TALLER
Fuentes de información para la selección de los medicamentos

Manejo práctico de las mismas:
APREPITANT

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Colaboran: Eva Alfaro y Trinidad Desongles

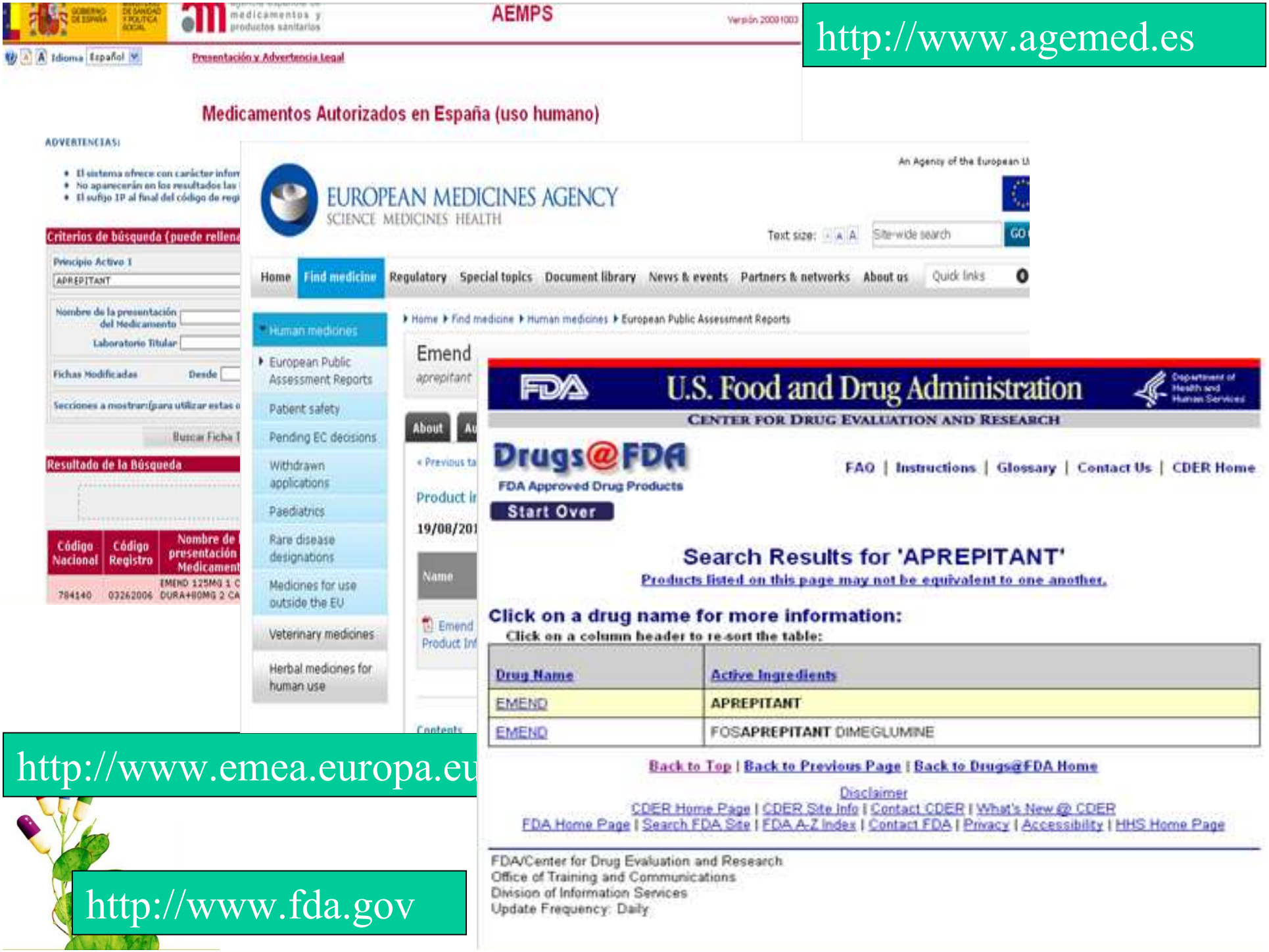
APREPITANT

Indicación Solicitada: prevención de las náuseas y los vómitos (N/V) agudos y diferidos asociados a QT antineoplásica altamente emetógena basada en el cisplatino o QT moderadamente emetógena

Datos básicos

Documentos elaborados por agencias reguladoras:

- Agencia Española del Medicamentos y Productos Sanitarios
- European Medicines Agency
- US Food and Drug Administration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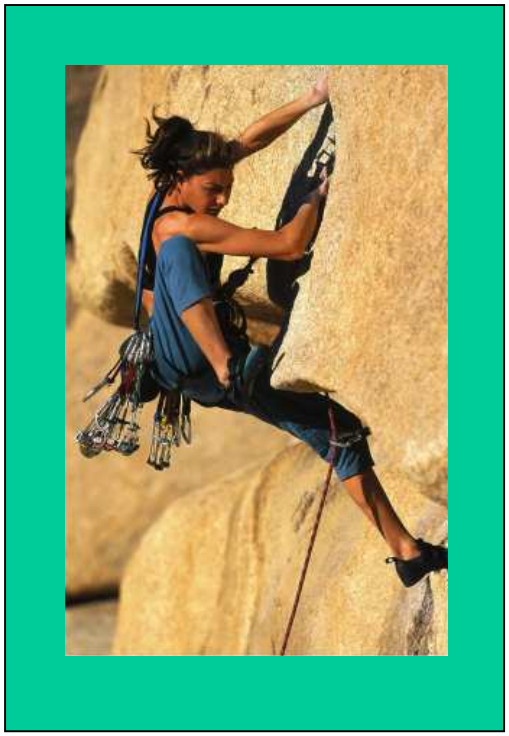
- Fuentes secundarias
- Posicionamiento terapéutico



