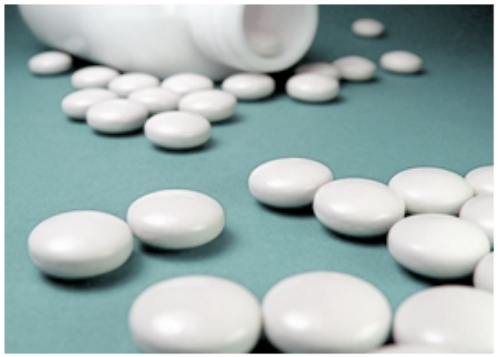
The page lists patient safety information from the last two years. For a full list of all changes made to a centrally authorised medicine, see its European public assessment report. For information on referrals, see referrals.

Patient safety	Last updated
EMA confirms positive benefit-risk for antidepressant Valdoxan/Thymanax (agomelatine)	26/09/2014
CMDh endorses restricted use of bromocriptine for stopping breast milk production	21/08/2014
CMDh endorses suspension of methadone oral solutions containing high molecular weight povidone	24/07/2014
Combined use of medicines affecting the renin-angiotensin system (RAS) to be restricted – CHMP endorses PRAC recommendation	23/05/2014
European Medicines Agency recommends revoking authorisations of Caustinerf arsenical and Xyanicid arsenical	

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/pha_listing.jsp&mid=WC0b01ac058001d126

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/09/news_detail_002173.jsp&mid=WC0b01ac058001d126

European database of suspected adverse drug reaction reports



bg	Европейска база данни относно съобщенията за подозирани нежелани лекарствени реакции
es	Base de datos europea de informes de presuntas reacciones adversas
cs	Evropská databáze hlášení podezření na nežádoucí účinky léčivých přípravků
da	Europæisk database over indberetninger om formodede bivirkninger
de	Europäische Datenbank gemeldeter Verdachtsfälle von Arzneimittelnebenwirkungen
et	Ravimite võimalike kõrvaltoimete teatiste Euroopa andmebaas
el	Ευρωπαϊκή βάση δεδομένων αναφορών πιθανολογούμενων ανεπιθύμητων ενεργειών φαρμάκων
en	European database of suspected adverse drug reaction reports
fr	Base de données européenne des rapports sur les effets indésirables suspectés des médicaments
ga	Bunachar sonraí Eorpach na dtuarascálacha um fhrithghníomh díobhálach amhrasta in aghaidh druga
it	Banca dati europea delle segnalazioni di sospette reazioni avverse ai farmaci
lv	Eiropas ziņojumu par iespējamām zāļu blakusparādībām datu bāze
lt	Pranešimų apie įtariamą nepageidaujamą reakciją į vaistus Europos duomenų bazė
hu	Feltételezett mellékhatásokról szóló jelentések európai adatbázisa
mt	Database Ewropea ta' rapporti dwar reazzjonijiet avversi ssuspettati għal mediċina
nl	Europese database van rapporten over vermoedelijke bijwerkingen van geneesmiddelen
no	Europeisk database over rapporter om antatte bivirkninger
pl	Europejska baza danych zgłoszeń o podejrzewanych działaniach niepożądanych leków
pt	Base de dados europeia de notificações de reações adversas medicamentosas suspeitas
ro	Baza europeană de date privind rapoartele despre reacţiile adverse suspectate la medicamente
sk	Európska databáza hlásení o podozreniach na nežiaduce účinky liekov
sl	Evropska podatkovna baza poročil o domnevnih neželenih učinkih zdravil
fi	EU:n tietokanta lääkkeiden epäiltyjä haittavaikutuksia koskevista ilmoituksista
sv	Europeiska databasen för rapporter om misstänkta läkemedelsbiverkningar

EUROPEAN MEDICINES AGENCY
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EudraVigilance

http://www.adrreports.eu/

Base de datos europea de informes de presuntas reacciones adversas

Contactos | Preguntas frecuentes | Glosario

español (es)

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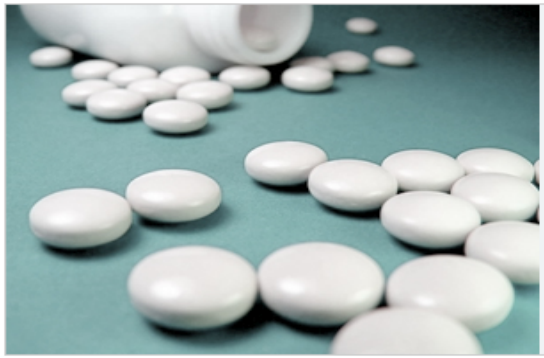
Acceso en línea a los informes de presuntos efectos secundarios



En esta web, usted podrá visualizar datos sobre **presuntos efectos secundarios** también conocidos como presuntas reacciones adversas a fármacos de los medicamentos autorizados en el Espacio Económico Europeo (EEE). En la actualidad, los datos se refieren únicamente a medicamentos aprobados a través del **procedimiento centralizado de autorización**.

Búsqueda de un informe

Busque aquí informes de presuntas reacciones adversas

Noticias

31/05/2012 European Medicines Agency boosts EU transparency with online publication of suspected side effect reports.

Otras noticias...

Cómo informar sobre un efecto secundario

Información clave

- La información de esta web se refiere a ***presuntos* efectos secundarios**, es decir, a acontecimientos médicos observados tras el uso de un medicamento, pero que **no necesariamente están relacionados con el medicamento o producidos por él**.
- La información sobre los presuntos efectos secundarios **no debe interpretarse** como que el medicamento o el principio activo producen el efecto observado ni como que **su uso no es seguro**. Sólo una evaluación detallada y una valoración científica de todos los datos disponibles permiten llegar a conclusiones sólidas sobre los beneficios y riesgos de un medicamento.
- La Agencia Europea de Medicamentos publica estos datos de modo que los grupos de interesados, entre los que se incluye el público general, puedan acceder a la información que utilizan las Autoridades Europeas Reguladoras para revisar la seguridad de un medicamento o principio activo. **La transparencia** es un principio clave de la Agencia.

http://www.adrreports.eu/


Base de datos europea de informes de presuntas reacciones adversas
Contactos | Preguntas frecuentes | Glosario
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Inicio | Contactos | Compatibilidad del navegador y Javascript | © 2012 - 2014
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EudraVigilance

