THE PRESCRIRE AWARDS FOR 2025

The annual Prescrire Awards are granted in total independence by the Prescrire Editorial Staff.

2025 Prescrire Drug Awards

Every month, Prescrire's Editorial Staff help health professionals decide which of the multitude of drugs on the market are worth adding to their list of useful treatment options, and which are no better than the standard treatment, or indeed worse, and to be avoided. We do this by conducting systematic, critical analyses of the relevant evaluation data available on new drugs, new indications, new pharmaceutical forms and new dose strengths authorised in Europe or in France. European authorisations account for the majority and are the focus of our English edition, *Prescrire International*. We also regularly re-examine the harm-benefit balance of drugs we have previously analysed, when new relevant data come to light.

The 2025 Prescrire Drug Awards were attributed by Prescrire's multidisciplinary team, based on the reviews published in the Marketing Authorisations section of our French edition in 2025, free from the influence of any companies or public agencies involved in the healthcare sector.

5 Prescrire Drug Awards granted in 2025, but no Pilule d'Or

None of the drugs whose evaluation data were analysed by Prescrire in 2025 represented a major therapeutic advance worthy of a Pilule d'Or (Golden Pill Award). Three drugs authorised for rare diseases earned a place on the 2025 Honours List, and two drugs were deemed "Noteworthy".

Cerliponase alfa in neuronal ceroid lipofuscinosis type 2: reduces mortality and slows disability progression. Neuronal ceroid lipofuscinosis type 2 is a rare enzyme deficiency of genetic origin. It presents as progressive cerebral and retinal degeneration, usually between the ages of 2 and 4 years. Most affected children develop multiple disabilities, including profound intellectual disability, and become visually impaired. They generally die in adolescence.

Cerliponase alfa (see also pp. 126-127) is a recombinant form of the deficient enzyme, administered by infusion into a cerebral ventricle. Non-comparative trials suggest that it greatly reduces mortality. In one trial, for example, after a follow-up of about 5 years, none of the patients treated with *cerliponase alfa* had died, versus 24% of the historical controls. In another trial, the estimated 10-year mortality among *cerliponase alfa*-treated patients was 4%, versus 34% in historical controls. It seems to slow disability progression, although considerable disability often remains in the mid to longer term.

Cerliponase alfa's adverse effects are frequent and sometimes serious, and include convulsions, hypersensitivity reactions and complications related to its route of administration, including meningitis.

Brineura® earned a place on the 2025 Honours List because it represents a therapeutic advance in a rare disease, despite the considerable disability that often persists in treated patients, the disadvantages associated with its route of administration, and its adverse effects. These drawbacks must be carefully explained to the child's family, and taken into account when deciding whether or not to initiate this treatment.

Nusinersen and onasemnogene abeparvovec in spinal muscular atrophy before the onset of symptoms: reduced mortality and disability. Spinal muscular atrophy is a rare genetic disorder that leads to progressive neuromuscular degeneration. In its most serious

Pilule d'Or

A Pilule d'Or (Golden Pill) is awarded to drugs that represent a major therapeutic advance in a particularly poorly served field.

None awarded for 2025

2025 Honours List

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

Brineura® (*cerliponase alfa*) - BioMarin

in neuronal ceroid lipofuscinosis type 2 disease (*Prescrire Int* n° 281)

Spinraza® (*nusinersen*) - Biogen Idec

in spinal muscular atrophy before the onset of symptoms (*Prescrire Int* n° 278)

Zolgensma® (*onasemnogene abeparvovec*) - Novartis Gene Therapies

in spinal muscular atrophy before the onset of symptoms (*Prescrire Int* n° 278)

Noteworthy

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

Alecensa® (*alectinib*) - Roche

first-line treatment in inoperable or metastatic ALK-positive non-small cell lung cancer (*Prescrire Int* n° 275)

Sirturo® (*bedaquiline*) - Janssen-Cilag

first-line treatment in pulmonary multidrug-resistant tuberculosis (*Prescrire Int* n° 274)

form, affected infants have severe motor disability, and severe respiratory and feeding difficulties. If left untreated, they often die before the age of 2 years. Less serious forms develop during childhood, and have less impact on motor and respiratory function, and on life expectancy.

