Prescrire Awards 1981-2013
33 years of Prescrire Drug Awards

Translated from ***Rev Prescrire*** **February 2014; 34 (364): 85-89**

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: english.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 2013 to be published in the April issue of *Prescrire International*.

Prescrire	Pilule d'Or/Golden Pill Award	Honours List
2013 (n°364)	(not awarded)	No awards for any new products or new indications
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° (*imatinib*) (inoperable and metastatic gastrointestinal stromal tumours, with more follow-up)
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° *(carglumic acid)*** (a second look)	• Glivec° (*imatinib*) (chronic myeloid leukaemia, a second look) • Herceptin°(NI) (*trastuzumab*)
2006 (n°280)	**ORFADIN° (*nitisinone*)**	• Egaten° (*triclabendazole*)
2005 (n°269)	(not awarded)	• Varivax° (*chickenpox vaccine*)
2004 (n°258)	(not awarded)	• Diacomit° (*stiripentol*) • Fuzeon° (*enfuvirtide*) • Morphine Aguettant° syrup (*oral morphine*) (1)
2003 (n°247)	(not awarded)	• Carbaglu° (*carglumic acid*) • IVheBex° (*hepatitis B immunoglobulin*) • Meningitec° (*conjugated meningococcal C vaccine*)
2002 (n°236)	(not awarded)	• Replagal° (*agalsidase alfa*) (2) • Ceprotin° (1), Protexel° (*human protein C*) • Stromectol° (NI) (*ivermectin*)
2001 (n°225)	(not awarded)	• Estérasine° (*C1 esterase inhibitor*) (1) • Trolovol° (NI) (*penicillamine*)
2000 (n°214)	(not awarded)	• Remicade° (*infliximab*)
1999 (n°203)	(not awarded)	• Sustiva° (*efavirenz*) • NorLevo° (*levonorgestrel*)
1998 (n°192)	**CRIXIVAN° (indinavir)**	• Cystagon° (*mercaptamine*) • Viagra° (*sildenafil*)
1997 (n°180)	(not awarded)	• Elisor°-Vasten° (NI) (*pravastatin*) • Novatrex° (NI) (*methotrexate*) • Vesanoïd° (NI) (*tretinoin*)
1996 (n°169)	**DIGIDOT° (antidigitalin antibodies)** (1)	• Cérédase° (*alglucerase*) (1) • Normosang° (*hemin arginine*) • Subutex° (*buprenorphine*) • Zocor° - Lodalès° (NI) (*simvastatin*) • Zeclar° - Naxy° (*clarithromycin*) ; Clamoxyl° - Gramidil° (1) (*amoxicillin*) ; Mopral° - Zoltum° (*omeprazole*) ; Ogast° - Lanzor° (*lansoprazole*) (same new indication)
1995 (n°158)	(not awarded)	• Chorhydrate de méthadone AP-HP° (*methadone*) • Retrovir° (NI) (*zidovudine*) • Kogenate° - Recombinate° (1) (*recombinant factor VIII*)
1994 (n°147)	(not awarded)	• Botox°-Dysport° (*botulinum toxin*) • Zophren° (ND) (*ondansetron*)
1993 (n°136)	(not awarded)	• Avlocardyl° (NI) (*propranolol*) • Daivonex° (*calcipotriol*) • Sporanox° (*itraconazole*)
1992 (n°125)	**SURFEXO° (pulmonary surfactant)** (1)	• Apokinon° (*apomorphine*) • Videx° (*didanosine*)
1991 (n°114)	(not awarded)	• Aredia° (*pamidronate*) (1) • Minirin° inj. (NI) (*desmopressin*) • Lévocarnil° (*L-carnitine*) • Sandostatine° (NI) (*octreotide*)
1990 (n°103)	(not awarded)	• Mopral° (*omeprazole*) • Narcan° (*naloxone*) • Pentacarinat° (*pentamidine*)
1989 (n°92)	**EPREX° (*epoetin alfa*)** **MECTIZAN° (*ivermectin*)**	• Malocide° (NI) (*pyrimethamine*) • Nimotop° inj. (NI) (*nimodipine*) • Sandostatin° (*octreotide*)
1988 (n°81)	**LARIAM° (*mefloquine*)** **RETROVIR° (*zidovudine*)**	• Anexate° (*flumazenil*) (1) • Nimotop° (*nimodipine*)
1987 (n°71)	**LUTRELEF° (*gonadorelin*)** **DECAPEPTYL° (*triptorelin*)**	• Introna° (interferon alfa) • Moscontin° (sustained release morphine) • Zovirax° cream (*aciclovir*) • Rifadine° (*rifampicin*) • Tégrétol° (NI) (*carbamazepine*)
1986 (n°61)	**ZOVIRAX° I.V. and tabs. (*aciclovir*)**	• GHRH Clin Midy° (*somatorelin*) (1) • Roaccutane° (*isotretinoin*) (1)
1985 (n°51)	(not awarded)	• Augmentin° (*amoxicillin + clavulanic acid*)
1984 (n°41)	(not awarded)	• Nizoral° (*ketoconazole*) (1) • Orimétène° (*aminoglutethimide*) (1) • Ulcar° (*sucralfate*)
1983 (n°31)	**LOPRIL° (*captopril*)**	• Tigason° (*etretinate*) (1)
1982 (n°21)	(not awarded)	• Didronel° (*etidronic acid*) (1) • Minirin° (*desmopressin*) • Nerfactor° (*isaxonine*) (1) • Vansil° (*oxamniquine*) (1)
1981 (n°10)	**VACCIN HEVAC B° *(hepatitis B vaccine)***	• Androcur° (*cyproterone*) • Armophylline°(*theophylline LP*) (1) • Cordium° (*bepridil*) (1) • Isoprinosine° (*inosine acedoben dimepranol*) • Pirilène° (*pyrazinamide*) • Tildiem° (*diltiazem*)