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Eficacia / Efectividad

Ensayos clínicos pivotales:

1. Buscar EPAR (*European Public Assessment Report)*
2. Buscar en bases de datos:

   PubMed, Embase, Trip Database

Paediatrics

Rare disease designations

Medicines for use outside the EU

Veterinary medicines

Herbal medicines for human use

Changes since initial authorisation of medicine

Name	Language	First published	Last updated
Emend : EPAR - Procedural steps taken and scientific information after authorisation	(English only)	12/08/2009	27/08/2010
Emend-H-C-527-II-14 : EPAR - Scientific Discussion - Variation	(English only)	14/02	
Emend-H-C-527-II-09 : EPAR - Scientific Discussion - Variation	(English only)	05/09	

Initial Marketing authorisation documents

Name	Language	First p
Emend : EPAR - Scientific Discussion	(English only)	05/09/
Emend : EPAR - Procedural steps taken before authorisation	(English only)	05/09/

Related information

- Emend: Paediatric Investigation Plan

Phase (Study title).	Protocol (ref.)	Dose	Duration of treatment	Number of patients/ patients enrolled	Study design. Description.
Phase III (MK-0869 for chemotherapy-induced nausea and vomiting).	P052	The study had 2 treatment groups MK-0869 regimen vs standard therapy. MK-0869 Regimen = MK-0869 125 mg orally on Day 1 and 80 mg orally once daily on Days 2 and 3 plus ondansetron 32 mg intravenous on Day 1 and dexamethasone 12 mg orally on Day 1 and 8 mg orally once daily on Days 2 to 4. Standard therapy = Ondansetron 32 mg IV on Day 1 plus dexamethasone 20 mg orally on Day 1 and 8 mg orally twice daily on Days 2 to 4.	MK-0869 regimen for 3 days (MK-0869 125 mg Day 1 and MK-0869 80 mg Days 2 and 3) in combination with ondansetron (Day 1) and dexamethasone (Days 1 to 4).	534	Multicentre, randomised, double-blind, parallel-group, controlled trial to assess the safety and efficacy of MK-0869 in the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients who were naive to cisplatin chemotherapy and who were treated with a chemotherapy regimen that included cisplatin ≥70 mg/m2. The protocol had 2 components. The first component focused on the first cycle (Cycle 1) of chemotherapy. The second component consisted of an optional multiple-cycle extension for up to 5 subsequent cycles of chemotherapy (maximum of 6 cycles total).
Phase III (MK-0869 for chemotherapy-induced nausea and vomiting).	P054	Idem study P052.	MK-0869 regimen for 3 days (MK-0869 125 mg on Day 1 and MK-0869 80 mg on Days 2 and 3) in combination with ondansetron on Day 1 and Dexamethasone daily on Days 1 to 4.	569	Multicentre, randomised, double-blind, parallel-group, controlled trial.

These two studies had similar objectives and design. As far as the inclusion criteria are concerned a site-specific amendment allowed the enrolment of adolescents older than 12 years old (younger than 18 years of age and weighting more than 40 kg) in study P052.

Búsqueda de los EC pivotales

Phase (Study title).	Protocol (ref.)	Dose	Duration of treatment	Number of patients/ patients enrolled	Study design. Description.
Phase III (MK-0869 for chemotherapy-induced nausea and vomiting)	P052	The study had 2 treatment groups MK-0869 regimen vs standard therapy. MK-0869 Regimen = MK-0869 125 mg orally on Day 1 and 80 mg orally once daily on Days 2 and 3 plus ondansetron 32 mg intravenous on Day 1 and dexamethasone 12 mg orally on Day 1 and 8 mg orally once daily on Days 2 to 4. Standard therapy = Ondansetron 32 mg IV on Day 1 plus dexamethasone 20 mg orally on Day 1 and 8 mg orally twice daily on Days 2 to 4.	MK-0869 regimen for 3 days (MK-0869 125 mg Day 1 and MK-0869 80 mg Days 2 and 3) in combination with ondansetron (Day 1) and dexamethasone (Days 1 to 4).	534	Multicentre, randomised, double-blind, parallel-group, controlled trial to assess the safety and efficacy of MK-0869 in the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients who were naive to cisplatin chemotherapy and who were treated with a chemotherapy regimen that included cisplatin ≥70 mg/m2. The protocol had 2 components. The first component focused on the first cycle (Cycle 1) of chemotherapy. The second component consisted of an optional multipl for up cycles (maxim total).
Phase III (MK-0869 for chemotherapy-induced nausea and vomiting)	P054	Idem study P052.	MK-0869 regimen for 3 days (MK-0869 125 mg on Day 1 and MK-0869 80 mg on Days 2 and 3) in combination with ondansetron on Day 1 and Dexamethasone daily on Days 1 to 4.	569	Multic random blind, control