Rivaroxaban: Reporte de sospechas de reacciones adversas

Base de datos europea de | Oracle BI Interactive Dashl

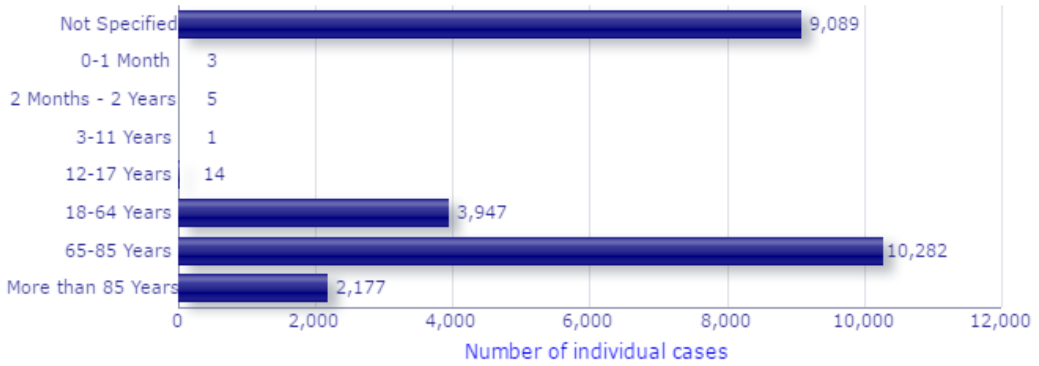
https://bi.ema.europa.eu/analyticsSOAP/saw.dll?PortalPages

Number of Individual Cases | Number of Individual Cases By Reaction Groups | Number of Individual Cases for a selected Reaction Group | Number of Individual Cases for a selected Reaction

The number of individual cases identified in EudraVigilance for **RIVAROXABAN** is **25,518** (up to Aug 2014)

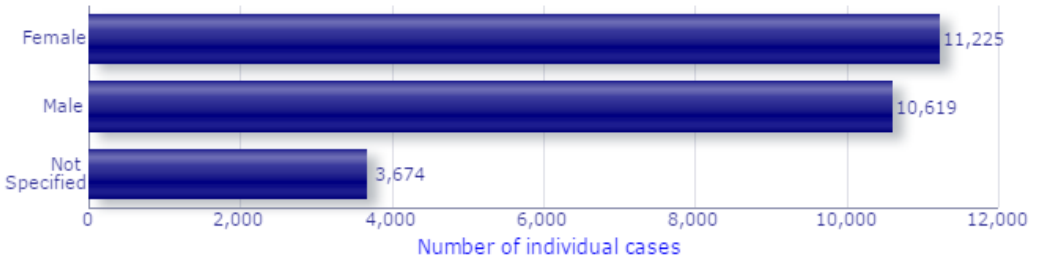
Number of individual cases by Age Group

Age Group	Cases	%
Not Specified	9,089	35.6%
0-1 Month	3	0.0%
2 Months - 2 Years	5	0.0%
3-11 Years	1	0.0%
12-17 Years	14	0.1%
18-64 Years	3,947	15.5%
65-85 Years	10,282	40.3%
More than 85 Years	2,177	8.5%
Total	**25,518**	**100.0%**



Number of individual cases by Sex

Sex	Cases	%
Female	11,225	44.0%
Male	10,619	41.6%
Not Specified	3,674	14.4%
Total	**25,518**	**100.0%**



Number of individual cases by Geographic Origin (EEA/Non-EEA)

Occurrence Country EEA/Non EEA	Cases	%
European Economic Area	10,138	39.7%

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD · agencia española de medicamentos y productos sanitarios

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La AEMPS | Medicamentos de uso humano | Medicamentos veterinarios | Productos san

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- Alertas
- Boletín mensual de la AEMPS
- Área de prensa
- Circulares
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- Listas correo electrónico
- Canales RSS
- Información y atención al ciudadano
- Campañas

Inicio › La AEMPS informa › Notas informativas › Medicamentos de uso humano

Notas informativas de medicamentos de uso human

Ciudadanos

2014 | 2013 | 2012 | 2011 | 2010 | 2009 | 2008 | 2007 |

Publicación en Web	Subcategoría
15/09/14	Agomelatina (Thyma Nota Informativa MU
03/09/14	Denosumab (Prolia® Nota Informativa MU Corrección de errata
01/09/14	Interferones beta (A

http://www.aemps.gob.es/informa/notasInform
eguridad/home.htm

Nota informativa

Agencia Española de Medicamentos y Productos Sanitarios
AEMPS

AGOMELATINA (THYMANAX®, VALDOXAN®) Y TOXICIDAD HEPÁTICA: NUEVAS RECOMENDACIONES DE USO

Información para profesionales sanitarios

(Recomendaciones del Comité para la Evaluación de Riesgos en Farmacovigilancia europeo-PRAC)

Fecha de publicación: 15 de septiembre de 2014

Categoría: MEDICAMENTOS DE USO HUMANO, SEGURIDAD.
Referencia: MUH (FV), 14/2014

Tras la revisión de los datos disponibles de alteraciones hepáticas en el contexto del uso terapéutico de agomelatina, se recomienda a los profesionales sanitarios:

- *No iniciar nuevos tratamientos con agomelatina en pacientes de 75 años de edad o mayores. En pacientes de estas edades que estén ya en tratamiento, revisar en la próxima consulta la idoneidad de continuar el tratamiento.*
- *En todos los pacientes, seguir estrictamente las recomendaciones sobre monitorización de la función hepática establecidas en la ficha técnica de Thymanax® y Valdoxan®.*
- *No iniciar el tratamiento, o suspenderlo, en aquellos pacientes que presenten un valor de enzimas hepáticas 3 veces superior al límite superior de la normalidad.*
- *Informar a los pacientes en tratamiento sobre los signos y síntomas de daño hepático, indicándoles que busquen asistencia médica en el caso de que estos se presenten.*

Agomelatina (Thymanax®, Valdoxan®) es un antidepresivo autorizado desde el año 2009 para el tratamiento de episodios de depresión mayor en pacientes adultos.

El riesgo de alteraciones hepáticas asociado a agomelatina es conocido y se encuentra descrito en las fichas técnicas de Thymanax® y Valdoxan®, así como las recomendaciones de monitorización de la función hepática en los pacientes en tratamiento, tanto antes del inicio como durante el mismo.