NI = New Indication; **ND** = New Dosage

1- No longer marketed in France.
2- 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).

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2013 Prescrire Drug Awards

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.

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 the reader distinguish, among the plethora of lavishly promoted commercial products, those medications worth adding to their drug list or worth using instead of existing products, as well as products 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 March issues of *Prescrire* and the June issues of *Prescrire International*). At the end of each year, the *Prescrire* Drug Awards are based on the review articles published that year in the French edition, 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.

2013: only one product providing modest progress. Once again, the Golden Pill award was not granted this year. In addition, no new drug or new indication for an existing drug was deemed worthy of inclusion on the Honours List in 2013.

A new vaccine that helps to protect certain infants was deemed "Noteworthy".

For children aged from one to two years who require protection against meningococcal infections caused by serogroups A, C, W135 and Y before travelling to an endemic area, existing unconjugated polyoside vaccines were poorly immunogenic. A tetravalent polyoside vaccine conjugated to tetanus toxoid (Nimenrix°) has documented immunogenicity and is the only vaccine authorised for this age group in the European Union. Its adverse effects are moderate, although it is less well tolerated than unconjugated vaccines.

Another tetravalent conjugated vaccine is already available for children over two years of age.

Still awaiting real progress. Once again, new drugs and indications authorised in 2013 provided no major therapeutic progress.

We need to improve the care of patients by integrating results of new evaluation or pharmacovigilance data into clinical practice. Rejecting drugs that have more adverse effects than benefits could be a source of tremendous progress for patients. For real improvements to be made, all healthcare professionals need to do their share.

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Pilule d'Or (Golden Pill) Award	The "Pilule d'Or" ("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	
Not awarded in 2013		
Honours List	Drugs included on the Honours List provide a clear advantage for some patients in comparison to existing therapeutic options, albeit with certain limitations.	
No inclusions in 2013		
Noteworthy	Drug providing a modest improvement in patient care.	
meningococcal conjugate vaccine against serogroups A,C,W135,Y	NIMENRIX° for IM injection GlaxoSmithKline	active immunisation of infants aged 1 to 2 years against meningococcal serogroups A,C,W135,Y (*Prescrire Int* n° 144)

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2013 Prescrire Information Awards

The Information Awards focus on the information provided to Prescrire by the pharmaceutical companies whose products we examined in the New Products section of our French edition in 2013.

