

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<sup>®</sup> and Zolgensma<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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**<sup>®</sup> 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<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> tablets - HAC Pharma; **Fludrocortisone Acetlab**<sup>®</sup> 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**<sup>®</sup> tablets (**melatonin**) - AGB Pharma (*Prescrire Int* n° 271) (French authorisation)

**Fampyra**<sup>®</sup> prolonged-release tablets (**fampridine**) - Merz Therapeutics (*Rev Prescrire* n° 506)

**Fruzaqla**<sup>®</sup> hard capsules (**fruquintinib**) - Takeda (*Prescrire Int* n° 279)

**Omjjara**<sup>®</sup> tablets (**momelotinib**) - GlaxoSmithKline (*Prescrire Int* n° 277)

**Primaquine Sanofi**<sup>®</sup> tablets (**primaquine**) - Sanofi Winthrop (*Rev Prescrire* n° 505) (French authorisation)

**Talzenna**<sup>®</sup> hard capsules (**talazoparib**) - Pfizer (*Prescrire Int* n° 270)

**Triplixam**<sup>®</sup> tablets (**perindopril + indapamide + amlodipine**) - Servier (*Rev Prescrire* n° 499) (French authorisation)

**Voydeya**<sup>®</sup> 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<sup>®</sup>, 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<sup>®</sup>** - Janssen-Cilag, **Risperidone Arrow<sup>®</sup>** - Arrow Génériques, **Risperidone EG<sup>®</sup>** - EG Labo, **Risperidone Teva Santé<sup>®</sup>** - Teva Santé, **Risperidone Viatris<sup>®</sup>** - Viatris Santé, and **Risperidone Zentiva<sup>®</sup>** - 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<sup>®</sup>** 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<sup>®</sup> 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<sup>®</sup>** oral solution (**liquid extract of pelargonium root**) - Arkopharma (*Rev Prescrire* n° 505)

**Fincrezo<sup>®</sup>** cutaneous spray, solution (**finasteride**) - Bailleul (*Rev Prescrire* n° 503)

**Nitrate d'argent Cooper<sup>®</sup>** stick (**silver nitrate**) - Cooper (*Rev Prescrire* n° 501)

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

**Metalyse<sup>®</sup>** 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<sup>®</sup> (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<sup>®</sup>** powder and solvent for solution for intramuscular injection (**attenuated chikungunya virus**) - Valneva (*Prescrire Int* n° 276)

The SmPC for this attenuated chikungunya vaccine (Ixchiq<sup>®</sup>) 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.

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