



The Packaging Awards focus on the quality of packaging for drugs evaluated during the previous year in the New Products section of our French edition (in 2012: issues 339 to 350).

Throughout the year, *Prescrire's* Editorial Staff systematically examines the packaging of about 150 pharmaceutical products. This provides us with an opportunity to identify high-quality packaging and to detect dangerous parts of the packaging that are potential sources of confusion and errors, in order to inform our readers.

Every appearance of the packaging is examined, including the labelling; any devices provided for drug preparation or administration; caps and stoppers; and the legibility and quality of the information provided in the patient leaflet.

At the end of each year, the Packaging Awards are granted following a review of the year's standardised analyses by the *Prescrire Packaging Working Group*, in total independence and with no input from drug or packaging manufacturers (rules available at english.prescrire.org).

No awards for 2012. Only one contender came close to obtaining the packaging award for 2012. Paratabs[®] (Actavis) was the first orodispersible *paracetamol* to be marketed in France in blister packs equipped with an anti-tamper film. This protects children by helping to prevent them from accessing the tablets. However, in order to peel off the anti-tamper film, it is necessary to detach each portion of the blister pack containing a tablet, and this results in the expiry date and lot number no longer being visible. *Prescrire* also regrets that the company decided to highlight the brand name to the detriment of the international nonproprietary name (INN): a missed opportunity to receive an award.

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Packaging Award

• Not attributed for 2012

Yellow Cards

(in alphabetical order)

- **Aldalix[®] (a) capsules** Pfizer (*furosemide + spironolactone*) (Rev Prescrire n° 348)
On the box, the international nonproprietary names (INN) are printed in such tiny characters that they appear simply to underline the brand name; in addition, the packaging resembles those of Aldactazine[®] (*altizide + spironolactone*) and Aldactone[®] (*spironolactone*).
- **Gelutrophyl[®] capsules** Jolly Jatel (*ethanolamine tenoate*) (Rev Prescrire n° 349) • **Saflutan[®] eye drops** MSD (*tafluprost*) (Rev Prescrire n° 344)
The primary packaging of these two products (blister packs, single-use containers) does not even mention the INNs.
- **Predyl[®] mouthwash** Pred (*povidone iodine*) (Rev Prescrire n° 348)
This product has an attractive appearance (mauve colour, flask shape) and lacks a child-proof cap.

a- Aldalix[®] is no longer marketed in France in 2013.

Red Cards (by type of packaging defect, and then in alphabetical order)

- **Biperidysflash[®] orodispersible tablets** Pierre Fabre Medicament (*domperidone*) (Rev Prescrire n° 340)
The patient leaflet fails to mention the risk of cardiac adverse effects.
- **Mycohydralin[®] cream** Bayer Santé Familiale (*clotrimazole*) (Rev Prescrire n° 340)
The patient leaflet fails to mention clearly that latex condoms might be at risk of rupture if placed in contact with this cream.
- **Ostram Vitamine D3[®] powder for oral suspension** Merck Serono (*tricalcium phosphate + colecalciferol*) (Rev Prescrire n° 342)
The information provided on the box no longer mentions the fact that this drug is contraindicated in case of renal impairment.
- **Xarelto[®] 15 mg and 20 mg tablets** Bayer Santé (*rivaroxaban*) (Prescrire Int n° 132)
The aspect of the two dose strengths is very similar, especially the blister packs and tablets.

Packaging that may put children at risk

- **Flixovate[®] cream and ointment** GlaxoSmithKline (*fluticasone*) (Rev Prescrire n° 341)
The dosing schedule still mentions twice-daily application (morning and evening), despite the fact that this product is now approved for use from the age of 3 months, in a single daily application. This creates a risk of overdose and adverse effects in this age group, which is particularly sensitive to the adverse effects of this potent topical corticosteroid.

- **Preterval[®] tablets** Servier (*indapamide + perindopril*) (Rev Prescrire n° 343) • **Suboxone[®] sublingual tablets** Reckitt Benckiser Pharmaceuticals (*buprenorphine + naloxone*) (Rev Prescrire n° 342)
For the lack of a safety cap on the bottle and the lack of an anti-tamper film on the blister pack, creating a risk of accidental ingestion by a child and potentially severe adverse effects.

Patient leaflets that endanger the unborn child

- **Alevetabs[®] tablets** Bayer Santé Familiale (*naproxen*) (Rev Prescrire n° 343) • **Rhinadvil[®] tablets** Pfizer Santé Familiale (*ibuprofen + pseudoephedrine*) (Rev Prescrire n° 345) • **Rhinureflex[®] tablets** Reckitt Benckiser Healthcare (*ibuprofen + pseudoephedrine*) (Rev Prescrire n° 348)
All three products contain a nonsteroidal anti-inflammatory drug (NSAID), but the accompanying information leaflet only states that they are contraindicated from the sixth month of pregnancy. Yet there are also a risk of miscarriage and malformations when NSAIDs are used during the first trimester, and a risk of life-threatening renal and cardiovascular disorders when they are used from the second trimester.
In addition, there is no mention of the fact that *pseudoephedrine* may possibly be teratogenic, based on weak but consistent evidence.