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

In addition to textbooks and bibliographic databases, *Prescrire* editors search the websites of drug regulatory agencies, organisations that carry out pharmacoeconomic evaluations, health technology assessment agencies and other bodies 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 organisations 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.

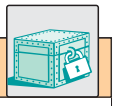
As is the case with the other *Prescrire* Awards, a systematic and totally independent process is used to grant the Information Awards (rules available on our website, at english.prescrire.org).

Rewarding accountable companies. Some drug companies respond to our requests for information in a timely manner and provide us with thorough and relevant information, 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: **EG Labo**
- Followed by: **Chauvin, GlaxoSmithKline, Lucane Pharma, Medac, Novartis Vaccines and Diagnostics, Reckitt Benckiser Pharmaceuticals, and Viropharma**

Red Cards (in alphabetical order)



- **Bayer Santé, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead Sciences, Novartis Pharma, Pfizer, Roche, Servier, and 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 of them delay as long as possible before responding and then fail to provide solid, exploitable data. Their pretexts include: lack of time; administrative delays; confidentiality issues; or objections from the parent company. Some companies appear to withhold information in retaliation for an unfavourable review in *Prescrire*.

"Red cards" for withholding information are a way of highlighting persistent shortcomings in the provision of information by certain drug companies.

Drug companies must take up the challenge of providing quality information. Some drug companies continue to provide *Prescrire* with high-quality information, reflecting a responsible attitude towards patients and healthcare professionals. Others, unfortunately, are more concerned with commercial promotion and appear to see no need for providing thorough and reliable information on the products they market. Some companies choose to withhold unfavourable data on their products to safeguard short-term interests. They clearly fail to realise that a company's transparency is evidence of its long-term credibility and is one of the criteria used to choose a particular drug, along with its efficacy, safety, ease of use and price.

Let's hope more companies take up this challenge.

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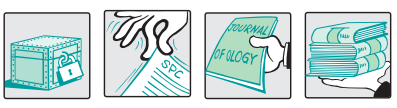
Whenever we examine a new drug or indication, the review is accompanied by one of four pictograms rating the transparency of the company concerned for their response to our request for information about their product (for details search for "ratings system" online at english.prescrire.org).



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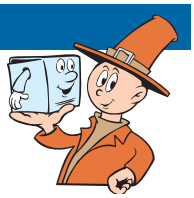
2013 Prescrire Packaging Awards



The Packaging Awards focus on the quality of packaging for drugs evaluated in 2013 in the New Products section of our French edition.

Throughout the year, we systematically examine the packaging of 150 to 250 pharmaceutical products. This provides us with an opportunity to identify high-quality packaging and to detect dangerous packaging that is a potential source of confusion and errors, in order to inform our readers (see the annual packaging review, to be published in our May issue). Every aspect of the packaging that could have an impact on the harm-benefit balance is examined, including the labelling (legibility of international nonproprietary names (INNs) and dosages, the appropriateness of dosing schedules or pictograms, and storage conditions); any devices provided for drug preparation or administration; the performance of tamper-proof devices such as stoppers and blister pack films; and the legibility and thoroughness of the patient leaflets, including dose preparation, adverse effects, and contraindications.

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

2013: some progress, but dangers continue to accumulate. Some improvements were observed in 2013: three drugs were considered worthy of a Packaging Award, a number that had not been reached since 2008.

However, the number of pharmaceuticals with substandard or dangerous packaging increased in 2013, with 33 products receiving a Yellow or Red Card.

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Packaging Awards

- **BCG-Medac° powder and solvent for intravesical suspension** Medac (BCG) (*Prescrire Int* n° 146)
  Contains all the materials required for patient care (solvent pouch, urinary probes) and reduces the risk of contamination (closed system for dose preparation, bag for waste disposal).
- **Suboxone° (*buprenorphine + naloxone*) and Subutex° (*buprenorphine*) sublingual tablets**
  Reckitt Benckiser Pharmaceuticals (*Rev Prescrire* n° 362)
  Reduction in the risk of accidental ingestion of these tablets by children, thanks to the addition of an effective tamperproof film to the blister packs (**a**).

a- Our tests show that it is almost impossible to break the tamperproof film with one's bare hands. To remove a tablet, it is first necessary to tear off a blister unit along the perforated lines, then to peel off the safety film, starting at the only corner where the film is not glued down.

