# THE PRESCRIRE AWARDS FOR 2016

The three annual Prescrire Awards, for Drugs, Packaging and Information, are granted in total independence by the Prescrire Editorial Staff. These awards complement the annual review published at the beginning of each year in our French edition and the following May in *Prescrire International*. The rules governing the three Prescrire Awards are available online at english.prescrire.org.

## 2016 Prescrire Drug Awards

New products or new indications evaluated during the previous year in the New Products section of our French edition are eligible for the Prescrire Drug Awards.

Each month, the *Prescrire* Editorial Staff publish comparative systematic analyses of the data available on: drugs newly authorised in France and the EU, new therapeutic indications granted for existing drugs, and existing drugs marketed in a new form or with different packaging. The goal is to help the reader distinguish, among the plethora of new products, those worth adding to their list of useful therapies, those worth using instead of older products, and those to be avoided.

Our analyses are based on rigorous procedures that include a thorough literature search, critical review by a group of reviewers specific to each article, and various quality controls to verify in particular that the text is consistent with all the data available (see our website for further information: english.prescrire.org).

**Total independence.** The *Prescrire* Editorial Staff conduct these analyses free from any industry or institutional influence. Our independence is made possible by the fact that we are financed exclusively by our subscribers, carry no paid advertising in either the French or the English edition, and receive no grants or subsidies of any kind (see our annual financial report in each June issue of *Prescrire International*).

The *Prescrire* Drug Awards are compiled at the end of each year, based on the reviews published that year in our French edition, and taking into account any new data made available since the initial articles were published. These awards honour drugs that constitute a therapeutic advance, in that they offer better efficacy, less frequent or less severe adverse effects (for similar efficacy), or safer or easier administration.

**Two drugs deemed "Noteworthy" in 2016.** Two of the products featured in the New Products section of our French edition in 2016 earned a *Prescrire* Drug Award this year. None of the new products examined constituted a sufficient therapeutic advance to warrant a "Pilule d'Or" (Golden Pill) Award or even a place on the "Honours List".

### "Pilule d'Or" not awarded for 2016

The two awards were for cancer drugs *Prescrire* deemed "Noteworthy". They have been shown to prolong survival by a few months on average, but with many serious adverse effects and a few that are sometimes fatal.



### Pilule d'Or / Golden Pill

The "Pilule d'Or" (Golden Pill) has been granted since 1981 to drugs that constitute a major therapeutic advance in a field in which no treatment was previously available.

| 2016 | NOT AWARDED |
|---|---|
| 2014 (Prescrire Int n° 157) | ORPHACOL° (*cholic acid*) |
| 2007 (Prescrire Int n° 94) | CARBAGLU° (*carglumic acid*) (a second look) |
| 2006 (Prescrire Int n° 88) | ORFADIN° (*nitisinone*) |
| 1998 (Prescrire Int n° 40) | CRIXIVAN° (*indinavir*) |
| 1996 (Prescrire Int n° 28) | DIGIDOT° (*digoxin-specific antibody*) (**a**) |
| 1992 (Prescrire Int n° 4) | SURFEXO° (*pulmonary surfactant*) (**a**) |
| 1989 (Rev Prescrire n° 92) | EPREX° (*epoetin alfa*) • MECTIZAN° (*ivermectin*) |
| 1988 (Rev Prescrire n° 81) | LARIAM° (*mefloquine*) • RETROVIR° (*zidovudine*) |
| 1987 (Rev Prescrire n° 71) | LUTRELEF° (*gonadorelin*) • DÉCAPEPTYL° (*triptorelin*) |
| 1986 (Rev Prescrire n° 61) | ZOVIRAX° IV and tablets (*aciclovir*) |
| 1983 (Rev Prescrire n° 31) | LOPRIL° (*captopril*) |
| 1981 (Rev Prescrire n° 10) | VACCIN HEVAC B° (*hepatitis B vaccine*) (**a**) |

Like this year no Golden Pill was awarded for 1982, 1984, 1985, 1990, 1991, from 1993 to 1995, for 1997, from 1999 to 2005, from 2008 to 2013, and for 2015.