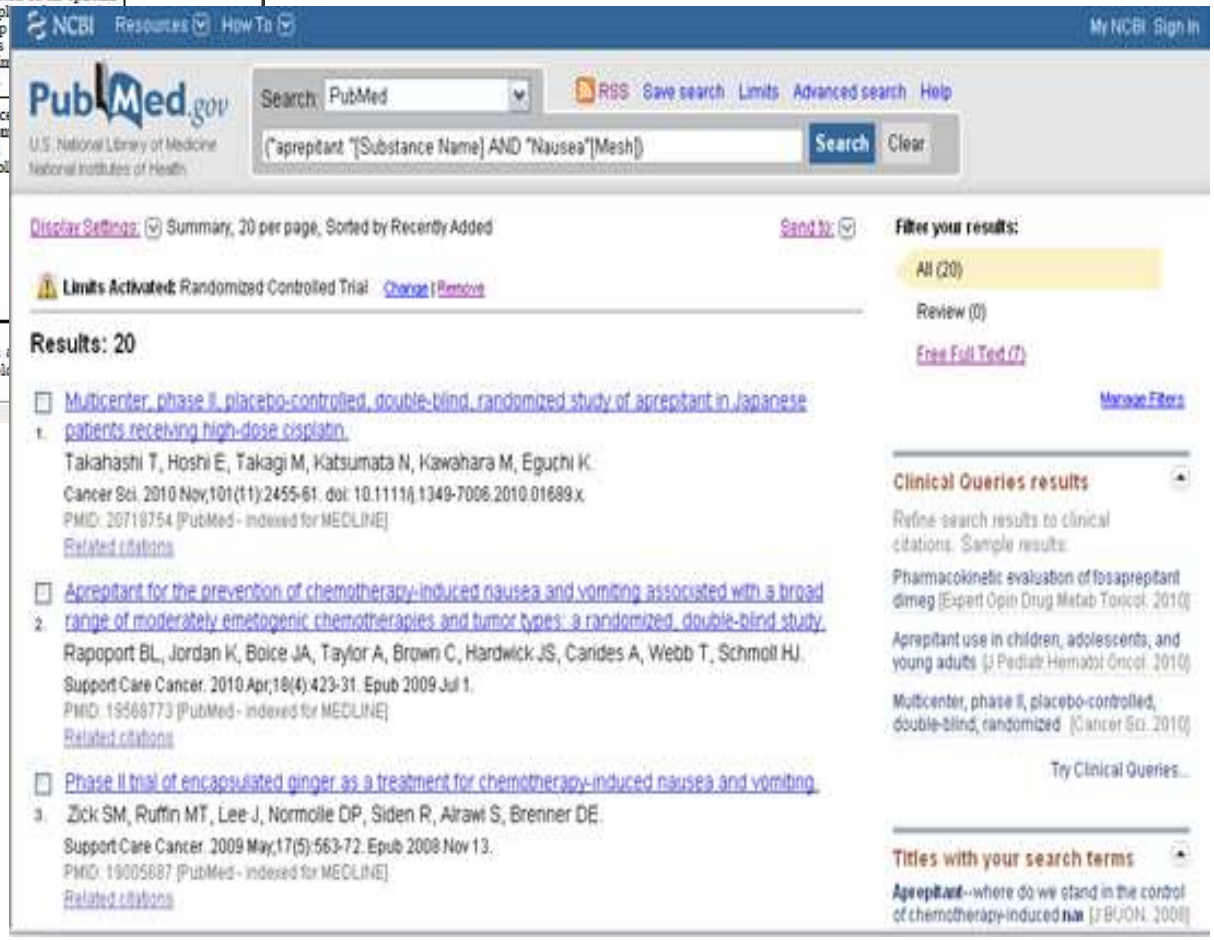
These two studies had similar objectives and design. As far as the inclusion criteria site-specific amendment allowed the enrolment of adolescents older than 12 years ol 18 years of age and weighting more than 40 kg) in study P052.

Ejemplo:

“aprepitant "[Substance Name] AND ("Vomiting"[Mesh]

+

Limits: “Randomized Controlled Trial”



Búsqueda de los EC pivotales

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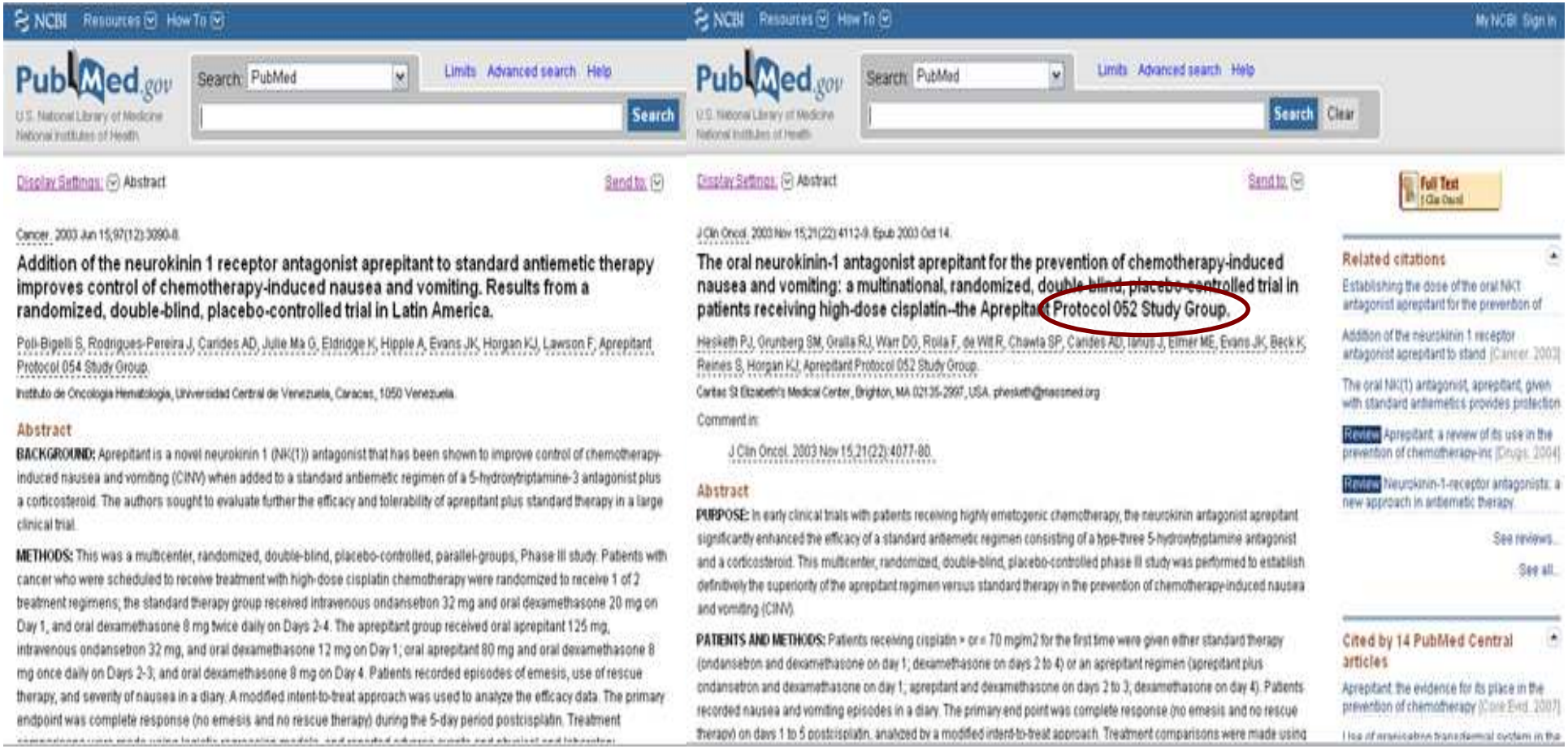
Fácil