En su reunión de septiembre de 2014, el Comité para la Evaluación de Riesgos en Farmacovigilancia europeo (PRAC), en la revisión periódica del

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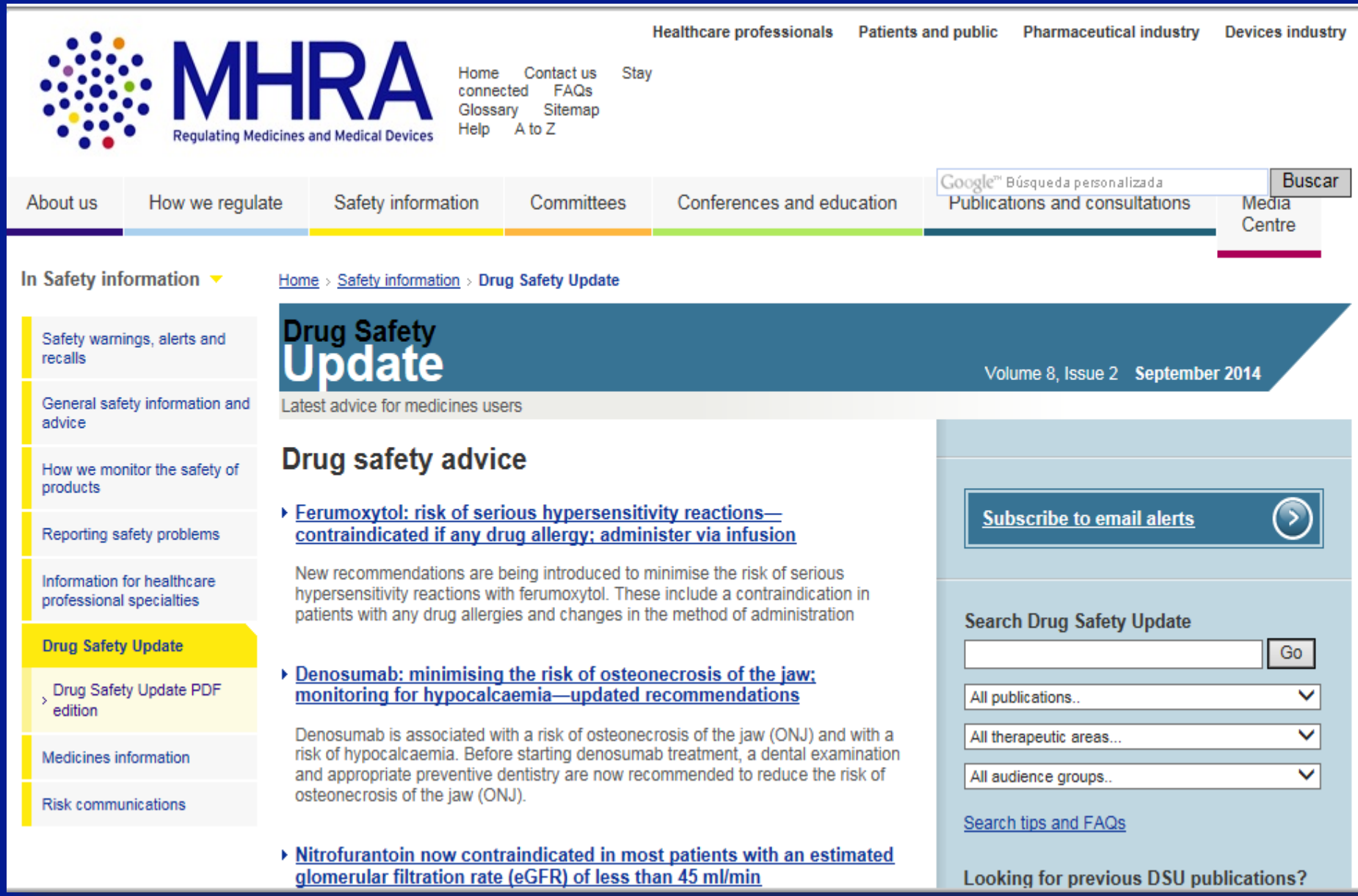

http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/index.htm

Publicaciones de la literatura Cientificas

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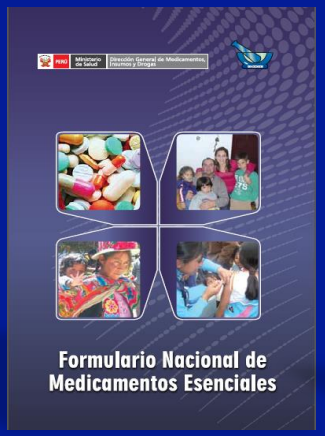