**a-** No longer marketed in France.



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## Honours List

Drugs are included on the "Honours List" because they represent a clear advance for some patients compared with existing therapeutic options, albeit with limitations.

| 2016 | No inclusions |
|---|---|
| 2015 (Prescrire Int n° 162) | • Hemangiol° (*propranolol* oral solution) |
| 2014 (Prescrire Int n° 157,154, 156) | • Glivec° (*imatinib*)<br>• Malacef° (intravenous *artesunate*)<br>• Sovaldi° (*sofosbuvir*) |
| 2010 (Prescrire Int n° 114) | • Glivec° (*imatinib*) |
| 2007 (Prescrire Int n° 98) | • Glivec° (*imatinib*)<br>• Herceptin° (*trastuzumab*) |
| 2006 (Prescrire Int n° 84) | • Egaten° (*triclabendazole*) |
| 2005 (Prescrire Int n° 77) | • Varivax° (*varicella-zoster vaccine*) |
| 2004 (Prescrire Int n° 76) | • Diacomit° (*stiripentol*)<br>• Fuzeon° (*enfuvirtide*)<br>• Morphine Aguettant° syrup (*morphine* oral solution) (1) |
| 2003 (Prescrire Int n° 66,69,74) | • Carbaglu° (*carglumic acid*)<br>• IVheBex° (*hepatitis B immunoglobulin*)<br>• Meningitec° (*conjugate meningococcal C vaccine*)(1) |
| 2002 (Prescrire Int n° 67,61) | • Replagal° (*agalsidase alfa*) (2)<br>• Ceprotin° (1) - Protexel° (*human protein C*)<br>• Stromectol° (*ivermectin*) (scabies) |
| 2001 (Prescrire Int n° 53) | • Estérasine° (*C1 esterase inhibitor*) (1)<br>• Trolovol° (*penicillamine*) (chelator) |
| 2000 (Prescrire Int n° 50) | • Remicade° (*infliximab*) |

Drugs were included on the Honours List every year between 1981 and 2007. No drugs were included for 2008, 2009, or 2011 to 2013. The full list of drugs included on the Honours List from 1981 to 2013 can be found in *Prescrire Int* n° 147 p. 79.

**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 *Prescrire Int* n° 67 pp. 168-171.

## Noteworthy

Drugs deemed "Noteworthy" provide a modest improvement in patient care.

| | |
|---|---|
| 2016 | • **OPDIVO° (*nivolumab*)**<br>**Bristol-Myers Squibb**<br>Metastatic or inoperable BRAF V600-negative melanoma (Prescrire Int n° 177) and metastatic or inoperable non-small cell lung cancer (Rev Prescrire n° 397) |
| | • **MEKINIST° (*trametinib*)**<br>**Novartis**<br>Metastatic or inoperable BRAF V600-positive melanoma, in combination with *dabrafenib* (Prescrire Int n° 177) |

**Nivolumab (Opdivo°) as monotherapy for some patients with melanoma or lung cancer.** *Nivolumab* is a monoclonal antibody that stimulates T cell activity in particular, thereby activating the immune response to tumour cells.

In a trial in patients with metastatic or inoperable melanoma whose tumour was negative for the BRAF V600 mutation and who had not yet received treatment for this stage of the disease, *nivolumab* was far more effective than *dacarbazine*: the estimated proportion of patients alive after 1 year was about 70% with *nivolumab* versus about 40% with *dacarbazine*. Additional evaluation is required however, in particular because *dacarbazine*, used in Europe until the early 2010s, has not been shown in comparative trials to prolong survival. A direct comparison with *ipilimumab*, another immunostimulant, would more clearly establish the role of *nivolumab* in the treatment of these cancers.

In patients with metastatic or inoperable non-small cell lung cancer who had already received one line of platinum-containing chemotherapy, *nivolumab* prolonged median survival by about 3 months and increased the proportion of patients alive after 1 year by about 15% compared with *docetaxel*, with somewhat fewer serious adverse effects in two non-blinded randomised clinical trials, with consistent results.

