

Prescrire Awards 1981-2012

32 years of Prescrire Drug Awards



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The three annual Prescrire Awards, for Drugs, Information and Packaging, are granted in total independence by the Prescrire Editorial Staff (rules available on our website: www.prescrire.org). These awards complement the annual review published at the beginning of each year in our French edition and a review of new drugs and indications in 2012 to be published in the next issue of *Prescrire International*.

(1)	Pilule d'Or/Golden Pill Award	Honours List
2012 (n°352)	(not awarded)	No awards for any new products or new indications
2011 (n°340)	(not awarded)	No awards for any new products or new indications
2010 (n°328)	(not awarded)	• Glivec° (<i>imatinib</i>) (inoperable and metastatic gastrointestinal stromal tumours, with more follow-up) (RA)
2009 (n°316)	(not awarded)	No awards for any new products or new indications
2008 (n°304)	(not awarded)	No awards for any new products or new indications
2007 (n°292)	CARBAGLU° (<i>carglumic acid</i>) (a second look) (B)	• Glivec° (<i>imatinib</i>) (chronic myeloid leukaemia, a second look) (RA) • Herceptin° (new indication) (<i>trastuzumab</i>) (OAA)
2006 (n°280)	ORFADIN° (<i>nitisinone</i>) (B)	• Egaten° (<i>triclabendazole</i>) (RA)
2005 (n°269)	(not awarded)	• Varivax° (<i>chickenpox vaccine</i>) (RA)
2004 (n°258)	(not awarded)	• Diacomit° (<i>stiripentol</i>) (OAA) • Fuzeon° (<i>enfuvirtide</i>) (OAA) • Morphine Aguettant° syrup (<i>oral morphine</i>) (OAA) (2)
2003 (n°247)	(not awarded)	• Carbaglu° (<i>carglumic acid</i>) (RA) • IVheBex° (<i>hepatitis B immunoglobulin</i>) (RA) • Meningitec° (<i>conjugated meningococcal C vaccine</i>) (OAA)
2002 (n°236)	(not awarded)	• Replagal° (<i>agalsidase alfa</i>) (RA) (3) • Ceprotin° (2), Protexel° (<i>human protein C</i>) (RA) • Stromectol° (new indication) (<i>ivermectin</i>) (OAA)
2001 (n°225)	(not awarded)	• Estérasine° (<i>C1 esterase inhibitor</i>) (RA) (2) • Trolovol° (new indication) (<i>penicillamine</i>) (RA)
2000 (n°214)	(not awarded)	• Remicade° (<i>infliximab</i>) (OAA)
1999 (n°203)	(not awarded)	• Sustiva° (<i>efavirenz</i>) (OAA) • NorLevo° (<i>levonorgestrel</i>) (OAA)
1998 (n°192)	CRIXIVAN° (<i>indinavir</i>) (RA)	• Cystagon° (<i>mercaptamine</i>) (RA) • Viagra° (<i>sildenafil</i>) (RA)
1997 (n°180)	(not awarded)	• Elisor°-Vasten° (new indication) (<i>pravastatin</i>) (RA) • Novatrex° (new indication) (<i>methotrexate</i>) (OAA) • Vesanoïd° (new indication) (<i>tretinoin</i>) (RA)
1996 (n°169)	DIGIDOT° (<i>antidigitalin antibodies</i>)(B)(3)	• Cérédase° (<i>alglucerase</i>) (RA) (2) • Normosang° (<i>hemin arginine</i>) (RA) • Subutex° (<i>buprenorphine</i>) (RA) • Zocor° - Lodalès° (new indication) (<i>simvastatin</i>) (RA) • Zeclar° - Naxy° (<i>clarithromycin</i>) ; Clamoxyl° - Gramidil° (2) (<i>amoxicillin</i>) ; Mopral° - Zoltum° (<i>omeprazole</i>) ; Ogast° - Lanzor° (<i>lansoprazole</i>) (same new indication) (RA)