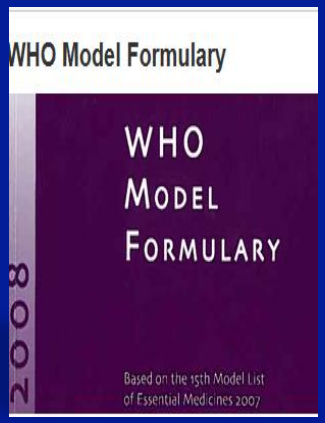

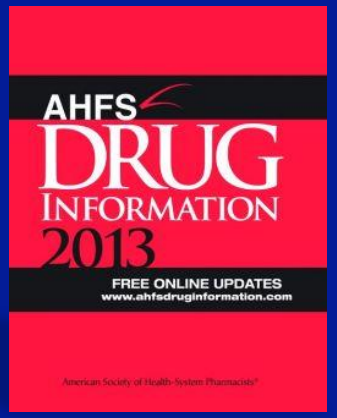

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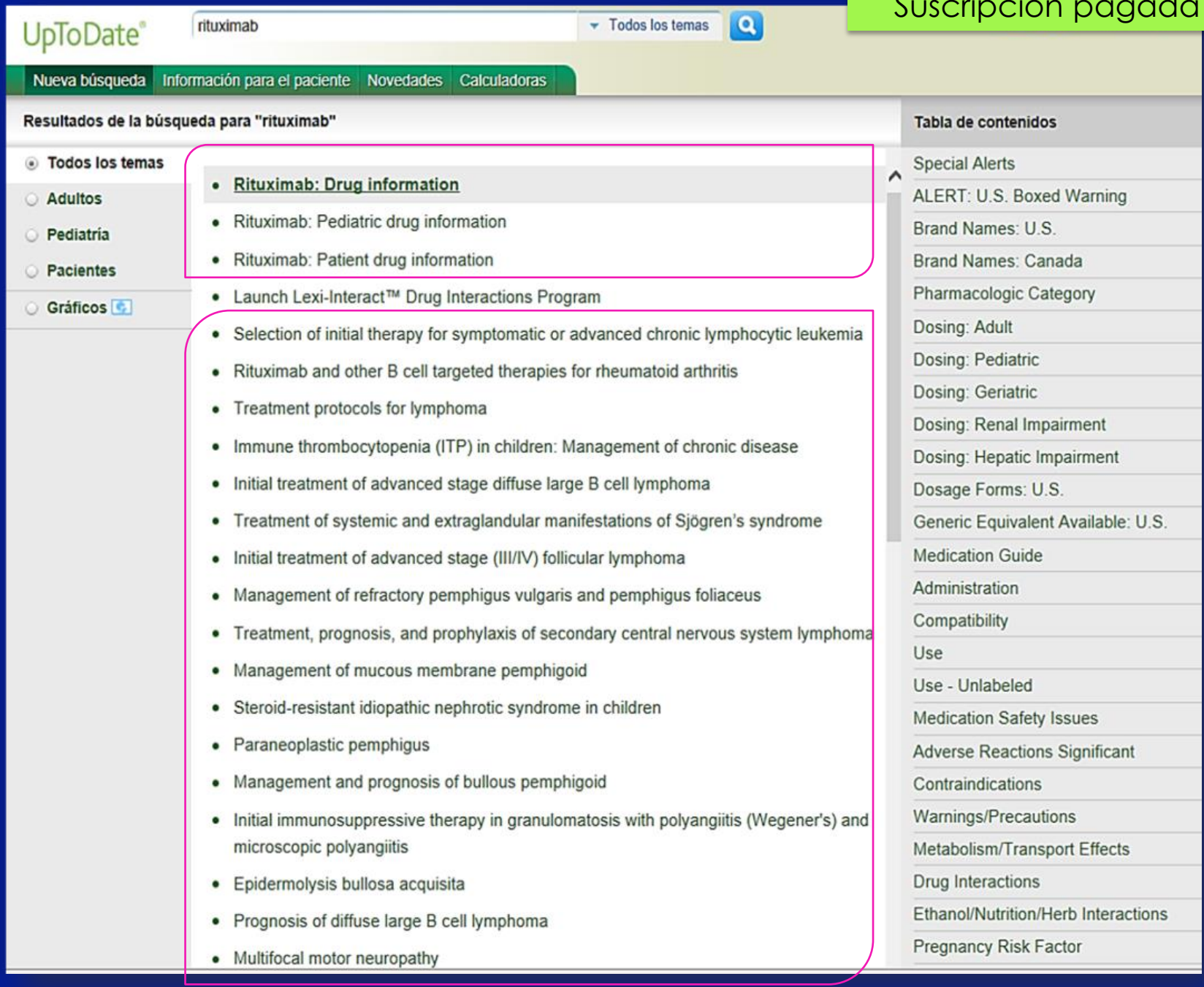

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rituximab

Buscar

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1-50 de 93 **Página: 1 2 Siguiente**

Rituximab

- Waldenstrom macroglobulinemia
- Non-Hodgkin lymphoma (NHL)
- Cryoglobulinemia (Type II)
- Ibritumomab
- Cryoglobulinemia (Type III)
- Chronic lymphocytic leukemia (CLL)
- Mantle cell lymphoma
- Biologic disease-modifying antirheumatic drugs (DMARDs) for rheumatoid arthritis
- Autoimmune hemolytic anemia
- Primary cardiac lymphoma
- Bendamustine
- Lymphocytoma cutis
- Combination therapies for rheumatoid arthritis
- Nephrotic syndrome in children
- Acquired Hemophilia A

Rituximab

- Risk of PML
- Warnings
- General Information
- Uses and Efficacy
- Dosage and Administration
- Cautions and Adverse Effects
- Interactions
- Mechanism of Action/Pharmacokinetics
- Stability and Compatibility
- Preparations
- Patient Information
- Guidelines and Resources
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Available Routes

Azithromycin

Azithromycin

Intravenous, Ophthalmic, Oral

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- Adult Dosing
- Pediatric Dosing
- FDA-Labeled Indications
- Non-FDA Labeled Indications
- Contraindications
- Precautions
- Pregnancy Category
- Breast Feeding
- Drug Interactions (single)
- Adverse Effects - Common
- Adverse Effects - Serious
- IV Compatibility (single)
- Drug Images (US)
- US Trade Names
- Class
- Regulatory Status
- Generic Availability
- Mechanism of Action/Pharmacokinetics
- Administration/Monitoring
- How Supplied
- Toxicology - Clinical Effects
- Toxicology - Treatment
- Toxicology - Range of Toxicity
- Clinical Teaching
- References

OTHER INFORMATION

MARTINDALE

- Azithromycin

INDEX NOMINUM

- Azithromycin (Rec.INN)

IT-DIALOGO SUI FARMACI

- AZACID 3 cpr riv 500 mg
- AZEPTIN 3 cpr riv 500 mg
- AZIPROME 3 cpr riv 500 mg
- AZITREDIL 3 cpr riv 500 mg

More

PRODUCT LOOKUP

- Tox & Drug: Azithromycin
- Martindale: Azithromycin

DRUG IMAGES (US)

More Images

DRUG CONSULTS (20 results)

- BACTERIAL ENDOCARDITIS PROPHYLAXIS - AHA GUIDELINES
- CHANCROID - CDC GUIDELINES
- CHLAMYDIAL INFECTIONS - CDC GUIDELINES
- DRUG-INDUCED MYASTHENIA GRAVIS

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COMPARATIVE EFFICACY (32 results)

- Amoxicillin
- Amoxicillin/Clavulanic Acid
- Cefaclor
- Cefadroxil

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FDA Approves First Test to Predict AKI in Critically Ill Patients

The FDA has approved the first laboratory test to evaluate the risk of developing moderate to

DRUG UPDATES

apremilast (Otezla)

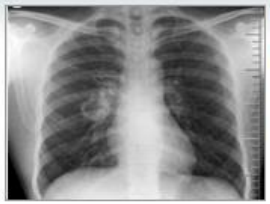
New indication for moderate-to-severe plaque psoriasis

dulaglutide (Trulicity)

FDA approves new once-weekly GLP-1 agonist for type 2 diabetes mellitus

naloxegol (Movantik)

FDA approves first peripherally-acting mu-opioid receptor antagonist (PAMORA) for opioid-induced constipation in adults with chronic noncancer pain



Tuberculosis: Diagnostic Imaging and Treatment Challenges

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ceftriaxone (Rx) - Rocephin

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Adverse Effects

>10%

Induration after IM injection (5-17%)