*Nivolumab* can provoke a great variety of sometimes serious adverse effects, generally of immunological origin, in particular: rash, interstitial lung disease, elevated liver enzymes and hepatitis, thyroid disorder, neuropathy and encephalitis. As *nivolumab* is the first of a new drug class, its adverse effect profile is only partially known.

**Trametinib (Mekinist°) combined with dabrafenib for some patients with melanoma.** In patients with metastatic or inoperable BRAF V600-positive melanoma who had not yet been treated for this stage of the disease, the addition of the MEK inhibitor *trametinib* to first-line treatment with *dabrafenib*, an inhibitor of the defective BRAF protein, prolonged survival by about 7 months on average compared with BRAF inhibitor monotherapy in two trials with consistent results. The addition of *trametinib* increases the frequency of serious adverse effects, including heart failure, deep vein thrombosis, bleeding, neutropenia, and gastrointestinal perforation. *Trametinib* monotherapy has not been shown to constitute a therapeutic advance.

**Few therapeutic advances again in 2016.** Once again, 2016 provided no major therapeutic advances. The few advances in cancer therapy highlighted in this year's *Prescrire* Drug Awards are worth noting but rare. This reality is at odds with the hype surrounding the multitude of new products that appear on the market each year and the exorbitant prices charged by pharmaceutical companies for cancer drugs.

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# 2016 Prescrire Packaging Awards

The Packaging Awards focus on the quality of the packaging of drugs evaluated in 2016 in our French edition.

*Prescrire*'s systematic reviews include evaluation of a drug's packaging. Does the packaging make the drug easy and safe to use? Do any aspects of the packaging constitute a therapeutic advance? Conversely, are any aspects of the packaging dangerous?

When analysing a drug's packaging, we consider the context in which the drug will be obtained, prepared and administered: the situations in which it will be used; the patients likely to receive it, especially children, pregnant women and elderly patients; whether it will be used in an emergency, hospital or community setting, obtained on prescription, on the advice of a community pharmacist, or bought on the patient's own initiative from a pharmacy or an internet retailer; whether or not a nurse will prepare and administer it; etc.

Every aspect of the packaging is examined to determine its quality and safety (clarity, accuracy, suitability to the situation). We examine: the information on the labelling that is useful for patient care, including the legibility of international nonproprietary names (INNs), whether different dose strengths are easily distinguishable, and any information presented graphically, such as dosing schedules and pictograms; any dosing devices supplied to prepare and administer the required doses; the measures taken to protect children from poisoning; and the quality and clarity of the information provided in the patient leaflet on dose preparation, adverse effects, and the situations and patient groups in which the drug poses a risk.

The *Prescrire* Packaging Awards are based on independent evaluations conducted by *Prescrire*'s Editorial Staff and our Packaging Working Group, free from any influence from packaging manufacturers.

## No Packaging Award for 2016



## YELLOW CARDS

**Brintellix°** 5 mg, 10 mg, 15 mg and 20 mg tablets **(*vortioxetine*)** Lundbeck (*Rev Prescrire* n° 391)
The labelling of the blister packs is ambiguous: the packs are divided into pairs of tablets by perforations, and the international nonproprietary name (INN) and dose strength are printed just once across each pair of blister pockets. Patients could mistakenly understand that in order to take the dose printed across the two blister pockets, they must swallow the contents of both pockets (2 tablets), whereas in fact the labelling refers to the dose contained in each tablet.

**Spagulax°** granules in multidose bags **(*ispaghula*)** Almirall (*Rev Prescrire* n° 397)
The primary packaging is a multidose bag containing 700 grams of granules. The transparent plastic bag is labelled with brief information, omitting the international nonproprietary name (INN). This multidose bag will be opened several times and is difficult to close properly after use. And its resemblance to bags commonly used for food trivialises the drug's use. It is better to choose the version supplied in single-dose sachets.