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Cancer. 2003 Jun 15;97(12):3090-8.

Addition of the neurokinin 1 receptor antagonist aprepitant to standard antiemetic therapy improves control of chemotherapy-induced nausea and vomiting. Results from a randomized, double-blind, placebo-controlled trial in Latin America.

Poli-Bigelli S, Rodrigues-Pereira J, Carides AD, Julie Ma G, Eldridge K, Hipple A, Evans JK, Horgan KJ, Lawson F; Aprepitant Protocol 054 Study Group.

Instituto de Oncologia Hematologia, Universidad Central de Venezuela, Caracas, 1050 Venezuela.

Abstract

BACKGROUND: Aprepitant is a novel neurokinin 1 (NK(1)) antagonist that has been shown to improve control of chemotherapy-induced nausea and vomiting (CINV) when added to a standard antiemetic regimen of a 5-hydroxytriptamine-3 antagonist plus a corticosteroid. The authors sought to evaluate further the efficacy and tolerability of aprepitant plus standard therapy in a large clinical trial.

METHODS: This was a multicenter, randomized, double-blind, placebo-controlled, parallel-groups, Phase III study. Patients with cancer who were scheduled to receive treatment with high-dose cisplatin chemotherapy were randomized to receive 1 of 2 treatment regimens; the standard therapy group received intravenous ondansetron 32 mg and oral dexamethasone 20 mg on Day 1, and oral dexamethasone 8 mg twice daily on Days 2-4. The aprepitant group received oral aprepitant 125 mg, intravenous ondansetron 32 mg, and oral dexamethasone 12 mg on Day 1; oral aprepitant 80 mg and oral dexamethasone 8 mg once daily on Days 2-3; and oral dexamethasone 8 mg on Day 4. Patients recorded episodes of emesis, use of rescue therapy, and severity of nausea in a diary. A modified intent-to-treat approach was used to analyze the efficacy data. The primary endpoint was complete response (no emesis and no rescue therapy) during the 5-day period postcisplatin. Treatment

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J Clin Oncol. 2003 Nov 15;21(22):4112-9. Epub 2003 Oct 14.

The oral neurokinin-1 antagonist aprepitant for the prevention of chemotherapy-induced nausea and vomiting: a multinational, randomized, double-blind, placebo-controlled trial in patients receiving high-dose cisplatin--the Aprepitant Protocol 052 Study Group.

Hesketh PJ, Grunberg SM, Gralla RJ, Warr DG, Roila F, de Wit R, Chawla SP, Carides AD, Ianus J, Elmer ME, Evans JK, Beck K, Reines S, Horgan KJ; Aprepitant Protocol 052 Study Group.

Caritas St Elizabeth's Medical Center, Brighton, MA 02135-2997, USA. phesketh@tiacomed.org

Comment in:

J Clin Oncol. 2003 Nov 15;21(22):4077-80.

Abstract

PURPOSE: In early clinical trials with patients receiving highly emetogenic chemotherapy, the neurokinin antagonist aprepitant significantly enhanced the efficacy of a standard antiemetic regimen consisting of a type-three 5-hydroxytryptamine antagonist and a corticosteroid. This multicenter, randomized, double-blind, placebo-controlled phase III study was performed to establish definitively the superiority of the aprepitant regimen versus standard therapy in the prevention of chemotherapy-induced nausea and vomiting (CINV).

PATIENTS AND METHODS: Patients receiving cisplatin > or = 70 mg/m2 for the first time were given either standard therapy (ondansetron and dexamethasone on day 1; dexamethasone on days 2 to 4) or an aprepitant regimen (aprepitant plus ondansetron and dexamethasone on day 1; aprepitant and dexamethasone on days 2 to 3; dexamethasone on day 4). Patients recorded nausea and vomiting episodes in a diary. The primary end point was complete response (no emesis and no rescue therapy) on days 1 to 5 postcisplatin, analyzed by a modified intent-to-treat approach. Treatment comparisons were made using

Related citations

Establishing the dose of the oral NK1 antagonist aprepitant for the prevention of

Addition of the neurokinin 1 receptor antagonist aprepitant to stand [Cancer. 2003]

The oral NK(1) antagonist, aprepitant, given with standard antiemetics provides protection

Review Aprepitant: a review of its use in the prevention of chemotherapy-ind [Drugs. 2004]