Nusinersen is an "antisense" oligonucleotide designed to increase the synthesis of the deficient protein. It is administered intrathecally (into the cerebrospinal fluid) at least 3 times per year. *Onasemnogene abeparvovec* is a gene therapy product administered as a one-time intravenous infusion. Each of these substances was evaluated in one non-comparative clinical trial in a few dozen infants with a genetic diagnosis of spinal muscular atrophy and who had not yet developed symptoms. After a median follow-up of 3 to 5 years, depending on the trial, all the children were still alive and none required permanent respiratory support. With *nusinersen*, most of the children were able to walk independently. With *onasemnogene abeparvovec*, most of the children were able to walk independently (at least 5 steps) by the age of 1.5 or 2 years.

Nusinersen exposes patients to the serious adverse effects of intrathecal injections, including pain, haemorrhage, meningitis and arachnoiditis. *Onasemnogene abeparvovec* carries a risk of sometimes fatal liver injury and thrombotic microangiopathy.

Spinraza° and Zolgensma° earned a place on this year's Honours List because they both represent a notable therapeutic advance for patients with serious forms of this disease. However, as of 2026, uncertainty persists, in particular because it is impossible to know whether all of the children included in the trials would have developed the most severe form of the disease without treatment.

Alectinib as first-line treatment in inoperable or metastatic ALK-positive non-small cell lung cancer: reduced mortality in two trials. Two non-blinded randomised trials compared *alectinib* versus *crizotinib* (both of which are antineoplastic drugs that inhibit various tyrosine kinases, including ALK) in a total of 490 patients with inoperable or metastatic non-small cell lung cancer harbouring a mutation in the *ALK* gene, who had not yet received treatment. After a median follow-up of 2 to 5 years, mortality was about 34% in the *alectinib* groups, versus 41% in the *crizotinib* groups (statistically significant difference).

Alectinib has the adverse effects of ALK inhibitors, in particular: interstitial lung disease, hepatic disorders, QT prolongation, gastrointestinal disorders and visual disturbances. In these two trials, one-quarter to one-third of the patients in each group experienced at least one serious adverse event.

One of the essential principles of experimental science is to demonstrate the reproducibility of the result of a scientific experiment, by conducting at least two experiments. This confirms that the results are not due to chance alone or to a flaw in the experimental design. This principle also applies to the clinical evaluation of drugs. Yet, all too often, antineoplastic drugs are only evaluated in a single randomised comparative trial.

Alecensa° was awarded a place as a Noteworthy drug because it was shown to extend survival in two randomised comparative trials.

Bedaquiline in first-line treatment in pulmonary multidrug-resistant tuberculosis: markedly shortens treatment duration. Tuberculosis is a potentially fatal, contagious, infectious disease that usually affects the lungs. Multidrug-resistant tuberculosis is treated with a combination of antituberculous drugs for several months, or for more than 1.5 years with certain regimens.

The antituberculous drug *bedaquiline* was authorised for use as part of a combination regimen with other antibiotics, as first-line treatment for multidrug-resistant tuberculosis. Its evaluation in this situation is based on several randomised trials conducted in hundreds of patients. Combinations of antituberculous drugs that included *bedaquiline* shortened the duration of treatment by several months compared with the combinations previously recommended by the World Health Organization (WHO), while providing similar bacteriological and clinical efficacy.

Bedaquiline has frequent adverse effects, including QT prolongation and liver injury. It has numerous foreseeable drug interactions, which can persist for several months after treatment cessation, because its elimination half-life is about 5 months.

Sirturo° earned the title of Noteworthy drug, because it markedly shortens the duration of treatment in multidrug-resistant tuberculosis, without compromising efficacy.

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2025 Prescrire Packaging Awards

When Prescrire evaluates a drug's harm-benefit balance, its packaging is an important consideration. Does the packaging help ensure the safety of patients, their families and caregivers? Do any aspects of the packaging increase the risk of medication errors or pose a particular danger? Is the packaging well-designed from the users' perspective, enabling accurate measurement of the doses to be administered, for example?

Our rigorous analysis of a drug's packaging takes many factors into account, including: the clinical situations in which the drug will be used; the patients liable to receive it, such as pregnant women, children, or older adults or patients with a disability who may, for example, have reduced manual dexterity; whether family members, carers or healthcare professionals will prepare and administer the drug; the context in which it will be used (e.g. in a healthcare facility, possibly in an emergency setting); and whether it will be obtained on prescription or on the advice of a community pharmacist.

