

# THE PRESCRIBE AWARDS FOR 2018

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## 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](http://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.



**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)