Review Neurokinin-1-receptor antagonists: a new approach in antiemetic therapy

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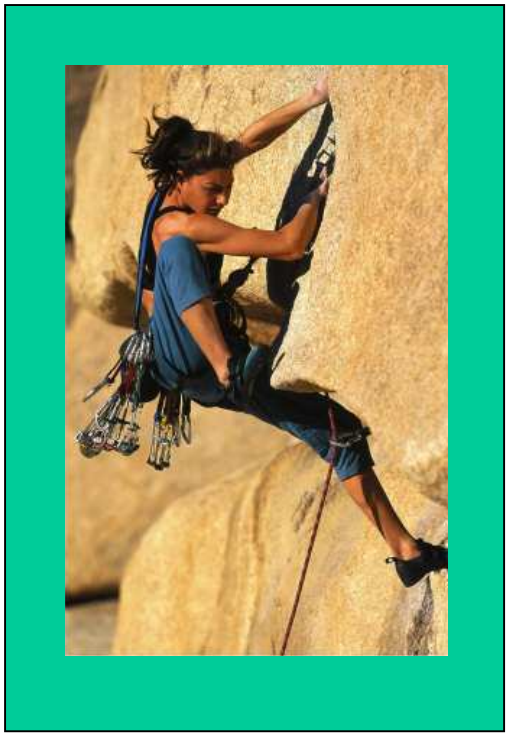
Aprepitant: the evidence for its place in the prevention of chemotherapy [Core Evid. 2007]



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Seguridad

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- Alertas de agencias reguladoras
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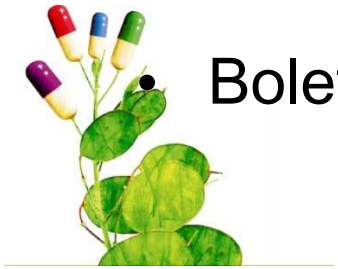

Seguridad

EPAR

Clinical safety

Aprepitant is the first product in a new class of medicinal products. There is therefore a very limited clinical experience as regards adverse reactions outside the studies programme for aprepitant[1].

Patient exposure

The safety profile of aprepitant was evaluated in approximately 3300 individuals (see table below).

Number of Subjects enrolled in the Development Programme of aprepitant

	Aprepitant formulation D	Aprepitant, formulations a, b, c	L-758298* (iv.)	Total
Clinical Pharmacology	356	229	114	699
Phase II	397	369	149	547
Phase III	549	0	0	549
Total CINV	946	369	149	1464
Non-CINV	180	926	66	1172
Total	1482	1524	329	3335

*L758298 is a prodrug of aprepitant administered by the IV route.

[1] The terms adverse drug reactions and adverse events are used according to the current EU legislation. An adverse drug reaction is defined by a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. A reaction, contrary to an event, is characterised by the fact that a causal relationship between the drug and the occurrence is suspected. An adverse event does not necessarily have a causal relationship with the treatment. Finally, the term "severe" is not