1995 (n°158)	(not awarded)	• Chorhydrate de méthadone AP-HP° (<i>methadone</i>) (RA) • Retrovir° (new indication) (<i>zidovudine</i>) (RA) • Kogenate° - Recombinate° (2) (<i>recombinant factor VIII</i>) (RA)
1994 (n°147)	(not awarded)	• Botox°-Dysport° (<i>botulinum toxin</i>) (OAA) • Zophren° (new dosages) (<i>ondansetron</i>) (OAA)
1993 (n°136)	(not awarded)	• Avlocardyl° (new indication) (<i>propranolol</i>) (RA) • Daivonex° (<i>calcipotriol</i>) (OAA) • Sporanox° (<i>itraconazole</i>) (OAA)
1992 (n°125)	SURFEXO° (<i>pulmonary surfactant</i>) (RA)(3)	• Apokinin° (<i>apomorphine</i>) (OAA) • Videx° (<i>didanosine</i>) (OAA)
1991 (n°114)	(not awarded)	• Aredia° (<i>pamidronate</i>) (RA) (2) • Minirin° inj. (new indication) (<i>desmopressin</i>) (RA) • Lévocarnil° (<i>L-carnitine</i>) (RA) • Sandostatine° (new indication) (<i>octreotide</i>) (RA)
1990 (n°103)	(not awarded)	• Mopral° (<i>omeprazole</i>) (RA) • Narcan° (<i>naloxone</i>) (RA) • Pentacarinat° (<i>pentamidine</i>) (OAA)
1989 (n°92)	EPREX° (<i>epoetin alfa</i>) (B) MECTIZAN° (<i>ivermectin</i>) (B)	• Malocide° (new indication) (<i>pyrimethamine</i>) (RA) • Nimotop° inj. (new indication) (<i>nimodipine</i>) (RA) • Sandostatine° (<i>octreotide</i>) (RA)
1988 (n°81)	LARIAM° (<i>mefloquine</i>) (B) RETROVIR° (<i>zidovudine</i>) (B)	• Anexate° (<i>flumazenil</i>) (RA) • Nimotop° (<i>nimodipine</i>) (RA)
1987 (n°71)	LUTRELEF° (<i>gonadorelin</i>) (B) DECAPEPTYL° (<i>triptorelin</i>) (RA)	• IntronA° (interferon alfa) (RA) • Moscontin° (sustained release morphine) (RA) • Zovirax° cream (<i>aciclovir</i>) (OAA) • Rifadine° (<i>rifampicin</i>) (RA) • Tégrétole° (new indications) (<i>carbamazepine</i>) (RA)
1986 (n°61)	ZOVIRAX° I.V. and tabs. (<i>aciclovir</i>) (B) and (RA)	• GHRH Clin Midy° (<i>somatorelin</i>) (RA) (2) • Roaccutane° (<i>isotretinoin</i>) (RA) (2)
1985 (n°51)	(not awarded)	• Augmentin° (<i>amoxicillin + clavulanic acid</i>) (OAA)
1984 (n°41)	(not awarded)	• Nizoral° (<i>ketocoazole</i>) (RA) (4) • Orimétène° (<i>aminoglutethimide</i>) (RA) (2) • Ulcar° (<i>sucralfate</i>) (RA)
1983 (n°31)	LOPRIL° (<i>captopril</i>) (RA)	• Tigason° (<i>etretinate</i>) (RA) (2)
1982 (n°21)	(not awarded)	• Didronel° (<i>etidronic acid</i>) (RA) • Minirin° (<i>desmopressin</i>) (RA) • Nerfactor° (<i>isaxonine</i>) (RA) (4) • Vansil° (<i>oxamniquine</i>) (2)(RA)
1981 (n°10)	VACCIN HEVAC B° (<i>hepatitis B vaccine</i>) (B)	• Androcur° (<i>cyproterone</i>) (RA) • Armophylline° (<i>theophylline LP</i>) (RA) (2) • Cordium° (<i>bepiridil</i>) (RA) • Isoprosinosine° (<i>inosine acedoben dimepranol</i>) (RA) • Pirilène° (<i>pyrazinamide</i>) (RA) • Tildiem° (<i>diltiazem</i>) (RA)