Every aspect of the packaging is analysed for its impact on quality of care and the safety of patients and the people around them. We examine, in particular:
– Whether international nonproprietary names (INNs) are clearly legible, and whether different dose strengths of the same drug are easily distinguishable;
– The clarity of any information presented graphically, such as diagrams showing how to prepare doses, dosing schedules, symbols or pictograms;
– The devices provided for dose preparation, measurement or administration;
– The quality, intelligibility and clarity of the information provided in the patient leaflet, especially in the sections on how to use the product, its adverse effects, and the situations in which the drug poses a particular risk, such as pregnancy or renal impairment;
– The risk of poisoning, e.g. through accidental ingestion by a child.

Prescrire examines the packaging of many drugs each year. The annual Prescrire Packaging Awards, prepared through an independent process by Prescrire's Editorial Staff, are based on these analyses.

Products with particularly well-designed packaging receive a Packaging Award. Those for which we identified packaging flaws, liable to increase the risk of medication errors or pose other dangers, receive a Packaging Red Card.

The 2025 Prescrire Packaging Awards pertain to the packaging of 172 products analysed in the Marketing Authorisations section of our French edition in 2025.

3 Packaging Awards for 2025

Better information for women who are planning a pregnancy

Fabhalta° hard capsules (***iptacopan***) - Novartis (*Prescrire Int* n° 276)

Iptacopan is a complement factor B inhibitor, authorised for use in adults with paroxysmal nocturnal haemoglobinuria. The INN and dose strength are clearly displayed on the box. The blister pack is pre-cut in such a way that two hard capsules (the daily dose recommended in the summary of product characteristics [SmPC]) can be separated from the rest of the pack. The back of each blister pocket is labelled with the first two letters of the day on which the capsule is to be taken, and a symbol representing a sun for the morning dose or a moon for the evening dose.

In France, if a drug's SmPC mentions a risk of teratogenicity or fetotoxicity, a warning pictogram must be displayed on the box. The warning pictogram on the back of the box of Fabhalta° informs users that it could pose a danger during pregnancy. The accompanying text states (our translation) "*Not to be used by pregnant women or women planning to become pregnant, unless there is no alternative treatment*". These warning pictograms too rarely explicitly refer to women who are planning a pregnancy, yet planning is essential for female patients who are taking a drug that is potentially dangerous for an unborn child.

Provision of all the equipment required for reconstituting and administering an injectable drug, and clear explanations

Winrevair° powder and solvent for solution for injection (***sotatercept***) - MSD (*Prescrire Int* n° 278)

Sotatercept is an activin A inhibitor, authorised for use in pulmonary arterial hypertension. It is supplied as a powder, which is reconstituted to produce a solution for injection. The solution is injected subcutaneously every 3 weeks by a healthcare professional or, after training, by a caregiver or the patient. The box contains the solvent and all the equipment required to prepare and inject the solution. Illustrations on the inner flap of the box itemise the equipment provided, which is arranged in two trays. The upper tray contains the materials required for dose preparation, and the lower tray contains the materials required for administration. An instruction booklet clearly explains how to prepare the solution, measure the dose and perform the injection, with the help of clear diagrams.

Generics marketed in France with a French authorisation in high-quality packaging, like the originator

Flucortac° tablets - HAC Pharma; **Fludrocortisone Acetlab°** tablets - Mitem Pharma (***fludrocortisone***) (*Rev Prescrire* n° 497)

Packaging Red Cards

Dry oral forms supplied in multidose bottles

(8 products, 5 with a European marketing authorisation)

Adaflex° tablets (***melatonin***) - AGB Pharma (*Prescrire Int* n° 271) (French authorisation)
Fampyra° prolonged-release tablets (***fampridine***) - Merz Therapeutics (*Rev Prescrire* n° 506)
Fruzaqla° hard capsules (***fruquintinib***) - Takeda (*Prescrire Int* n° 279)
Omjjara° tablets (***momelotinib***) - GlaxoSmithKline (*Prescrire Int* n° 277)
Primaquine Sanofi° tablets (***primaquine***) - Sanofi Winthrop (*Rev Prescrire* n° 505) (French authorisation)
Talzenna° hard capsules (***talazoparib***) - Pfizer (*Prescrire Int* n° 270)
Triplixam° tablets (***perindopril + indapamide + amlodipine***) - Servier (*Rev Prescrire* n° 499) (French authorisation)
Voydeya° tablets (***danicopan***) - Alexion (*Prescrire Int* n° 276)

Multidose bottles have several disadvantages compared with pre-cut unit-dose blister packs. For example, when the tablet or capsule is removed from the bottle and placed in a pill organiser, it is almost impossible to identify the drug and its dose strength with any certainty, and the drug is no longer protected

from environmental conditions such as humidity or light. There is also a greater risk of accidental spillage of the bottle's contents and, consequently, of accidental ingestion of the drug by someone other than the patient, especially a child.