Seguridad


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The page lists patient safety information from the last two years. For a full list of all changes made to centrally authorised medicines, see the European public assessment report. For information on referrals, see referral procedures.
Patient safety
Date
European Medicines Agency completes its review of Avastin used in breast cancer
16/12/2010
European Medicines Agency concludes that benefit-risk balance of Invirase remains positive
21/10/2010
European Medicines Agency recommends suspension of Octagam in all EU Member States
24/09/2010
European Medicines Agency recommends suspension of Avandia, Avandamet and Avaglim
23/09/2010
European Medicines Agency concludes review of modified-release oral opioids of the WHO level III scale for the management of pain
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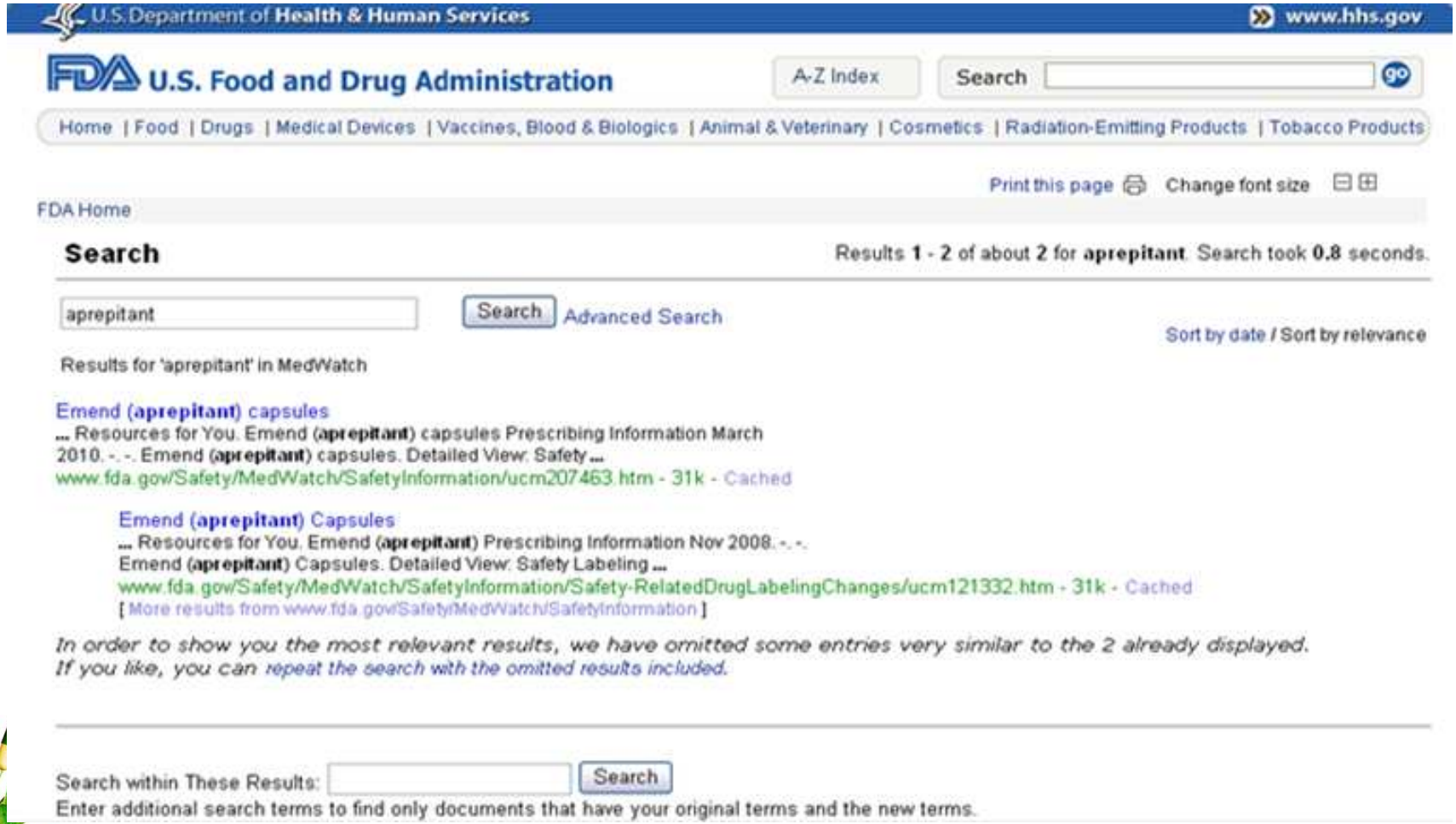
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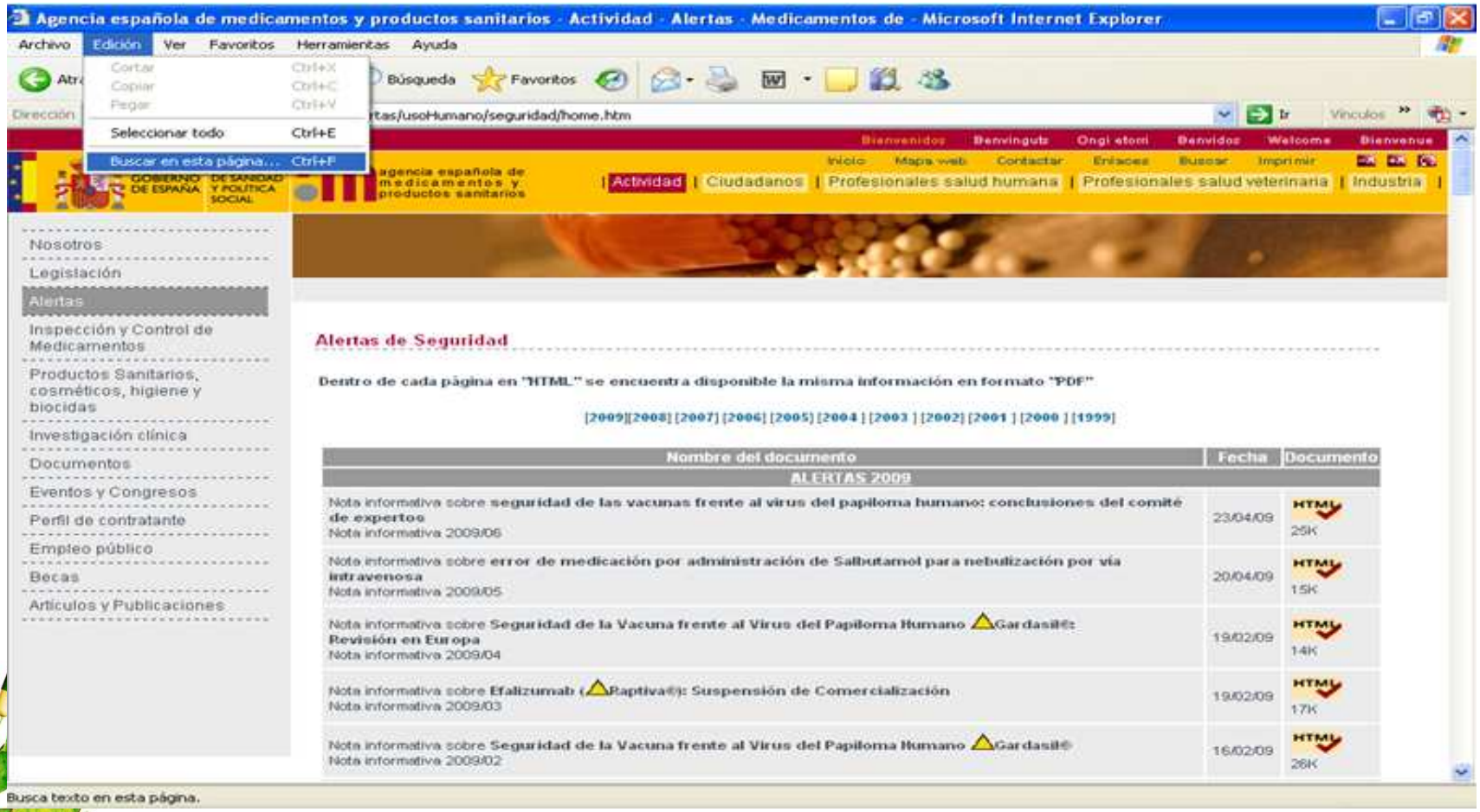

