THE PRESCRIRE AWARDS FOR 2024

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

2024 Prescrire Drug Awards

Every month, Prescrire's Editorial Staff help health professionals decide which of the multitude of newly authorised products or indications are worth adding to their list of useful treatment options, and which are to be avoided. We do this by conducting systematic 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*. The 2024 Prescrire Drug Awards are based on the reviews published in the Marketing Authorisations section of our French edition in 2024.

The multidisciplinary Prescrire team behind these annual independent drug awards is free from the influence of any companies involved in the healthcare sector.

One Pilule d'Or for a neglected disease

Prescrire awarded one Pilule d'Or (Golden Pill) this year, to a drug for a neglected disease. One other drug (authorised in France) was deemed "Noteworthy". Although some of the other drugs analysed in Prescrire over the course of 2024 represented a therapeutic advance for certain patients, especially in the field of oncology, we chose not to give them an award because their clinical evaluation was insufficiently robust (see editorial "Why drugs should be evaluated in several randomised comparative trials", p. 115).

A Pilule d'Or for fexinidazole in sleeping sickness due to Trypanosoma brucei rhodesiense. In southern and eastern Africa, human African trypanosomiasis (sleeping sickness) is mainly due to infection with *Trypanosoma brucei rhodesiense*. If left untreated, it is almost always fatal within a few weeks to a few months. Before the arrival of *fexinidazole* (a 5-nitroimidazole derivative with antiparasitic activity), treatment of *T. brucei rhodesiense* infection was based on intravenous drugs, in particular the arsenic derivative *melarsoprol*. With these treatments, mortality is less than 22%. *Melarsoprol* has frequent serious adverse effects, including reactive encephalopathy, which occurs in 5% to 18% of patients and is fatal in 10% to 70% of cases.

A non-comparative trial included 45 *T. brucei rhodesiense*-infected patients living in Uganda and Malawi, 35 of whom had second-stage disease (the most serious). They all received oral *fexinidazole*. After a one-year follow-up, 44 patients were still alive. Given the natural course of this disease, this result provides sufficiently strong evidence that *fexinidazole* is highly effective in this infection, despite the absence of a control group. In addition, *fexinidazole*'s adverse effect profile is fairly well known, due to the long history of use of nitroimidazole drugs and its use in sleeping sickness caused by a different parasite. It includes fewer serious adverse effects than that of *melarsoprol*.

Fexinidazole is administered orally, making it easier to use than intravenous *melarsoprol* in patients who live in regions with limited health infrastructure.

The clinical research on *fexinidazole* in sleeping sickness was conducted by the Drugs for Neglected Diseases initiative (DNDi), a non-profit organisation that aims to develop treatments for neglected populations, i.e. patients with infectious diseases for which no treatments exist, or where the treatments available are ineffective, more dangerous than beneficial, unaffordable, or unsuited to these patients' circumstances (see also "Development of fexinidazole: a product of exemplary collaboration" *Prescrire Int* December 2020).

Fexinidazole Winthrop° was awarded the 2024 Pilule d'Or in recognition of this major therapeutic advance in the treatment of a neglected disease.

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.

Fexinidazole Winthrop° (*fexinidazole*)
Sanofi Winthrop

In sleeping sickness due to infection with *Trypanosoma brucei rhodesiense* (*Prescrire Int* n° 269)

Honours List

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

No drugs made the Honours List in 2024

Noteworthy

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

Bicafres° (*sodium bicarbonate*)
Fresenius Medical Care

In metabolic acidosis due to chronic kidney disease, (*Rev Prescrire* n° 487)

Noteworthy: sodium bicarbonate tablets with marketing authorisation, an old drug that is useful in metabolic acidosis associated with chronic kidney disease. Patients with chronic kidney disease can develop metabolic acidosis with potentially serious clinical consequences. *Sodium bicarbonate* is a drug of choice, with probable efficacy in limiting the progression of renal failure, and possibly in reducing mortality.

It is an old drug, of course. The new development honoured in the 2024 Prescrire Drug Awards is that *sodium bicarbonate* gastro-resistant tablets have been granted marketing authorisation in France, where, previously, oral *sodium bicarbonate* was only available as an extemporaneous preparation. This marketing authorisation constitutes a therapeutic advance because it guarantees high-quality manufacturing standards and labelling, including the provision of a patient leaflet.

Bicafres° earned the title of Noteworthy drug in recognition of this administrative procedure, which guarantees the quality of a cheap and useful drug.

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2024 Prescrire Packaging Awards

When Prescrire evaluates a drug's harm-benefit balance and ease of use, its packaging is an important factor to take into account and analyse. Does the packaging help ensure the safety of patients, their families and their 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 packaging analyses take 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 nurses 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 the dose to be administered, 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 and patient populations in which the drug poses a particular risk;
– The risk of accidental ingestion, for example by a child.

The 2024 Prescrire Packaging Awards pertain to the packaging of drugs evaluated in our French edition in 2024. One product has earned an award for its particularly well-designed packaging. Those for which we identified packaging flaws that increase the risk of medication errors or pose other dangers received a Packaging Red Card.

One Packaging Award in 2024

A product with well-designed packaging, marketed in France

Lidocaine Aguettant 10 mg/ml solution for injection in pre-filled syringes (***lidocaine***) - Aguettant (*Rev Prescrire* n° 494)

Pre-filled syringes containing 100 mg of *lidocaine* in 10 ml of solution per syringe (10 mg/ml) are authorised in France for local anaesthesia and peripheral nerve block in adults and children from 2 years of age, and for intravenous regional anaesthesia of the upper limbs in adults. Prescrire examined this product when it became available in the community, rather than just in hospitals. This ready-to-use presentation simplifies aseptic preparation of the injection. It is both convenient for healthcare professionals and safe for patients.

Packaging Red Cards

11 dry oral forms packaged in multidose bottles, authorised in the European Union

Ayvakyt° tablets (***avapritinib***) - Blueprint Medicines (*Prescrire Int* n° 262)
Biktarvy° tablets (***bictegravir*** 30 mg + ***emtricitabine*** 120 mg + ***tenofovir alafenamide*** 15 mg) - Gilead Sciences (*Prescrire Int* n° 261)
Brukinsa° hard capsules (***zanubrutinib***) - Beigene (*Prescrire Int* n° 261)
Cufence° hard capsules (***trientine***) - Intsel Chimos (*Rev Prescrire* n° 493)
Genvoya° tablets (***elvitegravir*** 90 mg + ***cobicistat*** 90 mg + ***emtricitabine*** 120 mg + ***tenofovir alafenamide*** 6 mg) - Gilead Sciences (*Prescrire Int* n° 265)