Each pack of Voydeya°, one of the products that received a Red Card for this packaging flaw, contains 2 multidose bottles of very similar appearance, each containing a different dose strength of *danicopan*. This creates a risk of confusion between the 2 bottles and wrong-dose errors.

Products authorised for paediatric use with an unsuitable dosing device

(6 French authorisations)

The oral solutions **Risperdal°** - Janssen-Cilag, **Risperidone Arrow°** - Arrow Génériques, **Risperidone EG°** - EG Labo, **Risperidone Teva Santé°** - Teva Santé, **Risperidone Viatris°** - Viatris Santé, and **Risperidone Zentiva°** - Zentiva (***risperidone***) (*Prescrire Int* n° 277).

The dosing device (an oral syringe) provided in the box with each of the above-mentioned oral solutions of the neuroleptic *risperidone* has a total capacity of 3 ml to 7.5 ml, depending on the product. This far exceeds the small volume to be administered to children who weigh less than 50 kg, for whom the recommended doses correspond to 0.25 ml to 0.5 ml. Overdoses caused by measurement errors, usually tenfold overdoses through administration of 2.5 ml of solution instead of 0.25 ml, have caused sometimes serious adverse effects: drowsiness, sedation, tachycardia, hypotension, extrapyramidal symptoms, QT prolongation and seizures. To protect young patients, a paediatric pack should be marketed, equipped with a dosing device suitable for accurately measuring these small volumes.

Risk of wrong-dose errors due to poor labelling of an injectable cytotoxic drug

(French authorisation)

Bugvi° powder for dispersion for infusion (**albumin-bound *paclitaxel***) - EG Labo (*Rev Prescrire* n° 504)

Paclitaxel, a cytotoxic drug of the taxane class for intravenous use, is authorised as a "conventional" form and an albumin-bound form. The two forms are administered differently. Bugvi° is an albumin-bound form marketed in France. The warning on the box and on the vial label, stating that albumin-bound *paclitaxel* should not be substituted for or with the conventional form, is insufficiently prominent. In addition, the dose strength is expressed in a confusing manner on the box and the vial label. The concentration "5 mg/ml" is displayed alongside the quantity of the drug present in the total volume, i.e. "100 mg/20 ml". To add to the confusion, both items are also labelled "1 vial of 50 ml", which refers to the total capacity of the vial rather than the volume of solution it contains (20 ml).

Packaging that fails to protect users from accidental exposure

(3 French authorisations)

Activox Rhume Pelargonium° oral solution (***liquid extract of pelargonium root***) - Arkopharma (*Rev Prescrire* n° 505)
Fincrezo° cutaneous spray, solution (***finasteride***) - Bailleul (*Rev Prescrire* n° 503)
Nitrate d'argent Cooper° stick (***silver nitrate***) - Cooper (*Rev Prescrire* n° 501)

Impractical packaging for an injectable drug for use in an emergency setting

Metalyse° powder for solution for injection, 25-mg (5000-unit) dose strength (***tenecteplase***) - Boehringer Ingelheim (*Prescrire Int* n° 278)

The 25-mg dose strength of the thrombolytic agent *tenecteplase*, for use in acute ischaemic stroke, is supplied as a vial of powder, but the box does not contain the equipment required for its reconstitution (syringe, needle and water for injections). The 50-mg dose strength of *tenecteplase*, which has been marketed for over 20 years, is supplied with a syringe of solvent and an adapter with which to attach the syringe to the vial of powder.

The patient leaflet does not explain how to reconstitute or administer the drug. In response to our request for information, the pharmaceutical company informed us, in late December 2025, that this important information is contained in a brochure that "*will soon accompany each order*" of Metalyse° (our translation).

Neither the box nor the vial label states which solution should be used to dilute the reconstituted *tenecteplase* solution, whereas the SmPC recommends only 0.9% sodium chloride. The poor packaging of the 25-mg dose strength is unacceptable for a drug used in an emergency setting.

