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Reactions Weekly

BASES DE DATOS BIOMÉDICAS PARA PROFESIONALES DEL MEDICAMENTO

21 y 22 de febrero de 2008

REACTIONS WEEKLY

David Cimadevilla

Centre de Farmacovigilància Illes Balears

Fuentes bibliográficas utilizadas en farmacovigilancia:



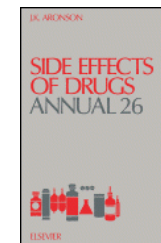
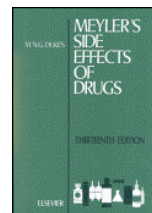
Martindale: Guía Completa de Consulta Farmacoterapéutica



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“...el universo de la bases de datos biomédicas...”



REACCIONS WEEKLY

Valoración de causalidad según el SEFV:

- Secuencia temporal.
- **Conocimiento previo**
- Efecto de retirada del fármaco
- Efecto de reexposición
- Existencia de causas alternativas

- RAM bien conocida
- RAM conocida en referencias ocasionales
- RAM desconocida
- Existe información en contra de la relación

← REACCIONS WEEKLY

FICHA TÉCNICA:

- ✓ Tema: **Seguridad de los medicamentos.**
- ✓ Idioma: **Inglés**
- ✓ Actualización: **Semanal (48 números al año)**

FDA MedWatch criteria

- ✓ **Muerte**
- ✓ **Pone en peligro la vida**
- ✓ **Precisa hospitalización**
- ✓ **Provoca incapacidad**
- ✓ **Anomalía congénita**
- ✓ **Requiere intervención para evitar deterioro o daño permanente**

✓ Dirigido a:

- **Centros de farmacovigilancia**
- **Farmacólogos clínicos y farmacéuticos**
- **Especialistas en toxicología**
- **Investigadores clínicos de la industria farmacéutica**
- **Cualquier profesional sanitario que tenga un interés en la seguridad de los medicamentos.**

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Conselleria de Salut i Consum > Biblioteca Virtual de Ciències de la Salut de les Illes Balears



La **Biblioteca Virtual de Ciències de la Salut de les Illes Balears** és un projecte cooperatiu entre la **Conselleria de Salut i Consum** i el **Servei de Salut de les Illes Balears (Ib-salut)**, coordinat pel **Servei de Documentació Biomèdica de les Illes Balears**. Aquesta biblioteca, accessible les 24 hores del dia des de qualsevol ordinador connectat a Internet, és una aposta de futur per a la formació continuada de tots els professionals sanitaris de les Illes Balears, que els permet l'accés a informació i documentació científica rellevant i actualitzada.

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ID Password

Cal respectar els caràcters en majúscules i en minúscules a l'hora d'introduir les claus



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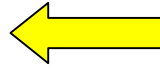
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Renal dysfunction possible with aprotinin during off-pump surgery

Issue: Volume (1189), 16 February 2008, p 1
Publication Type: [Clinical study]
Publisher: Copyright 2008 Adis Data Information BV

ISSN: 0114-9954
Accession: 00128415-200811890-00001
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➤ Fifteen unexpected deaths have been reported in a multicentre, double-blind trial investigating the effects of probiotics.

Links

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Combination of aprotinin and ACE inhibitors during off-pump cardiac surgery appears to be associated with an increased risk of renal dysfunction, according to results of a retrospective observational study published in *The Lancet*; however, no such risk with aprotinin was observed during on-pump surgery irrespective of use of ACE inhibitors.

Using data from the Bristol Royal Infirmary, researchers identified 9106 eligible patients who had undergone on-pump ($n = 5434$) or off-pump cardiac surgeries between 1 January 2000 and 30 September 2007. Patients had either received aprotinin or tranexamic acid 2g; aprotinin was administered as a loading dose of 280mg, followed by a maintenance infusion of 70 mg/h and was also used for priming of the cardiopulmonary bypass pump with 280mg. ACE inhibitor use was defined as administration within 24 hours before surgery.