**L-Thyroxine Serb°** 150 microg/ml oral solution **(*levothyroxine*)** SERB (*Rev Prescrire* n° 389) • **Contramal°** Grünenthal and **Topalgic°** Sanofi Aventis, 100 mg/ml oral solutions **(*tramadol*)** (*Rev Prescrire* n° 397)
The dosing device supplied with the bottles of these drugs for dose preparation is a dropper, a device known to cause dosing errors, especially when a large number of drops must be counted. These solutions are highly concentrated, increasing the risk of an overdose or underdose if the drops are miscounted. Given that the adverse effects of *tramadol* are dose-dependent and *levothyroxine* has a narrow therapeutic index, it is particularly important to count the number of drops of these drugs accurately.

**Tarka LP°** 240 mg/2 mg tablets, 240 mg/4 mg tablets **(*verapamil + trandolapril*)** Mylan Medical (*Rev Prescrire* n° 389)
The two dose strengths resemble each other so closely that one could be confused for the other, resulting in an overdose or underdose of *trandolapril.*



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**No Award for 2016 but serious deficiencies.** None of the packaging examined in 2016 met all the safety and quality standards required to earn a *Prescrire* Packaging Award. The persistent failure of pharmaceutical regulators and companies to take packaging quality seriously was yet again in evidence: umbrella brands continue to expand despite the risk of patients confusing products that have very different compositions; dangerous drugs continue to be marketed in bottles without a child-proof cap; drugs that require accurate dose preparation are supplied with inaccurate dosing devices; patient leaflets are not adequately clear about risks; etc.

Together with the annual drug packaging review (to be published in a coming issue), the *Prescrire* Packaging Awards reflect the actual situation regarding the measures being taken for the safe use of medicines. The low standards to which regulators hold pharmaceutical companies with regard to this important aspect of the quality of healthcare are disturbing, because they jeopardise patients' safety.

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## RED CARDS

### DANGEROUS DEFICIENCIES IN THE LABELLING OR PATIENT LEAFLET, INCLUDING UMBRELLA BRANDS

**Toplexil°** syrup and sugar-free oral solution **(*oxomemazine*)** Sanofi Aventis (*Rev Prescrire* n° 387)
The brand name Toplexil° printed in large, bold characters on the box overshadows the international nonproprietary name (INN). It is liable to confusion with the herbal preparation Toplexil Phyto°, as its box is also printed with the name Toplexil° in the same typographic style. Patients who mistake the *oxomemazine*-containing drug Toplexil° for the plant extract-containing preparation Toplexil Phyto° would be exposed to the sedative and antimuscarinic adverse effects of this phenothiazine antihistamine.

**Fervex Rhume Jour et Nuit°** tablets **(*paracetamol + vitamin C + pseudoephedrine + chlorphenamine*)** and **Fervex État Grippal°** granules in sachets **(*paracetamol + vitamin C + pheniramine*)** UPSA (*Rev Prescrire* n° 389)
These two products are liable to confusion due to the close visual resemblance between their boxes: both are printed in the same combination of colours and display the umbrella brand name Fervex° in extremely large, bold characters. Furthermore, the INNs are difficult to read on the boxes and overshadowed by the brand name. The fact that a variety of herbal preparations are also sold under the Fervex° brand only adds to the confusion.

**Lysopaïne Maux de Gorge Ambroxol°** lozenges **(*ambroxol*)** and **Lysopaïne Maux de Gorge Cétylpyridinium Lysozyme°** compressed lozenges **(*cetylpyridinium + lysozyme*)** Boehringer Ingelheim (*Rev Prescrire* n° 397)
These products are liable to confusion due the resemblance between their boxes: both display the umbrella brand name Lysopaïne° in large, bold characters, but also the indication, "*Maux de Gorge*" (meaning sore throat). Undue promotion is given to the various flavours of the lozenges rather than to important information such as the INNs of the drugs they contain.
This labelling makes it difficult for patients to tell that these similar-looking products have different compositions, and that some Lysopaïne° products contain *ambroxol*, which can cause allergies.

