THE PRESCRIRE AWARDS FOR 2018

The three annual Prescrire Awards, for Drugs, Packaging and Information, are granted in total independence by the Prescrire Editorial Staff. The rules governing the three Prescrire Awards are available online at english.prescrire.org

2018 Prescrire Drug Awards

New products or new indications eligible for the Prescrire Drug Awards are those evaluated in 2018 in the New Products section of our French edition

Each month, the Prescrire Editorial Staff publish systematic analyses of the data available on: new drugs, new indications authorised for existing drugs, and existing drugs marketed in a new form or with different dose strengths. The goal is to help readers distinguish, among the plethora of new products, those worth adding to their list of useful therapies, those worth using instead of other products, and those to be avoided.

Our analyses are based on rigorous procedures, described in detail at english.prescrire.org. 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.

The Prescrire Drug Awards are determined 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 of a drug with a favourable harm-benefit balance.

Five Prescrire Drug Awards for 2018, but no Pilule d'Or. For the fourth year running, none of the drugs examined in 2018 offered a therapeutic advance worthy of a Pilule d'Or (Golden Pill Award). Nevertheless, five drugs received a Prescrire Drug Award for 2018: two that earned a place on the Honours List and three that were deemed "Noteworthy" (see on page 79).

Naloxone: wider availability of a life-saving drug. All opioid receptor agonists carry a risk of overdose, irrespective of the situation in which they are taken. *Naloxone* is the first-choice antidote after an opioid overdose: it effectively prevents death through respiratory depression in this situation. *Naloxone* has been available in France for several decades as an injectable solution, in ampoules, but was only authorised for use by health professionals.

In 2018, two new products containing *naloxone* became available in France: Nalscue°, for nasal administration; and Prenoxad°, a kit containing a pre-filled syringe for intramuscular injection. Both products are authorised for administration by the person who has taken an opioid overdose, by relatives or friends.

It has been shown in the real-world setting that when *naloxone* is made available, nasal administration in cases of opioid overdose has similar efficacy to intramuscular administration. Nasal administration appears straightforward. Nalscue° has thus earned a place on the 2018 Honours List.

The availability of Prenoxad° for opioid users is also a therapeutic advance, because the intramuscular route is a useful option when the nasal route cannot be used, for example in the event of nasal congestion. However, flaws in this product's packaging could result in needlestick injuries or injection of all five doses contained in the syringe in one go. For this reason, Prenoxad° was only rated as "Noteworthy".

The wider availability of a life-saving drug is a welcome development, even though it took decades to materialise.

Sebelipase alfa: extends survival, but long-term data are lacking. Infants under the age of 6 months with a symptomatic form of lysosomal acid lipase deficiency generally die during the first year of life. In this situation, *sebelipase alfa* (Kanuma°) appears to prolong the survival of some infants by several years at least, and their childhood development is satisfactory. In terms of adverse effects, it frequently provokes hypersensitivity reactions and occasionally anaphylactic reactions.

These data earned *sebelipase alfa* a place on this year's Honours List. It did not receive a Pilule d'Or award due to limited experience, with an evaluation focused on 19 infants, most of whom were monitored for less than 3 years, whereas *sebelipase alfa* is intended for lifelong use. The lack of transparency shown by the company that markets this drug (Alexion) was also regrettable. The company sent us no documentation on its product, and in particular provided no longer-term follow-up data on the children enrolled in the clinical trials, although it probably had the means to collect this type of data.

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Lidocaine + prilocaine for premature ejaculation: an evaluation focused on couples' satisfaction. For couples who are distressed because they feel ejaculation occurs too quickly, local anaesthetics are sometimes used off-label to reduce penile sensitivity, although robust evaluation is generally lacking.

Fortacin° (*lidocaine* + *prilocaine* spray), authorised for use in premature ejaculation and introduced on the French market in 2018, was awarded a place on this year's Noteworthy list. Its evaluation was adequate, including two well-conducted comparative trials. Using the simple and meaningful endpoint of the couples' sexual satisfaction, these trials showed that *lidocaine* + *prilocaine* was far more effective than placebo. And its adverse effects were infrequent and generally mild.

Pharmacological treatment is admittedly not the only solution for couples who are troubled because they feel ejaculation occurs too quickly. But when it is a major problem, despite explanations that there is no "normal" time to ejaculation, and when psychological and behavioural techniques are not sufficiently effective, some couples are likely to find *lidocaine* + *prilocaine* spray helpful.