After propensity adjustment, patients who received aprotinin and ACE inhibitors, and underwent off-pump cardiac surgery, showed greater than two-fold increase in the risk of renal dysfunction (odds ratio [OR] 2.87; 95% CI 1.25, 6.58), compared with those who had not received any antifibrinolytic agent. However, aprotinin appeared to be safe during on-pump cardiac surgery. The ORs between aprotinin and an increased renal dysfunction risk were 1.73 (95% CI 0.56, 5.32) with ACE inhibitor and 1.81 (0.79, 4.13) without ACE inhibitor.

1. Mouton R, Finch D, Davies J, Binks A, Zacharowski K. Effect of aprotinin on renal dysfunction in patients undergoing on-pump and off-pump cardiac surgery: a retrospective observational study. *Lancet* 371: 475-482, No. 9611, 9 Feb 2008

Editorial Comment: In 2007, Bayer temporarily suspended the marketing of Trasylol (aprotinin) worldwide after an analysis of the data from the BART trial showed increased all-cause mortality in patients receiving aprotinin (see Reactions 1177 p1).

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Reactions Weekly

Antineoplastics/prednisolone: Ewing's sarcoma (first report for asparaginase and mercaptopurine?): case report

Issue: Volume (1189), 16 February 2008, pp 7-8

Publication Type: [Case report]

Publisher: Copyright 2008 Adis Data Information BV

Institution(s): An event is serious (FDA MedWatch definition) when the patient outcome is:

ISSN: 0114-9954

Accession: 00128415-200811890-00020

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◀ Pharmacogenetic screening avoids abacavir hypersensitivity reaction.

➤ Amoxicillin: Drug hypersensitivity: case report.

Links

Complete Reference

* congenital anomaly
* requires intervention to prevent permanent impairment or damage
* First published case report

A 16-year-old boy developed Ewing's sarcoma following treatment with antineoplastics and prednisolone for acute lymphoblastic leukaemia (ALL).

The boy was diagnosed with ALL at age 10. He was treated with vincristine, asparaginase, methotrexate, mercaptopurine and prednisolone [dosages not stated], and doxorubicin and cyclophosphamide (cumulative dosages 315 mg/m² and 430 mg/kg, respectively). He achieved complete remission after induction therapy, and then received maintenance chemotherapy until he was 13 years old. At age 16 years, he presented with dysuria and gross haematuria. The haematuria continued for 2 months, after which tumour cells became apparent in his urine. An intraveical papillate mass was visible on ultrasound and cystoscopy, and confirmed on a CT scan.

The boy underwent a transurethral resection of the bladder tumour. Histology showed the tumour to be highly cellular and malignant, made of small round blue cells, with several mitoses and little cytoplasm. It was mainly localised to the bladder submucosa: there was no evidence of distant metastasis. He was diagnosed with a localised tumour from the Ewing's sarcoma family of tumours (ESFT), arising from the urinary bladder. An echocardiogram at this time demonstrated mild cardiac dysfunction, thought to be due to previous doxorubicin therapy. He was treated with cyclophosphamide, pirarubicin, vincristine, ifosfamide and etoposide. Two years after treatment he was well, with no signs of disease recurrence. *Author Comment* 'It is difficult to conclude whether the bladder [ESFT] of our case was therapy-related or a second de novo neoplasm.'

1. Osone S, Hosoi H, Tanaka K, Tsuchiya K, Iehara T, Morimoto A, Hashida T, Yamashita M, Kawabata K, Nishijo K, Toguchida J, Hata J, Sugimoto T. A case of a Ewing sarcoma family tumor in the urinary bladder after treatment for acute lymphoblastic leukemia. *Journal of Pediatric Hematology/Oncology* 29: 841-844. No. 12. Dec 2007 - Japan

Editorial Comment: A search of AdisBase, Medline and Embase did not reveal any previous case reports of Ewing's sarcoma associated with asparaginase or mercaptopurine. The WHO Adverse Reactions database contained one report of sarcoma associated with asparaginase and one report of sarcoma associated with mercaptopurine.



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Efavirenz: Hypersensitivity reaction with rash, hepatitis and fever: case report

Issue: Volume (1189), 16 February 2008, pp 16-17

Publication Type: [Case report]

Publisher: Copyright 2008 Adis Data Information BV

Institution(s): An event is serious (FDA MedWatch definition) when the patient outcome is:

ISSN: 0114-9954

Accession: 00728415-2008011690-00040

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◀ DTaP vaccine: Arthus reaction and brachial neuritis: case report

▶ Erlotinib: Skin eruption with severe pruritus treated with colloidal oatmeal lotion: case report.