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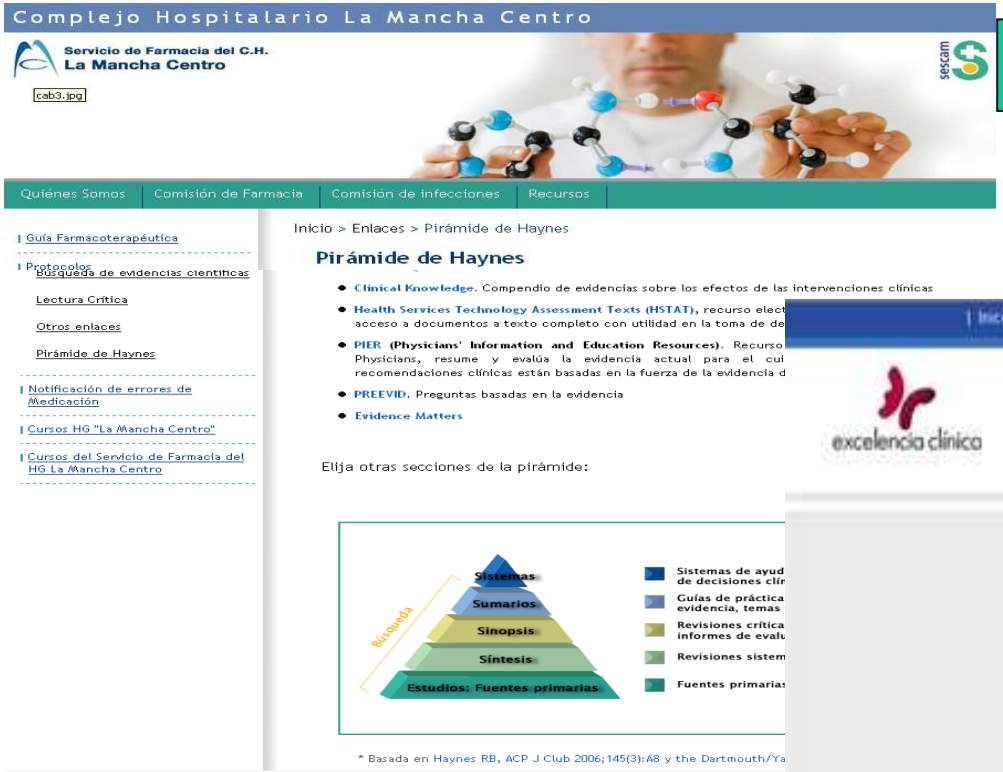

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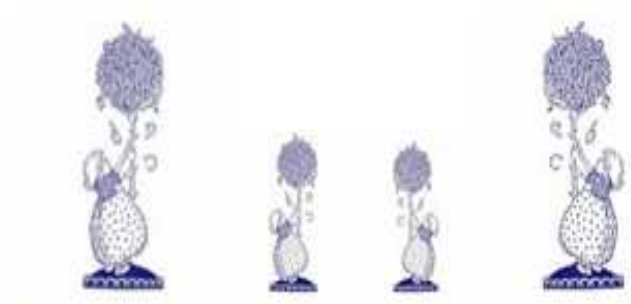

Buscador especializado en la obtención de información independiente no publicada en revistas científicas
orientado a la selección de medicamentos y su posicio
Actualización 1 de Septiembre 201

Coordinador

Fernando do Pazo Oubiña. Hospital Clínico. Barcelona. FDOPAZO@clinic.ub.es nandodo_pazo@hotmail.com

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Pere Ventayol. Hospital Universitario Son Dureta. Palma de Mallorca pere.ventayol@ssib.es

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www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=11190
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Motor de búsqueda elaborado por Fernando do Pazo

Evaluaciones previas por otros organismos independientes

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EVALUACIÓN DE NUEVOS MEDICAMENTOS

noviembre de 2005 ENM 18/05

Aprepitant
(Emend ®)

Código ATC : A04AD12 DDD : 95 mg

MEDICAMENTO DE UN NUEVO GRUPO FARMACOLÓGICO

Aportación Terapéutica: *NULA*

D.L.: AS-5627-04

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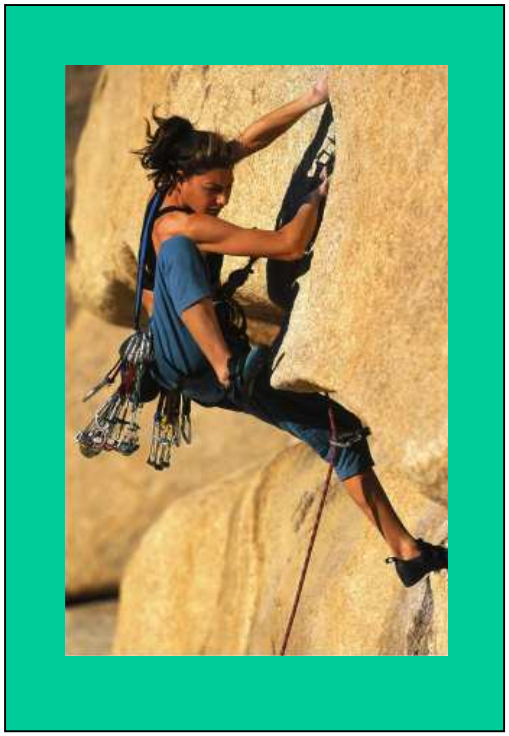