Arsenic trioxide in acute promyelocytic leukaemia: greater chance of long-term survival and shorter treatment. Ideally, the efficacy of a drug should always be demonstrated in at least two well-conducted clinical trials. For this reason, several new products and new indications authorised in oncology that were shown to extend survival by a few months were excluded from this year's Prescrire Drug Awards because their evaluation was based on a single clinical trial.

Arsenic trioxide (Trisenox°), in combination with *tretinoin*, for patients with acute promyelocytic leukaemia at low or intermediate risk of relapse, was an exception however. We considered this drug Noteworthy because it is rare in haematology to see a trial conducted over several years, with a demonstrated efficacy on life span rather than on haematological surrogate endpoints. In addition, the combination of *arsenic trioxide* and *tretinoin* is administered for between 7 and 10 months, thus avoiding several years of exposure to cytotoxic agents. The main adverse effects of *arsenic trioxide* are leukocyte activation syndrome, and hepatic, neurological and cardiac disorders.

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Pilule d'Or/Golden Pill

The Pilule d'Or (Golden Pill) is granted to drugs that constitute a major therapeutic advance in a field in which no treatment was previously available

2018	NOT AWARDED

2018 Honours List

Drugs included on the Honours List constitute a clear advance for some patients compared with existing therapeutic options, albeit with limitations.

- **KANUMA° (*sebelipase alfa*)**
  Alexion
  Lysosomal acid lipase deficiency, in infants under the age of 6 months (Prescrire Int n° 200)
- **NALSCUE° (*naloxone* nasal spray)**
  Indivior
  Emergency treatment of opioid overdose at home or in other non-medical settings (Prescrire Int n° 199)

Noteworthy in 2018

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

- **FORTACIN° (*lidocaine + prilocaine*)**
  Bouchara Recordati
  Primary premature ejaculation (Prescrire Int n° 197)
- **PRENOXAD° (*naloxone* kit for IM injection)**
  Ethypharm
  Emergency treatment of opioid overdose at home or in other non-medical settings (Rev Prescrire n° 417)
- **TRISENOX° (*arsenic trioxide*)**
  Teva
  Acute promyelocytic leukaemia at low or intermediate risk of relapse, in combination with *tretinoin* (Prescrire Int n° 193)

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2018 Prescrire Packaging Awards

The Packaging Awards focus on the quality of the packaging of drugs evaluated in 2018 in our French edition

No Packaging Awards for 2018

Prescrire's systematic reviews of drugs include evaluation of their packaging. Does the packaging make the drug easy to use? Does it constitute a therapeutic advance or is it inferior to existing alternatives? Does it pose a danger to patients?

Our packaging evaluation takes many factors into account: the situation in which the drug will be used; the patients likely to receive it, especially children, pregnant women or 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.

Every aspect of the packaging is examined to determine its quality and safety. We examine: whether international nonproprietary names (INNs) are legible and not overshadowed by the promotional components of the drug's labelling (brand name, brand graphics, logos, fanciful illustrations); whether different dose strengths of the same product are clearly marked and easily distinguishable; the clarity of any information presented graphically, such as dosing schedules and pictograms; the presence and quality of dosing devices required to prepare and administer the drug; the risk that children will be able to access the drug unnoticed by their carers; 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.

Our Packaging Awards are based on independent evaluations conducted by the Editorial Staff and its Packaging working group, free from any influence from manufacturers.

No Packaging Awards for 2018, but a variety of dangers to avoid. None of the drug packaging examined in 2018 met all the safety and quality standards required to earn a *Prescrire* Packaging Award.

Our evaluations of drug packaging in 2018 revealed a string of flaws and dangers, as illustrated by the 25 products that received a Red or Yellow Card. In too many cases, rather than prioritising the information required to use the medicine properly and prevent errors (INN and dose strength), this information was overshadowed on the labelling by the brand name and logos. Too many medicines are manufactured without due attention to their administration, to how users should prepare the dose (very few are marketed in unit-dose containers, some lack a device for preparing paediatric doses). Most medicines lack sufficient measures to protect children from poisoning. Some package leaflets omit information that is important for patient safety. All of these points should be addressed to ensure that medicines are safe and easy for patients to use.

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YELLOW CARDS

Vicks vaporub° ointment (***camphor + eucalyptus oil + levomenthol + thymol + turpentine oil***) Procter & Gamble Pharmaceuticals (Rev Prescrire n° 417)
For marketing an ointment containing concentrated terpenes, which can cause seizures and allergies, in a jar. A packaging going against the prevention of misuse, some cases of which were reported. This packaging exposes patients to a large quantity or cosmetic type application (application on the eyelids, face).