Yellow Cards

- **Oralair° sublingual tablets** Stallergènes (***allergenic extract of five grass pollens***) (*Rev Prescrire* n°352) • **Quinofree° eye drops** Théa (***ofloxacin***) (*Rev Prescrire* n° 356) • **Voltarènophta° eye drops** Théa (***diclofenac***) (*Rev Prescrire* n° 354) • **Zalerg° eye drops** Théa (***ketotifen***) (*Rev Prescrire* n° 354)
  The primary packaging (blister packs, single-dose units) of these four products fails to mention the international nonproprietary names.
- **Tamiflu° powder for oral suspension** Roche **(*oseltamivir*)** (*Rev Prescrire* n° 354)
  The syringe is insufficiently precise for measuring a dose for a newborn, and it is graduated in millilitres, requiring the user to convert the prescribed dose from milligrams into millilitres, thus creating a risk of error and overdose.
- **Bromocriptine Zentiva inhibition de la lactation° tablets** Sanofi Aventis (*bromocriptine*) (*Rev Prescrire* n° 352)
  The dosing schedule printed on the box ("morning", "midday", "evening") is inappropriate, as the dose regimen recommended by the SPC is between one-half and two tablets a day; this creates a risk of overdose.

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2013 Prescrire Packaging Awards

Red Cards

Dangerous lack of information on the labelling or patient leaflet

- **Antalnox° Ge tablets** Pierre Fabre Médicament (*naproxen*) (*Rev Prescrire* n° 359) • **Rhinadvil Rhume Ibuprofène/pseudoéphédrine° tablets** Pfizer Santé Familiale (*ibuprofen + pseudoephedrine*) (*Rev Prescrire* n° 352). The patient leaflets fail to adequately warn patients of the dangers posed by these nonsteroidal anti-inflammatory drugs (NSAIDs). They do not mention the possible increased risk of miscarriage and malformations when used during the first trimester of pregnancy, or the potentially life-threatening renal and cardiovascular effects on the unborn child following exposure from the second trimester. Instead, they simply mention a contraindication from the 6th month of pregnancy. Finally, they fail to mention converging data that suggest *pseudoephedrine* may be teratogenic.
- **Jakavi° tablets** Novartis Pharma (*ruxolitinib*) (*Prescrire Int* n° 137). The patient leaflet describes adverse effects as mild or moderate and usually transient, yet *ruxolitinib* can cause severe bleeding and other serious adverse effects such as confusion.
- **Clarix toux sèche dextrométhorphane Adultes° sachets of oral solution** Coopération pharmaceutique française (*dextromethorphan*) (*Rev Prescrire* n° 354). The INN, which would allow users to identify this opioid, is not clearly printed on the box, even though the Clarix° umbrella line includes various other active substances.