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Posicionamiento terapéutico

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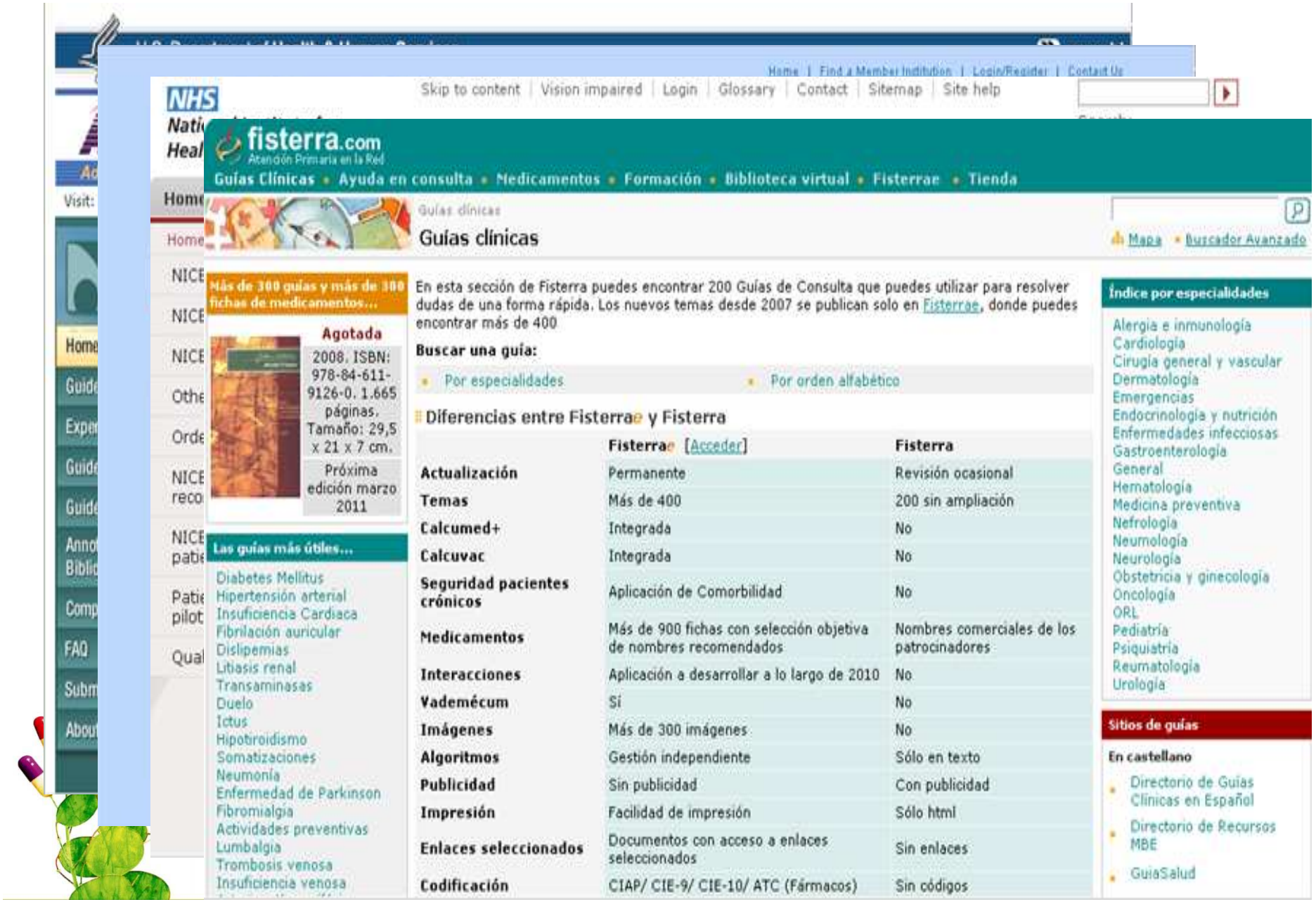
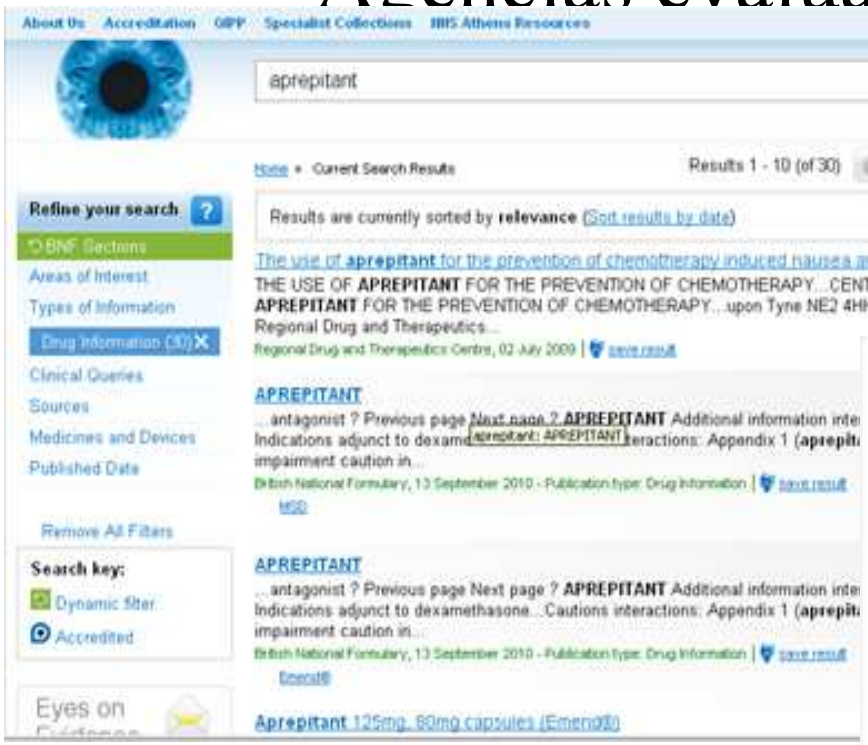
- Protocolos de utilización de fármacos
- Informes de evaluación elaborados por otros organismos o compañeros

GUÍAS DE PRÁCTICA CLÍNICA



Posicionamiento terapéutico

Agencias evaluadoras independientes:



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GRACIAS