The table above lists the drugs along with their initial ratings in the New Products section of our French edition:

B = Bravo;
RA = Real Advance
OAA = Offers An Advantage

1- Year and issue of the Prescrire French edition in which the annual awards were published.

2- Product no longer marketed in France, as of 10 January 2013.

3- New data published after the inclusion of this drug on the Honours List led us to revise our rating (see French edition n°241 p. 498-499).

4- Drug since withdrawn from the French market, because of adverse effects.

Products evaluated during the previous year in the New Products section of our French edition are eligible for the Prescrire Awards for new drugs and indications (in 2012: issues 339 to 350).



Each month, the *Prescrire* Editorial Staff presents systematic and comparative analyses of available data on all newly approved drugs in France, and on new therapeutic indications granted for existing drugs. The goal is to help readers to distinguish, among the plethora of lavishly promoted commercial products, those medications worth adding to their prescribing lists or worth using instead of existing products; also to distinguish which products are to be avoided.

This evaluation is based on rigorous procedures that include a thorough literature search, a large panel of reviewers (specific to each project) and a quality control system to verify that the text is consistent with the data in the references (see our website for further information: english.prescrire.org).

Total independence. This work is carried out by the Editorial Staff in total independence. *Prescrire* is financed exclusively by subscribers. Neither the French nor the English edition carries any paid advertising, nor do we receive grants or subsidies of any kind (see our annual financial report in the June issue of *Prescrire International*). At the end of each year, the Prescrire Drug Awards are based on the review articles published in the French edition in that year, and take into account any new data available since the initial articles were published.

The rules governing the Drug Awards are available online, at english.prescrire.org.

"Therapeutic advance" is defined as better efficacy, fewer or less severe adverse effects (for similar efficacy), or safer or more convenient administration.

2012: two minor advances. Once again, the Golden Pill Award was not attributed this year (see above and page 79). In addition, no new drugs and no new indications for existing drugs were deemed worthy of inscription on the Honours List for 2012.

Two new drugs marketed in 2012 provided a slight advantage for certain patients.

Abiraterone is an antiandrogen with a mechanism of action different from that of *cyproterone*. A good-quality trial, in men with metastatic prostate cancer

Pilule d'Or/Golden Pill Award

Not attributed for 2012

The "Golden Pill" award is granted to drugs that provide a major therapeutic advance for patients and healthcare professionals in a field in which no treatment was previously available.

Honours List

No inclusions for 2012

Drugs included on the Honours List provide a clear advantage for some patients in comparison to existing therapeutic options, albeit with certain limitations.

Noteworthy

The following drugs provided a modest improvement in patient care.

abiraterone	ZYTIGA [®] tablets Janssen-Cilag	Metastatic prostate cancer following failure of castration and chemotherapy; in combination with a corticosteroid (<i>Prescrire Int</i> n° 128)
boceprevir	VICTRELIS [®] capsules Merck Sharp & Dohme	Chronic hepatitis C due to a genotype 1 virus, previously untreated or after failure of the <i>peginterferon alfa</i> + <i>ribavirin</i> combination (<i>Prescrire Int</i> n° 126)

in whom androgen suppression followed by chemotherapy had failed, showed that *abiraterone* prolonged overall survival by about 4 months (to 15 months, versus 11 months in the placebo group). Adverse effects, including hepatic and cardiac disorders are sometimes severe but are acceptable if patients are closely monitored. It is given orally.

Boceprevir is an antiviral agent that inhibits NS3/4A serine protease (**a**). In patients with chronic hepatitis C due to a genotype 1 virus, who had never been treated or in whom the *peginterferon alfa* + *ribavirin* combination had failed, oral *boceprevir* add-on therapy increased the rate of sustained virological responses by 30% to 40%, although follow-up is too short to judge the efficacy of *boceprevir* on clinical outcomes (mortality, liver transplantation, cirrhosis). Its main adverse effects are potentially severe haematological disorders, which can be anticipated and possibly corrected.

A continuing lack of therapeutic advance. 2012 was another disappointing year for patients and healthcare professionals, as the pharmaceutical industry failed to provide new drugs with tangible therapeutic advantages.

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a-Telaprevir, un antiviral drug belonging to the same class as boceprevir, is a useful alternative to boceprevir but carries a risk of unpredictable and potentially severe cutaneous adverse reactions. This is why telaprevir did not receive an award.

The Information Awards focus on the quality of the information provided to *Prescrire* by the pharmaceutical companies whose products we examined in the New Products section of our French edition during the previous year (in 2012: issues 339 to 350).



Prescrire's reviews dealing with new drugs and indications are based on a thorough literature search for documents relating to the drug's pre-approval assessment, especially clinical trial reports.