Links

Complete Reference

- * congenital anomaly
- * requires intervention to prevent permanent impairment or damage

- * death
- * death
- * life-threatening
- * hospitalisation
- * disability

A 30-year-old man with HIV infection developed a hypersensitivity reaction with rash, hepatitis and fever during treatment with efavirenz.

The man, who was receiving pyrimethamine, sulfadiazine and fluconazole, started receiving efavirenz 600mg once daily and emtricitabine/tenofovir; his transaminase levels were slightly elevated. Eleven days after HAART initiation, he developed a generalised maculopapular erythematous rash, predominantly on his neck, torso and proximal extremities.

The man received hydroxyzine and fluconazole was discontinued and his sulfadiazine and pyrimethamine doses were reduced by 50%. His rash persisted, but he was instructed to continue HAART treatment and return if his symptoms worsened. Eighteen days after HAART initiation, he re-presented with burning epigastric pain, vomiting, nausea and diarrhea. He had a marked increase in his total bilirubin level with an ALT level of 699 U/L (baseline 67), an AST level of 455 U/L (28), an ALP level of 1073 U/L (82) and a total bilirubin level of 3.0 mg/dL (0.2). All medications were stopped. His rash improved but, 2 days later, he was hospitalised with vomiting, nausea, diarrhoea and severe epigastric and periumbilical pain. His liver enzymes had significantly increased with an ALT level of 1181 U/L, an AST level of 1162 U/L and a total bilirubin level of 4.2 mg/dL. On hospital day 2, his temperature peaked at 39.5°C. A diagnosis of drug-induced hepatitis was made and he received supportive therapy, aggressive intravascular repletion and antiemetics. Five days after HAART discontinuation, his liver enzymes peaked (AST 3470 U/L, ALT 2132 U/L). His INR peaked at 2.6 and his lactate dehydrogenase and blood ammonia levels were markedly increased at 644 U/L and 119 µg/dL, respectively. One week later, he was discharged with largely resolved hepatitis symptoms and decreased transaminase levels. Tests for viral hepatitis were negative. He was lost to follow-up. However, 1 year later, he was rehospitalised with *Toxoplasma gondii* encephalitis; his liver enzyme levels were normal. Subsequently, he received emtricitabine/tenofovir, atazanavir and ritonavir without evidence of hepatitis, rash or fever. *Author Comment*: Use of the Naranjo probability scale indicated a probable relationship between the hypersensitivity reaction consisting of rash and hepatitis and efavirenz in our patient... Another confounding variable is treatment with sulfadiazine, which has been associated with hepatotoxicity, although it seems unlikely due to the timing of the reaction. However, it cannot be ruled out that sulfadiazine... may have contributed to the susceptibility of the efavirenz adverse event.

1. Leung JM, D'Brien JG, Wong HK, Winslow DL. Efavirenz-induced hypersensitivity reaction manifesting in rash and hepatitis in a Latino male. *Annals of Pharmacotherapy* 42: Online first: [6 pages], Mar 2008. Available from: URL: <http://www.theanrals.com> - IJSA



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Caso práctico:

- **RAM: Pancreatitis necrotizante** (Cod MedDRA 10056219)
- **Medicamento sospechoso: EZETIMIBE**



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Caso práctico:

- **RAM: Pancreatitis necrotizante** (Cod MedDRA 10056219)
- **Medicamento sospechoso: EZETIMIBE**



Current: Reactions Weekly

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▼ Search History (0 searches) (Click to close)

<input type="checkbox"/>	#	Searches	Results	Display
<input type="button" value="Remove Selected"/>

Combine selections with:



Basic Search | Find Citation | Search Fields | Advanced Ovid Search

Check Spelling Include Related Terms

► Limits (Click to expand)

Search: Search

▼ Search History (2 searches) (Click to close)

<input type="checkbox"/>	#	Searches	Results	Display
<input type="checkbox"/>	1	ezetimibe necrotising pancreatitis {No Related Terms}	440	DISPLAY
<input type="checkbox"/>	2	ezetimibe necrotising pancreatitis {No Related Terms}	440	DISPLAY

Remove Selected | Combine selections with: And Or Save Search History

View Saved

OvidSP Tip

Easily search across journals, books, and databases simultaneously with OvidSP.