Insufficient information about the risks during pregnancy

Ixchiq° powder and solvent for solution for intramuscular injection (***attenuated chikungunya virus***) - Valneva (*Prescrire Int* n° 276)

The SmPC for this attenuated chikungunya vaccine (Ixchiq°) mentions that it is not known whether the vaccine virus can be transmitted to and harm the fetus when administered during pregnancy. Explicit information about this risk in the patient leaflet is warranted (as is a warning pictogram on the box, in France), in order to encourage discussions between women, those around them and healthcare professionals, but such information is not provided.

► Excerpt from *Rev Prescrire* February 2026
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2025 Prescrire Information Awards

Prescrire's annual Information Awards are based on pharmaceutical companies' responses to requests by Prescrire's Editorial Staff for the information we need to produce the analyses published in the Marketing Authorisations section of our French edition. Prescrire's Information Awards reflect the level of transparency that companies have shown towards Prescrire over the year.

What information does Prescrire request from pharmaceutical companies, and why? Pharmaceutical companies hold a wealth of data that are not available elsewhere. Since its inception, Prescrire has therefore systematically asked companies to send us data on their products, from the drug development stage through to post-marketing surveillance. We also conduct a systematic search for information from other sources, such as health authorities and the scientific literature.

We mainly ask for: evaluation data concerning the drug's efficacy and adverse effects; its packaging; the conditions under which patients can access the drug; its reimbursement status in France; its availability; and, where applicable, the reasons for its market withdrawal. Prescrire's Editorial Staff analyse all the information and materials companies provide.

The purpose of these requests is to help keep healthcare professionals fully informed and up to date, in order to improve the quality of patient care, by promoting the correct use of drugs and by increasing patient safety.

Only 9 pharmaceutical companies made the 2025 Honours List. 9 of the 85 pharmaceutical companies from which Prescrire requested information in 2025 earned a place on this year's Information Awards Honours List, for providing useful documentation that addressed every aspect of our requests. One of them, Cevidra, was rated as "Outstanding" for its rapid response times and the provision of detailed documentation, including particularly useful information and documents that are not publicly available, such as:

– Clinical study reports, providing details about the results of clinical trials;
– A periodic benefit-risk evaluation report (PBRER), enabling a better understanding of the drug's risks, through the data collected since its market introduction;
– Other documents containing information about clinical trials, such as their protocols and statistical analysis plans;
– Photos of packaging items.

Conversely, 15 pharmaceutical companies decided not to provide Prescrire with any information or documentation. These companies received an information "Red Card" (see figure opposite).

Unpublished data that are useful for healthcare professionals: what does Prescrire expect from companies? One of the pharmaceutical companies on this year's Honours List, Cemag Care, sent us detailed and appropriate documentation about its product, but omitted to mention that it had also applied to the French Health Products Agency (ANSM) to reclassify the substance concerned, in order to be able to market the product over the counter. This information would have been useful for Prescrire's analysis.

When Prescrire requests information from a pharmaceutical company, we expect to receive all important data relating to the product, so that we can analyse them and provide health professionals with any information relevant to health care.

More transparency. Other pharmaceutical companies that we contact frequently, such as GlaxoSmithKline, Lilly, Roche, Takeda and Viatris, earned a place on this year's Honours List for their regular and rapid responses to our requests. Their responses were partial, however. More comprehensive responses, including all the relevant data of use to healthcare professionals and patients, would be a sign of greater transparency. Prescrire encourages them to go that extra mile!

Transparency towards teams such as Prescrire, whose aim is to promote high-quality health care, first and foremost in the interest of patients, should be an ethical requirement for pharmaceutical companies.

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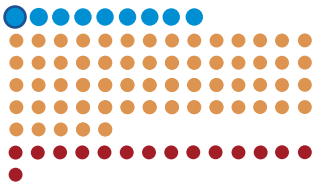
Prescrire Information Awards

Of the 85 companies we contacted for information



- **9 companies made the Honours List**
- **61 companies neither made the Honours List nor received a Red Card**
- **15 companies received a Red Card**

Honours List

Outstanding:
Cevidra

Followed by:
Celltrion Healthcare, Cemag Care, EG Labo, GlaxoSmithKline, Lilly, Roche, Takeda, Viatris

Red Cards

Alexion, Almirall, Bayer Healthcare, Gedeon Richter, Intsel Chimos, Janssen-Cilag, Kyowa Kirin Pharma, Orion Pharma, Otsuka Pharmaceutical, Panpharma, PharmaBlue, Teva, Theramex, UCB Pharma, Zentiva