1-10%

Eosinophilia (6%)

Thrombocytosis (5%)

Diarrhea (3%)

Elevated hepatic transaminases (3%)

Leukopenia (2%)

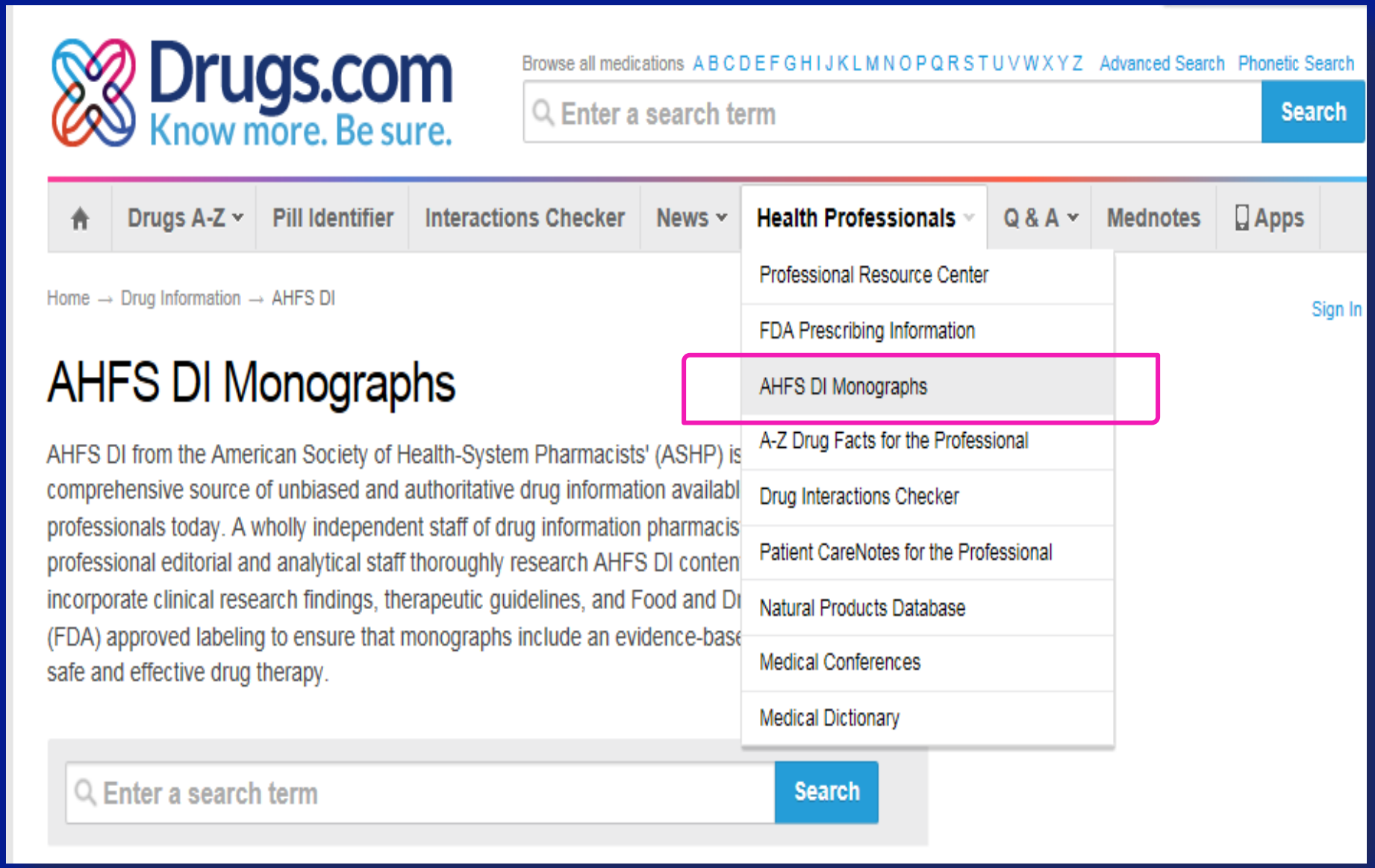
Rash (2%)

Increased blood urea nitrogen (BUN) (1%)

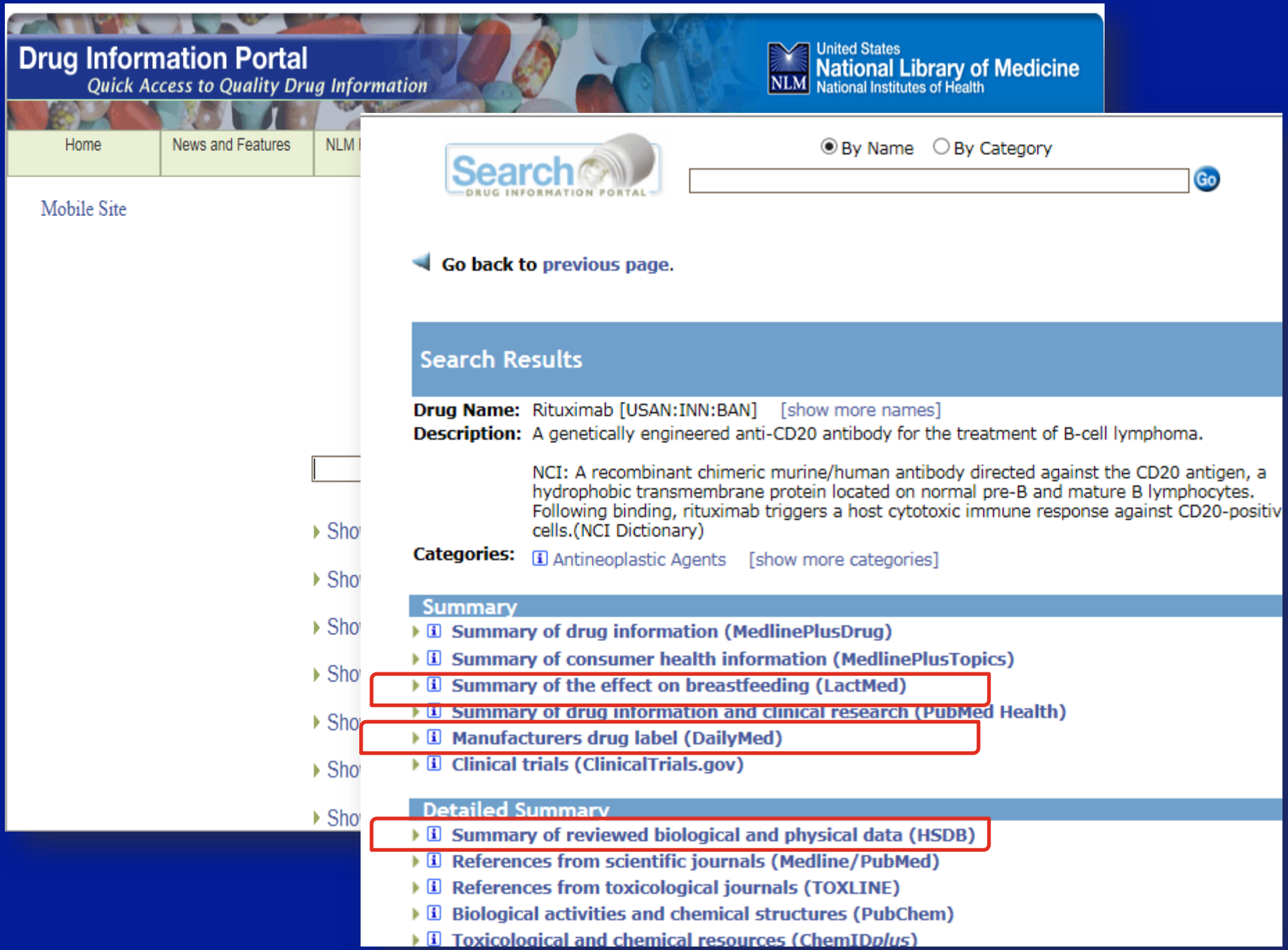
Induration at IV site (1%)