Absent or indistinct INNs. Every year, we see so many examples of drug labelling that fails to give due prominence to the drug's true name, its international nonproprietary name (INN), that it would be difficult to mention them all. This packaging flaw makes it difficult for users to identify the active substance or substances. Examples include **Efferalgan°** orodispersible tablets, **Dolko°** oral solution, **Apaisylgel°**, **Sédermyl°** cream, and **Vicks vaporub°**.

Androgel° gel in a multidose bottle with a metering pump (***testosterone***) Besins International (Rev Prescrire n° 415). For not displaying the INN sufficiently clearly on the box and the bottle, which trivialises the dangers particularly in situations of chronic overdose, especially since other aspects of its packaging (its pharmaceutical form, the bottles' appearance) are more reminiscent of a cosmetic product.

Softacort° eye drops in single-dose containers (***hydrocortisone***)Théa (Rev Prescrire n° 418). For not displaying the INN at all on the single-dose containers.

Trolovol° tablets (***penicillamine***) X.O (Rev Prescrire n° 418). For not displaying the INN sufficiently clearly on the (non-unit-dose) blister packs.

Femi° tablets (***ethinylestradiol + norgestimate***) Effik (Rev Prescrire n° 422). For not displaying the INN sufficiently clearly on the box and blister packs, or in the patient leaflet, where the brand name is over-represented.

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RED CARDS

PACKAGING AND DOSE PREPARATION ERRORS

When a drug's indications have been extended to include paediatric use, failure to adapt the packaging accordingly poses a risk to children, in particular the risk of errors during dose preparation.

Vimpat° 10 mg/ml syrup (***lacosamide***) UCB Pharma (Rev Prescrire n° 414). For providing two different dosing devices in the box (a syringe and a measuring cup) without specifying the corresponding child's weight on each device; and because the dosing devices are graduated in millilitres, thus requiring users to convert the number of milligrams prescribed into the number of millilitres to measure, with a consequent risk of calculation errors.

Renvela° powder for oral suspension in 2.4 g sachets (***sevelamer***) Genzyme (Prescrire Int n° 193). For not supplying a dosing device in the box to prepare the doses recommended for children, for not marketing lower dose strengths even though they have been authorised in France, and because a 0.4 g dose strength has not been authorised, even though this dose is recommended for certain children in the European summary of product characteristics (SPC).

Inadequate packaging also exposed adults to the risk of dosing errors.

Tresiba° 200 units/ml solution for injection in a pre-filled pen (***insulin degludec***) Novo Nordisk (Prescrire Int n° 202). For the fact that each graduation of the pre-filled pen corresponds to 2 units of *insulin*. The pen can only be used to deliver an even number of units, which is problematic for patients choosing to dial in an odd number of units. As with the other *insulin* pens on the French market, the pen makes a clicking sound with each dose step, which is useful for visually impaired patients, but each click up on the Tresiba° pen adds 2 units of *insulin* to the dose, instead of 1 unit with other pens. Both of these problems can cause errors when preparing the dose.

A 313° 50 000 international units, soft capsules (***vitamin A***) Pharma Développement (Rev Prescrire n° 412). For marketing such a large number of capsules (30) in a bulk bottle, when the dose stated in the French summary of product characteristics (SPC) is only 1 to 2 capsules every 10 days. This could confuse patients, resulting in dosing frequency errors and the potentially serious risk of chronic overdose (**a**).

***a-** The firm Pharma Développement has already informed us that it is improving its packaging and plans to market this drug in a blister pack containing six capsules. We will announce this development when it materialises.*

PACKAGING THAT POSES A RISK OF POISONING TO CHILDREN

A 313° soft capsules (***vitamin A***) Pharma Développement (Rev Prescrire n° 412); **Dolko°** oral solution (***paracetamol***) Therabel Lucien Pharma; **Efferalgan°** orodispersible tablets (***paracetamol***) UPSA; **Fluconazole Arrow°**, **Fluconazole Biogaran°**, **Fluconazole EG°**, **Fluconazole Mylan°**, **Fluconazole Sandoz°**, **Fluconazole Teva°**, **Fluconazole Zentiva°** powders for oral suspension (***fluconazole***) (Rev Prescrire n° 419); **Fluoxetine Biogaran°**, **Prozac°** oral solutions (***fluoxetine***) Lilly (Rev Prescrire n° 416); **Mucoplexil°** syrup (***carbocisteine***) Sanofi Aventis (Rev Prescrire n° 414); **Panfurex°** oral suspension (***nifuroxazide***) Bouchara Recordati (Rev Prescrire n° 412); **Théralène°** syrup (***alimemazine***) X.O (Rev Prescrire n° 415, 421)

For the absence of a child-proof cap on the bottles of these 15 medicines. The caps used on the bottles do not sufficiently protect children from the adverse and toxic effects of the drugs they contain in a situation where a child gains access to the medicine without their carers' knowledge and is tempted to taste or ingest the contents.