In addition to textbooks and bibliographic databases, *Prescrire* editors search the websites of drug regulatory agencies, health economics institutions, health technology assessment agencies and other institutions specialising in the relevant therapeutic field. *Prescrire* regularly asks drug regulatory agencies to provide specific information and unpublished documents. We also search other independent journals who are members of the International Society of Drug Bulletins (ISDB), and any independent institutions that have evaluated the drug in question.

Drug companies also hold a wealth of data. We also request relevant information from the companies that market each drug we analyse in France, to ensure that we take into account all data, including unpublished data, used to justify marketing approval or to modify an existing marketing authorisation. These unpublished data, such as expert reviews and Periodic Safety Update Reports (PSURs) are held both by the regulatory agency that examined the application and by the company that obtained marketing authorisation for its product.

As is the case with the other *Prescrire* Awards, a systematic and totally independent process is used to grant the Information Awards (rules available on our website, at english.prescrire.org).

Rewarding accountable companies. Some drug companies respond to our requests for information in a timely manner and provide us with thorough and relevant data, including unpublished data. These companies are placed on the Honours List. The companies rated as "Outstanding" provided us with exhaustive and detailed information, without delay and sometimes without being asked.

Honours List (in alphabetical order)

- Outstanding: **Ageps-EPHP, Janssen-Cilag**
- Followed by: **Addmedica, Chauvin, EG Labo, GlaxoSmithKline, Mayoly Spindler, Sanofi Pasteur MSD**

Red Cards (in alphabetical order)

- **Allergan, Bayer Santé, Biogen Idec, Boehringer Ingelheim, Bristol-Myers Squibb, MSD, Servier, Takeda**

What do unhelpful companies have to hide? Other drug companies either fail to respond to our requests for information or provide only limited data. Some avoid responding for as long as possible and then fail to provide solid, exploitable data. Others fail to provide the most relevant data. Their usual pretexts include a lack of time, administrative delays, confidentiality issues, or a veto from their headquarters. Some companies appear to withhold information in retaliation for an unfavourable review in *Prescrire*.

"Red cards" are a way of highlighting persistent shortcomings in the provision of information by certain drug companies. These companies should rather take advantage of the opportunity offered by *Prescrire* to provide healthcare professionals with reliable information on their products.

2012: once again, no noteworthy improvement. The situation has barely changed over the years. Some companies continue to provide *Prescrire* with high-quality information, reflecting a responsible attitude towards patients and healthcare professionals. Others, unfortunately, place the accent on self-promotion and appear to see no need to provide thorough and reliable information on the products they market. They clearly fail to realize that a company's transparency is evidence of its credibility and is one of the criteria for choosing a particular drug, alongside efficacy, safety, usability, and price.

Some companies foster confusion between information and publicity. Their marketing documents are often biased and incomplete, being designed

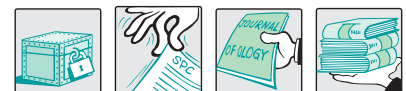
more to boost sales than to ensure safe and effective patient care.

It is up to healthcare professionals to make sure the information they receive comes from trustworthy, independent sources. This will also reassure their patients.

Some companies expressed a willingness to change their policy following the Mediator^o disaster in France but that did not translate in tangible actions in 2012.

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Whenever we examine a new drug or indication, the review is accompanied by one of four pictograms rating the transparency of the company concerned for their response to our request for information about their product (for details search for "ratings system" online at english.prescrire.org).



The Packaging Awards focus on the quality of packaging for drugs evaluated during the previous year in the New Products section of our French edition (in 2012: issues 339 to 350).



Throughout the year, *Prescrire's* Editorial Staff systematically examines the packaging of about 150 pharmaceutical products. This provides us with an opportunity to identify high-quality packaging and to detect dangerous parts of the packaging that are potential sources of confusion and errors, in order to inform our readers.

Every appearance of the packaging is examined, including the labelling; any devices provided for drug preparation or administration; caps and stoppers; and the legibility and quality of the information provided in the patient leaflet.

At the end of each year, the Packaging Awards are granted following a review of the year's standardised analyses by the *Prescrire Packaging Working Group*, in total independence and with no input from drug or packaging manufacturers (rules available at english.prescrire.org).