Search Aid

Your search
Search terms used:
ezetimibe
necrotising
pancreatitis

Narrow search
Narrow your results by:
► Journals

Broaden search
Add Related Terms

Results Manager
A d i s

Customize Display | Reset Display | View All Abstracts: Sort By: SCORE | Results Per Page:

Results of your search: ezetimibe necrotising pancreatitis {No Related Terms}

Viewing 1-10 of 440 Results
Go to #: GO

How Relevancy is Calculated

Score: ★★★★★

1. Ezetimibe: Necrotising pancreatitis: 4 case reports. Reactions Weekly. (1182);18, December 15, 2007. Find Similar

Score: ★★★★★

2. Ezetimibe: Pancreatitis: case report. Reactions Weekly. (1149);13-14, April 28, 2007. Find Similar

Complete Reference
Table of Contents
Ovid Full Text

Complete Reference
Table of Contents
Ovid Full Text

Next Re



Ezetimibe: Necrotising pancreatitis: 4 case reports

Issue: Volume (1182), 15 December 2007, p 18

Publication Type: [Case report]

Publisher: Copyright 2007 Adis Data Information BV

Institution(s): An event is serious (FDA MedWatch definition) when the patient outcome is:

ISSN: 0114-9954

Accession: 00128415-200711820-00056

Email jumps!art

«: Table of Contents

About this Journal »

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«: Heparin/warfarin: Phlegmasia caerulea dolens following heparin withdrawal: case report.

»: Glucocorticoids/steroid receptor agonists: Myopathy mimicking therapy-resistant asthma: case report

Search Results:

»: Ezetimibe: Pancreatitis: case report.

Links

Complete Reference

- * congenital anomaly
- * requires intervention to prevent permanent impairment or damage

Four patients developed necrotising pancreatitis during treatment with ezetimibe [dosages, duration of therapies to reaction onset, therapeutic indication and patient outcomes not stated].

A 59-year-old woman and a 76-year-old woman developed necrotising pancreatitis during treatment with ezetimibe and were reported to the New Zealand Pharmacovigilance Centre; one of these patients also developed diabetes mellitus. The 55-year-old woman had also developed acute pancreatitis 2 years before erlotinib administration. The 76-year-old woman was also taking another suspected causative agent [drug not identified] but, ezetimibe had been started closer to the onset of pancreatitis.

A 51-year-old man and a 42-year-old man developed necrotising pancreatitis during treatment with ezetimibe and were reported to the WHO Adverse Drug Reactions database. Both of these patients were receiving concomitant medications known to cause pancreatitis, but these drugs were not considered suspect.

1. Savage RI, Tatley M. Pancreatitis with serious sequelae in patients taking ezetimibe. Drug Safety 30: 959, No. 10, 2007 - New Zealand



- Acceso rápido a la información
- Alta cobertura
- Facilidad manejo plataforma OVID
- Información muy reciente

- Sólo inglés
- Falta de detalles de la información
- Acceso restringido (claves proporcionadas por la Biblioteca virtual de la Conselleria de Salut i Consum)

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- ➔ Manual per al control i prevenció de la tuberculosi
- ➔ Estratègia de salut mental a les Illes Balears
- ➔ Estratègia de VIH-SIDA a les Illes Balears
- ➔ Guia per a presa de decisions responsables front el consum d'alcohol
- ➔ Enquesta sobre l'ús problemàtic d'internet, ludopaties i addiccions a la feina i a les compres a les Illes Balears
- ➔ Guia d'intervenció grupal per a l'abordatge del tabaquisme en Atenció Primària





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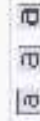
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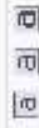
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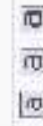
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21/02/2008

Targeta groga

Farmàcia

- > Farmacovigilància
- > Farmacovigilància de medicaments d'ús humà
- > Targeta groga

Formulari de notificació de reaccions adverses a medicaments d'ús humà.