Packaging that poses a risk for children

- **Revatio° power for oral suspension** Pfizer **(*sildenafil*)** (*Rev Prescrire* n° 352). There is a risk of massive overdose with the measuring device provided: the graduations on the syringe exceed the maximum dose; its graduation in millilitres (ml) requires the user to convert the dose from milligrams to millilitres; the dual graduation of the syringes in "ml" and "tsp" (teaspoon) is confusing; and the 30-ml cup provided to reconstitute the suspension could be confused with the dose measuring device.
- **Dolstic° 10% oral solution** Bioprojet Pharma (***paracetamol***) (*Rev Prescrire* n° 359). The two presentations of this product are not sufficiently distinct, as they contain measuring devices of different capacities, one for children up to 3 years of age, and the other for children from 3 to 10 years. Use of the latter device to treat infants could result in serious overdose.
- **Théralène° 4% oral solution and 0.05% syrup** Erempharma (***alimemazine***) (*Rev Prescrire* n° 362). The two products are too similar in appearance. However, the concentration of the oral solution is 80 times that of the syrup, and children would be exposed to a risk of severe adverse effects from this neuroleptic in case of confusion. In addition, the bottles of syrup lack a child-proof cap.
- **Codoliprane° 500 mg/30 mg divisible effervescent tablets** Sanofi Aventis **(*paracetamol + codeine*)** (*Rev Prescrire* n° 351). This type of tablet and the dosage are inappropriate for a product intended for children as young as three years; in addition, the lack of a child-proof cap on the tube creates a risk of overdose.
- **Trophirès composé enfants° suppositories** Sanofi Aventis **(*paracetamol + eucalyptus essential oil + tenoate sodium*)** (*Rev Prescrire* n° 353). The presence of *paracetamol* is not highlighted on the front of the box, which is similar to that of the *paracetamol*-free product belonging to this product line, creating a risk of confusion and overdose if another product containing *paracetamol* is used concomitantly.
- Five **suppositories** containing **terpene derivatives: • Biquinol enfants°** Merck Médication familiale • **Bronchodermine enfants°** S.E.R.P. • **Bronchorectine au citral enfants°** Mayoly Spindler • **Coquelusedal enfants°** Élerté • **Ozothine enfants°** Zambon (*Rev Prescrire* n° 353). The labelling on the front the boxes and the blister packs fails to mention the names of the terpene derivatives, which should be avoided in children because of the risk of seizures.
- **Huvanof° sachets of powder for oral solution** Sanofi Aventis **(*acetylsalicylic acid*)** (*Rev Prescrire* n° 361). The labelling on the boxes and sachets fails to highlight the presence of *aspirin,* and it is difficult to differentiate between the various dose strengths, creating a risk of overdose in children.
- **Ritaline° LP 10 mg capsules** Novartis Pharma **(*methylphenidate*)** (*Rev Prescrire* n° 357). The use of bulk bottles is inappropriate for this amphetamine psychostimulant intended for "hyperactive" children, and trivialises the risk associated with handling these drugs.
- **Imeth°** Nordic Pharma, **Méthotrexate Bellon°** Sanofi Aventis, **Novatrex°** Pfizer, **tablets (*methotrexate*)** (*Prescrire Int* n° 126) • **Clarix toux sèche dextrométhorphane mépyramine adultes° syrup** Coopération pharmaceutique française **(*dextromethorphan + mepyramine*)** (*Rev Prescrire* n° 357) • **Bricanyl° LP tablets** AstraZeneca **(*terbutaline*)** (*Rev Prescrire* n° 362) • **Rivotril° drops of oral solution** Roche **(*clonazepam*)** (*Rev Prescrire* n° 354). The bottles for these six products all lack a child-proof cap, creating a risk of accidental ingestion by a child, who would be exposed to the potentially severe adverse effects of these drugs.

Risk of dosing errors in adults

- **Januvia°** Merck Sharp & Dohme, **Xelevia°** Pierre Fabre Medicament, **tablets (*sitagliptin*)** (*Rev Prescrire* n° 352). The resemblance between the two dose strengths (50 mg and 100 mg) on the boxes and blister packs is a source of confusion, since patients with moderate renal failure must not ingest more than 50 mg per intake.
- **Maginjectable° IV or IM solution** Coopération pharmaceutique française **(*magnesium*)** (*Rev Prescrire* n° 362). The printing on the vials is poorly legible, especially regarding the hypertonic nature of the solution. In addition, the route of administration and the mode of IV injection are not mentioned, the dosage is expressed in two ways on the front of the box, and the information in the patient leaflet on the signs and treatment of hypermagnesaemia is inadequate.
- **Zyloric° tablets** H.A.C. Pharma **(*allopurinol*)** (*Rev Prescrire* n° 356). The INN and dosages are poorly legible on the blister packs, which also have a similar appearance, creating a risk of confusion; yet this drug can cause serious, dose-dependent, cutaneous hypersensitivity reactions.
- **Vimpat° syrup** UCB Pharma **(*lacosamide*)** (*Rev Prescrire* n° 352). The measuring cup is imprecise and graduated in millilitres (ml), requiring the user to convert milligrams to millilitres, thus creating a risk of underdosing or overdosing.

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