**Ibupradoll°** 200 mg and 400 mg tablets and soft capsules **(*ibuprofen*)** Sanofi Aventis (*Rev Prescrire* n° 398)
The patient leaflets contain insufficient information about the harms of nonsteroidal anti-inflammatory drugs (NSAIDs) during pregnancy. They fail to warn patients about concerns that NSAIDs may increase the risk of spontaneous abortion and provoke malformations when taken during the first trimester of pregnancy, or about the sometimes irreversible renal damage or pulmonary arterial hypertension reported in children following exposure to an NSAID during the second trimester. These leaflets only state that the product is contraindicated from the sixth or seventh month of pregnancy. NSAIDs should be avoided throughout pregnancy until evidence is obtained that they are safe to use before the sixth month of pregnancy.

### PACKAGING THAT POSES A RISK OF POISONING FOR CHILDREN

**Eucalyptine Le Brun°** syrup **(*codeine + cineole*)** Hepatoum • **Néo-Codion Enfants°** syrup **(*codeine + sodium benzoate*)** Bouchara-Recordati • **Tussipax°** oral solution **(*codeine + ethylmorphine*)** Bailleul (*Rev Prescrire* n° 391)
None of the bottles used for these 3 products has a child-proof cap. Children who ingest the contents unnoticed by family members and carers would be exposed to the serious adverse effects of *codeine*, including respiratory depression. These products also have a significant amount of ethanol.

**Ascabiol°** cutaneous emulsion **(*benzyl benzoate*)** Zambon (*Rev Prescrire* n° 392)
The bottle lacks a child-proof cap, yet the contents could provoke seizures in children who ingest the contents unnoticed by family members and carers. It has also a significant amount of ethanol.



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# 2016 Prescrire Information Awards

The Information Awards focus on the information provided to *Prescrire* by the companies whose products we examined in the New Products section of our French edition in 2016.

## HONOURS LIST
(in alphabetical order)

**Outstanding:**
- **CTRS (Cell Therapies Research & Services)**
- **EG Labo**

**Followed by:**
- Accord Healthcare
- Arrow Génériques
- Delbert
- Eumedica
- GlaxoSmithKline
- Mayoly Spindler
- Medac

## RED CARDS
(in alphabetical order)

- **Allergan**
- **Bayer Healthcare**
- **Bristol-Myers Squibb**
- **Celgene**
- **Effik**
- **Genévrier**
- **Genzyme (Sanofi Group)**
- **Menarini**
- **Pfizer**
- **Sanofi Aventis**
- **Shire**

**Quality of information from pharmaceutical companies**

We use a 4-point scale to rate the quality of the information provided by companies in response to our systematic requests


Company provided detailed information including unpublished data and packaging items.


Company provided information limited to published regulatory data or packaging information.


Company provided minimal information, mainly regulatory and packaging information.


Company provided no information.

Pharmaceutical companies hold a wealth of information on the drugs they market or withdraw from the market. They have a responsibility to share this information, in part to help ensure that their drugs are used appropriately, and to protect patients from certain risks.

As part of its systematic literature search, *Prescrire* requests clinical data, packaging, and administrative and regulatory information from drug companies, then compares them with information obtained from other sources.

*Prescrire*'s Information Awards reflect how each company assumes this responsibility to share information. Our aim is to encourage companies that have a responsible policy on the provision of information, and to urge companies that fail in this responsibility to do better.

**Lack of transparency persists.** On the whole, pharmaceutical companies provide *Prescrire* with a lot of information, some new and some that we have already obtained elsewhere. But they are less cooperative when asked to provide relevant, detailed documentation, including unpublished data, which may for example contain details about adverse effects.

Some companies choose to be transparent with *Prescrire* and demonstrate this by sending us quality information. These companies are placed on the Honours List. And those rated as "Outstanding" provided us with useful, detailed data without delay and sometimes without being asked.

Other drug companies fail to respond to some or all of our requests for information, or provide only limited data. Some of them delay their response, then fail to provide usable information. Some omit the most important or sensitive data. Red Cards are given to highlight persistent deficiencies in the provision of information by certain drug companies.

As in previous years, few pharmaceutical companies embraced transparency in 2016 by agreeing to share all the data they hold with healthcare professionals. Yet transparency demonstrates a company's commitment to improving medication safety.

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