UMBRELLA BRANDS: STILL NOT BANNED!

Apaisylgel° cutaneous gel (***isothipendyl***) Merck Médication Familiale (Rev Prescrire n° 411), **Sédermyl°** cream (***isothipendyl***) Cooper (Rev Prescrire n° 411), **Mucoplexil°** syrup (***carbocisteine***) Sanofi Aventis (Rev Prescrire n° 414)

The principle of an umbrella brand is to sell various medicines containing different active substances, with different harms, under the same brand name. For example, the brand name **Apaisyl°** is used for: Baby**Apaisyl** Soin Après Piqûre° a topical cosmetic product, Cort**Apaisyl**° containing *hydrocortisone*, **Apaisyl**gel° containing *isothipendyl*, and others. This marketing strategy, which capitalises on a well-known brand name, displayed prominently on the labelling to attract the consumer's eye and make the products easier to recognise, can cause confusion between products, and unawareness of the dangers posed by the active substances they contain, such as interactions with other drugs.

The resemblance between their labelling serves to enhance brand recognition. It also increases the likelihood of confusion between products of the same umbrella brand, by emphasising the umbrella name through the use of large, bold, eye-catching lettering, and other shared graphic elements (logos, illustrations). Meanwhile, INNs are often barely readable.

Some companies create an umbrella brand by incorporating a brand segment into the individual brand names, such as "plexil" in To**plexil**° (*oxomemazine*) and Muco**plexil**° (*carbocisteine*), and by using the same graphics on the products' boxes and bottles, in this case a swirl of yellow syrup.

As of early 2019, umbrella brands are still not banned in France, yet the French Health Products Agency (ANSM), has acknowledged their dangers.

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2018 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 2018

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 adverse effects.

As part of its systematic literature search, *Prescrire* requests clinical data, packaging, administrative and regulatory documentation from pharmaceutical companies, and crosses this information against that obtained from other sources.

Prescrire's Information Awards reflect how each company assumes this responsibility to share information.

Information requested from 86 firms in 2018, with only 7 firms being transparent. In 2018, we requested information from 86 pharmaceutical companies. Some companies chose to be transparent, and demonstrated this by providing detailed, relevant information in response to *Prescrire*'s requests. These companies earn a place on the Honours List (7 out of the 86 companies approached for information in 2018). Those rated as "Outstanding" provided us with particularly useful and detailed information without delay and sometimes without being asked (2 companies out of the 86 approached).

A lack of transparency, putting corporate interest before patients' interest. Other drug companies failed to respond to some or all of our requests for information, or provided only limited data. Some of them delayed their response and failed to provide usable information. Some omitted the most important or sensitive data. Red Cards are given to highlight persistent deficiencies in the provision of information by some pharmaceutical companies (16 of the 86 companies approached). Some of the other 63 companies provided a bare minimum of information, sometimes after several reminders. These firms appear to be open to Prescrire's requests, but in fact practice a false pretence of information sharing.

The years go by, yet nothing changes. In 2018 as in previous years, few pharmaceutical companies agreed to share the data they hold with the health professionals who subscribe to *Prescrire*. They chose to keep the relevant documentation, such as unpublished evaluation data, secret. This attitude raises doubts about the existence of information unfavourable to their products, which patients and healthcare professionals should nevertheless be aware of.

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HONOURS LIST
(in alphabetical order)

Outstanding:
- EG Labo
- Ethypharm

Followed by:
- Amomed Pharma
- Arrow Génériques
- Bouchara Recordati
- Endoceutics
- Lucane Pharma

RED CARDS
(in alphabetical order)

- Allergan
- Bayer Healthcare
- Bristol-Myers Squibb
- Celgene
- Centre Spécialités Pharmaceutiques
- Genévrier
- Genzyme (Sanofi Group)
- Indivior
- Janssen Cilag
- Menarini
- MSD
- MSD Vaccins
- Pfizer
- Sandoz
- Sanofi Aventis
- UCB Pharma

How we rate the quality of the information provided by pharmaceutical companies

Detailed information including unpublished data and packaging items.

Information limited to published administrative or packaging items.

Minimal information, mainly administrative and packaging items.

No information.

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