Document Microsoft Word

Targeta_groga[1].doc
* Document Microsoft Word / Grandària: 38 KB

Organisme: SERVEI DE CONTROL DE MEDICAMENTS I PRODUCTES SANITARIS
Data d'actualització: 13/09/2007

CONFIDENCIAL / CONFIDENCIAL

Notificació de sospita de reacció adversa a un medicament Notificación de sospecha de reacción adversa a un medicamento

1. Per favor, notifiqueu totes les reaccions a fàrmacs recentment introduïts en el mercat i les reaccions greus o les estranyes per a la resta de fàrmacs (incloent vacunes, medicaments parenterals, radiofàrmacs, plantes medicinals, fórmules magistral, gases medicinals i medicaments homeopàtics).
2. Notifiqueu en la primera línia el fàrmac que considere més sospitós d'haver produït la reacció, o bé, poseu un assentit demunt el nom dels medicaments sospitosos, si creieu que n'hi ha més d'un.
3. Notifiqueu tots els altres fàrmacs, incloent els d'automedicació, prescs en els tres mesos anteriors. Per a les magistralcons coneguts, notifiqueu tots els fàrmacs prescs durant la gestació.
4. No deixeu de notificar una part de la informació que us demanem per deconter-la.

1. Por favor, notifique todas las reacciones a fármacos recientemente introducidos en el mercado y las reacciones graves o las extrañas para el resto de fármacos (incluidos vacunas, medicamentos parenterales, radiofármacos, plantas medicinales, fórmulas magistrales, gases medicinales y medicamentos homeopáticos).
2. Notifique en la primera línea el fármaco que considere más sospechoso de haber producido la reacción, o bien ponga un asenso junto al nombre de los medicamentos sospechosos, si cree que hay más de uno.
3. Notifique todos los demás fármacos, incluidos los de automedicación, tomados en los tres meses anteriores. Para las magistralcons conegidas, notifique todos los fármacos tomados durante la gestación.
4. No deje de notificar por deconter una parte de la información que le pedimos.

NOM DEL PACIENT / NOMBRE DEL PACIENTE

Sexe / Sexo: masclet / masculino femella / femenino

Edat / Edad: _____

Pes (kg.) / Peso (kg.): _____

(Amb la finalitat de saber si ha repetit alguna reacció, indiqueu també el número d'hospital per als pacients hospitalitzats)
(Con la finalidad de saber si se ha repetido alguna reacción, indique también el número de la clínica para los pacientes hospitalizados)

MEDICAMENT (S) / MEDICAMENTOS (S)*
(Indicar el nombre comercial) / (Indique el nombre comercial)

(Veguen-ne nota 2 / Véase nota 2)

	Data / Fecha		Motiu de la prescripció / Motivo de la prescripción
	Inici / Inicio	Final	
	.../.../...	.../.../...	
	.../.../...	.../.../...	
	.../.../...	.../.../...	
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* Per a les vacunes, indiqueu el número de lot / * Para las vacunas, indique el número de lote.

REACCIONS / REACCIONES

	Data / Fecha		Desenllaç / Desenlace
	Inici / Inicio	Final	
	.../.../...	.../.../...	
	.../.../...	.../.../...	
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	.../.../...	.../.../...	

PERSONA QUE NOTIFICA

Metge / Médico Farmacèutic / Farmacéutico DUEIANTS

Especialitat / Especialidad: _____ Centre de treball / Centro de trabajo: _____

Populació / Población: _____

Telèfon de contacte / Teléfono de contacto: _____ Data / Fecha: _____/_____/_____

Signatura / Firma: _____

Per favor, marqueu amb una creu si necessiteu més targetes / Por favor, marque con una cruz si necesita más tarjetas

Per favor, marqueu amb una creu si voleu informació addicional / Por favor, marque con una cruz si quiere información adicional

Centre de Farmacovigilància

- **E-mail:**

gmelero@dgfarmacia.caib.es

dcimadevilla@dgfarmacia.caib.es

- **Tlf:**

971- 17 69 68

- **Fax:**

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- **Web**

<http://portalsalut.caib.es>

**GRACIAS POR
VUESTRA ATENCIÓN**