Pain (1%)

<1%



http://www.drugs.com/monograph/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Search Results
Drug Name: Rituximab [USAN:INN:BAN] [show more names]
Description: A genetically engineered anti-CD20 antibody for the treatment of B-cell lymphoma.
NCI: A recombinant chimeric murine/human antibody directed against the CD20 antigen, a hydrophobic transmembrane protein located on normal pre-B and mature B lymphocytes. Following binding, rituximab triggers a host cytotoxic immune response against CD20-positiv cells.(NCI Dictionary)
Categories: Antineoplastic Agents [show more categories]
Summary
Summary of drug information (MedlinePlusDrug)
Summary of consumer health information (MedlinePlusTopics)
Summary of the effect on breastfeeding (LactMed)
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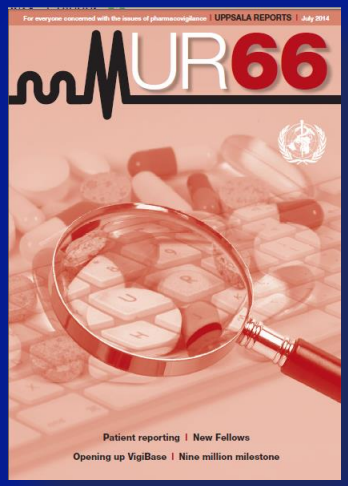
Clinical trials (ClinicalTrials.gov)
Detailed Summary
Summary of reviewed biological and physical data (HSDB)
References from scientific journals (Medline/PubMed)
References from toxicological journals (TOXLINE)
Biological activities and chemical structures (PubChem)
Toxicological and chemical resources (ChemIDplus)

Boletines independientes



Uppsala Reports

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Drug and Therapeutics Bulletin (DTB)

Australian Prescriber

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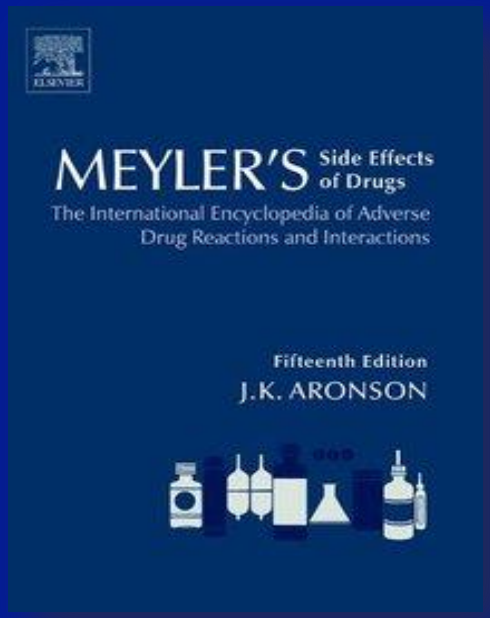
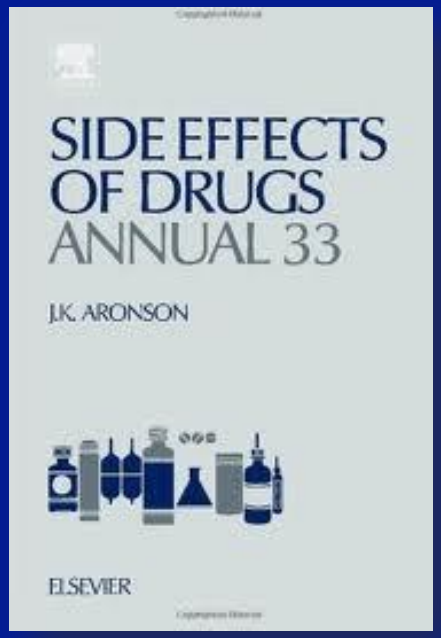
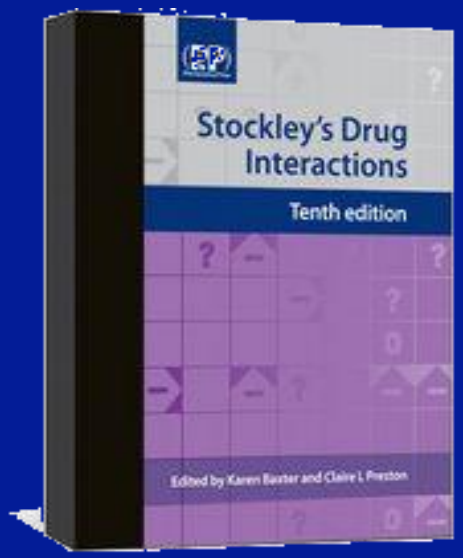


Meyler's Side Effect of Drugs – 15th ed.