No awards for 2012. Only one contender came close to obtaining the packaging award for 2012. Paratabs° (Actavis) was the first orodispersible *paracetamol* to be marketed in France in blister packs equipped with an anti-tamper film. This protects children by helping to prevent them from accessing the tablets. However, in order to peel off the anti-tamper film, it is necessary to detach each portion of the blister pack containing a tablet, and this results in the expiry date and lot number no longer being visible. *Prescrire* also regrets that the company decided to highlight the brand name to the detriment of the international nonproprietary name (INN): a missed opportunity to receive an award.

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Packaging Award



• Not attributed for 2012

Yellow Cards

(in alphabetical order)



- **Aldalix° (a) capsules** Pfizer (*furosemide + spironolactone*) (*Rev Prescrire* n° 348)
On the box, the international nonproprietary names (INN) are printed in such tiny characters that they appear simply to underline the brand name; in addition, the packaging resembles those of Aldactazine° (*altizide + spironolactone*) and Aldactone° (*spironolactone*).
- **Gelutrophyl° capsules** Jolly Jatel (*ethanolamine tenoate*) (*Rev Prescrire* n° 349) • **Saflutan° eye drops** MSD (*tafluprost*) (*Rev Prescrire* n° 344)
The primary packaging of these two products (blister packs, single-use containers) does not even mention the INNs.
- **Predyl° mouthwash** Pred (*povidone iodine*) (*Rev Prescrire* n° 348)
This product has an attractive appearance (mauve colour, flask shape) and lacks a child-proof cap.

a- Aldalix° is no longer marketed in France in 2013.

Red Cards (by type of packaging defect, and then in alphabetical order)



- **Biperidysflash° orodispersible tablets** Pierre Fabre Medicament (*domperidone*) (*Rev Prescrire* n° 340)
The patient leaflet fails to mention the risk of cardiac adverse effects.
- **Mycohydralin° cream** Bayer Santé Familiale (*clotrimazole*) (*Rev Prescrire* n° 340)
The patient leaflet fails to mention clearly that latex condoms might be at risk of rupture if placed in contact with this cream.
- **Ostram Vitamine D3° powder for oral suspension** Merck Serono (*tricalcium phosphate + colecalciferol*) (*Rev Prescrire* n° 342)
The information provided on the box no longer mentions the fact that this drug is contraindicated in case of renal impairment.
- **Xarelto° 15 mg and 20 mg tablets** Bayer Santé (*rivaroxaban*) (*Prescrire Int* n° 132)
The aspect of the two dose strengths is very similar, especially the blister packs and tablets.

Packaging that may put children at risk

- **Flixovate° cream and ointment** GlaxoSmithKline (*fluticasone*) (*Rev Prescrire* n° 341)
The dosing schedule still mentions twice-daily application (morning and evening), despite the fact that this product is now approved for use from the age of 3 months, in a single daily application. This creates a risk of overdose and adverse effects in this age group, which is particularly sensitive to the adverse effects of this potent topical corticosteroid.

- **Preterval° tablets** Servier (*indapamide + perindopril*) (*Rev Prescrire* n° 343) • **Suboxone° sublingual tablets** Reckitt Benckiser Pharmaceuticals (*buprenorphine + naloxone*) (*Rev Prescrire* n° 342)
For the lack of a safety cap on the bottle and the lack of an anti-tamper film on the blister pack, creating a risk of accidental ingestion by a child and potentially severe adverse effects.

Patient leaflets that endanger the unborn child

- **Alevetabs° tablets** Bayer Santé Familiale (*naproxen*) (*Rev Prescrire* n° 343) • **Rhinadvil° tablets** Pfizer Santé Familiale (*ibuprofen + pseudoephedrine*) (*Rev Prescrire* n° 345) • **Rhinureflex° tablets** Reckitt Benckiser Healthcare (*ibuprofen + pseudoephedrine*) (*Rev Prescrire* n° 348)
All three products contain a nonsteroidal anti-inflammatory drug (NSAID), but the accompanying information leaflet only states that they are contraindicated from the sixth month of pregnancy. Yet there are also a risk of miscarriage and malformations when NSAIDs are used during the first trimester, and a risk of life-threatening renal and cardiovascular disorders when they are used from the second trimester.
In addition, there is no mention of the fact that *pseudoephedrine* may possibly be teratogenic, based on weak but consistent evidence.