Side Effects of Drugs Annual



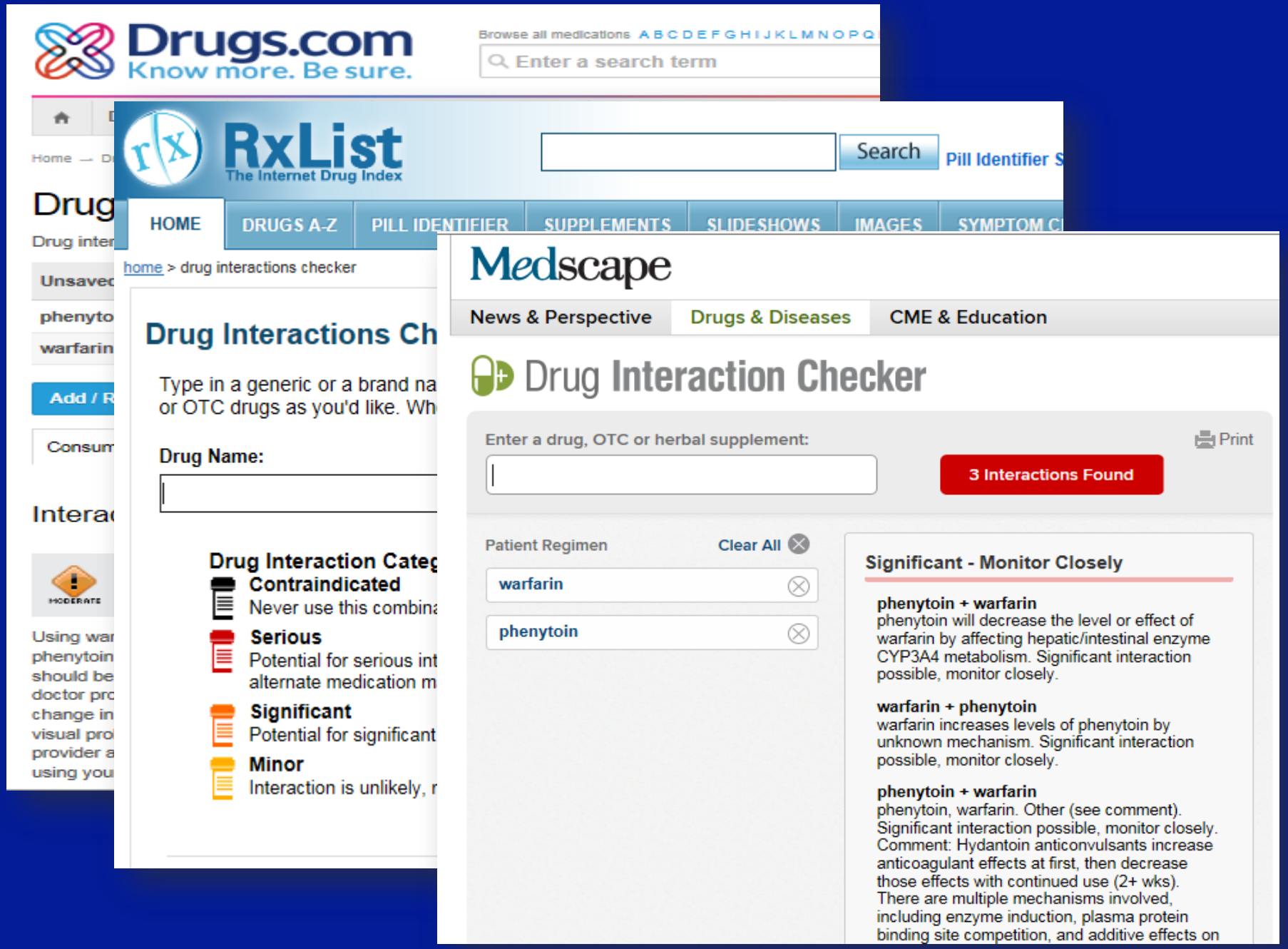
Stockley`s Drug Interactions

INTERACCIONES

- Drug Interaction Checker de Medscape
  http://reference.medscape.com/drug-interactionchecker

- Drug Interaction Checker de Drugs.com
  http://www.drugs.com/drug_interactions.php

- Drug Interactions Checker de Rx List
  http://www.rxlist.com/drug-interaction-checker.htm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Drug Interactions Ch
Type in a generic or a brand na
or OTC drugs as you'd like. Wh
Drug Name:
Drug Interaction Categ
Contraindicated
Never use this combina
Serious
Potential for serious int
alternate medication m
Significant
Potential for significant
Minor
Interaction is unlikely, r
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Drug Interaction Checker
Print
Enter a drug, OTC or herbal supplement:
3 Interactions Found
Patient Regimen
Clear All
warfarin
phenytoin
Significant - Monitor Closely
phenytoin + warfarin
phenytoin will decrease the level or effect of warfarin by affecting hepatic/intestinal enzyme CYP3A4 metabolism. Significant interaction possible, monitor closely.
warfarin + phenytoin
warfarin increases levels of phenytoin by unknown mechanism. Significant interaction possible, monitor closely.
phenytoin + warfarin
phenytoin, warfarin. Other (see comment). Significant interaction possible, monitor closely. Comment: Hydantoin anticonvulsants increase anticoagulant effects at first, then decrease those effects with continued use (2+ wks). There are multiple mechanisms involved, including enzyme induction, plasma protein binding site competition, and additive effects on

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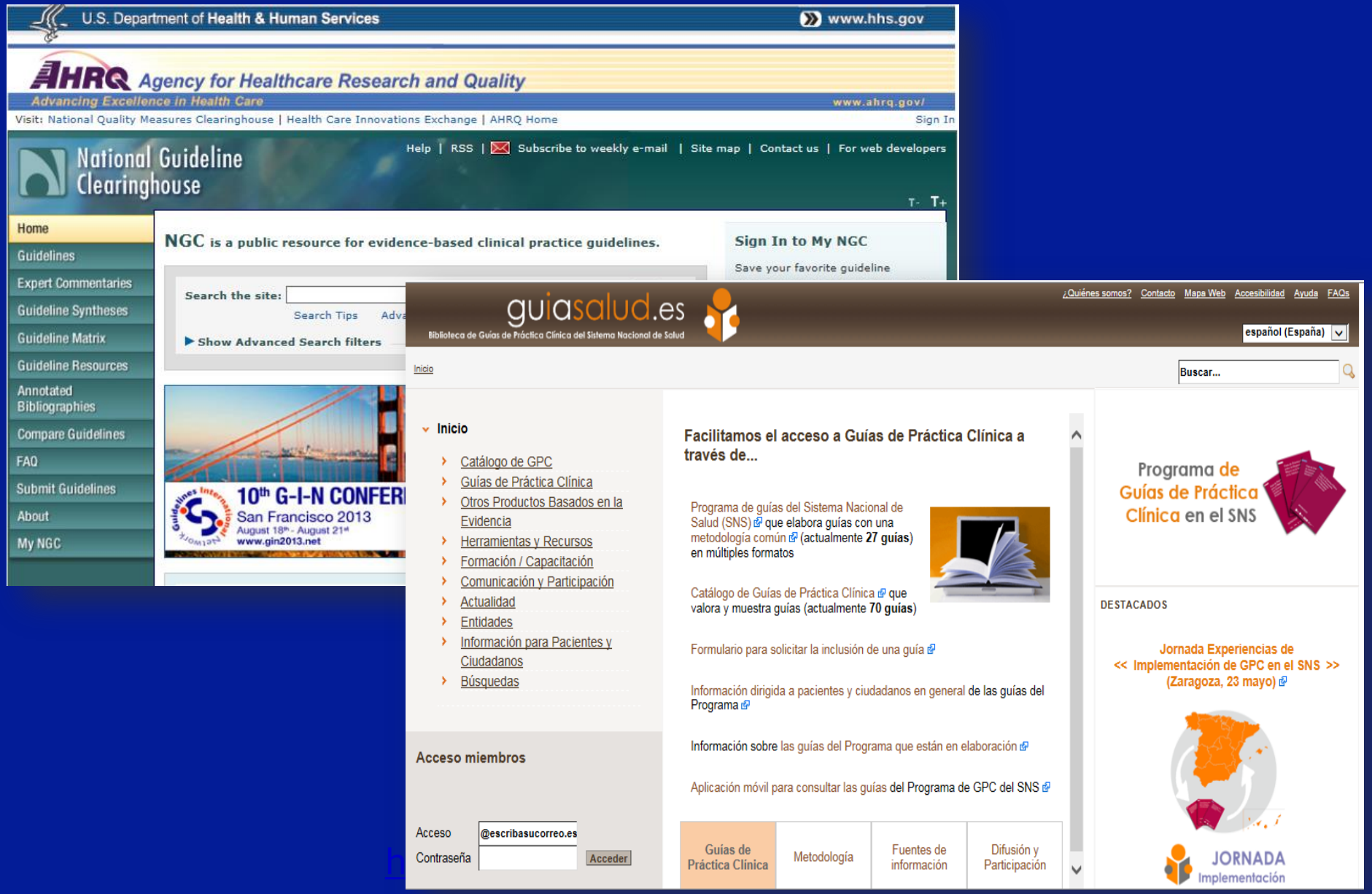

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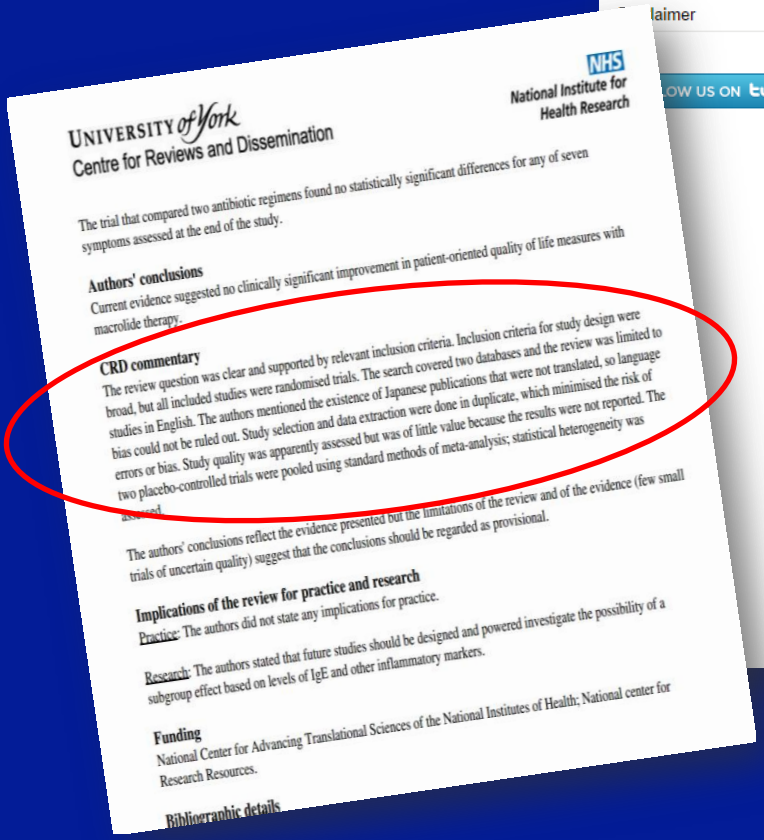

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NHS
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The trial that compared two antibiotic regimens found no statistically significant differences for any of seven symptoms assessed at the end of the study.

Authors' conclusions

Current evidence suggested no clinically significant improvement in patient-oriented quality of life measures with macrolide therapy.

CRD commentary

The review question was clear and supported by relevant inclusion criteria. Inclusion criteria for study design were broad, but all included studies were randomised trials. The search covered two databases and the review was limited to studies in English. The authors mentioned the existence of Japanese publications that were not translated, so language bias could not be ruled out. Study selection and data extraction were done in duplicate, which minimised the risk of errors or bias. Study quality was apparently assessed but was of little value because the results were not reported. The two placebo-controlled trials were pooled using standard methods of meta-analysis; statistical heterogeneity was assessed.

The authors' conclusions reflect the evidence presented but the limitations of the review and of the evidence (few small trials of uncertain quality) suggest that the conclusions should be regarded as provisional.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that future studies should be designed and powered investigate the possibility of a subgroup effect based on levels of IgE and other inflammatory markers.

Funding

National Center for Advancing Translational Sciences of the National Institutes of Health; National center for Research Resources.

Bibliographic details

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☐	2014	DARE	Clinical Infectious Diseases	Azithromycin versus doxycycline for the treatment of genital chlamydia infection: a meta-analysis of randomised controlled trials [Preview]	Request commentary
☐	2014	DARE	Antimicrobial Agents and Chemotherapy	Meta-analysis of the adverse effects of long-term azithromycin use in patients with chronic lung diseases [Preview]	Request commentary
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☐	2013	DARE	Otolaryngology - Head and Neck	Macrolide therapy for chronic rhinosinusitis: a meta-analysis [Preview]	Commentary available

Gracias por su atención