2017 Prescrire Packaging Awards

The Packaging Awards focus on the quality of the packaging of drugs evaluated in 2017 in our French edition.

2017 Packaging Award

• **Emtricitabine + tenofovir disoproxil Mylan°** tablets, Mylan (Prescrire Int n° 187)
Prominence is given on the box to the information that is useful in patient care and helps prevent medication errors, i.e. the international nonproprietary names (INNs) and dose strengths. The tablets are packaged in pre-cut unit-dose blister packs, where each detachable blister pocket is labelled with the INNs, dose strengths, batch number, and expiry date. Pre-cut unit-dose blister packs ensure that tablets remain identifiable, traceable and protected in many situations: in the home, or away from home; when a third party administers the drug; in hospitals that operate a unit-dose drug distribution system; etc. The *emtricitabine + tenofovir disoproxil* combination has been available in France since 2006 in bulk bottles containing 30 tablets, under the brand name Truvada°. Bulk bottles have several drawbacks: tablets can only be identified on the basis of their appearance, are unprotected once removed from the bottle, and must be repackaged in hospitals to enable unit-dose drug distribution.
Emtricitabine + tenofovir disoproxil Mylan° was marketed in 2017 and is the first unit-dose format of this combination to be made available in France.

Prescrire's systematic reviews include evaluation of the drug's packaging. Does the packaging make the drug easy and safe to use? Do any aspects of the packaging constitute a therapeutic advance? Conversely, are any aspects of the packaging dangerous?

When *Prescrire* analyses a drug's packaging, we consider the context in which the drug will be obtained, prepared and administered: the situations in which it will be used; the patients likely to receive it, especially if they are children, pregnant women or elderly patients; whether it will be used in an emergency, hospital or community setting, obtained on prescription, on the advice of a community pharmacist, or bought on the patient's own initiative from a pharmacy or an internet retailer; whether or not a nurse will prepare and administer it; etc.

Every aspect of the packaging is examined to determine its quality and safety. We examine: the legibility of international nonproprietary names (INNs), whether different dose strengths are easily distinguishable, and any information presented graphically, such as dosing schedules and pictograms; any dosing devices supplied to prepare and administer the required doses; the measures taken to protect children from poisoning; and the quality and clarity of the information provided in the patient leaflet on dose preparation, adverse effects, and the situations and patient groups in which the drug poses a risk.

The *Prescrire* Packaging Awards are based on independent evaluations conducted by *Prescrire*'s Editorial Staff and our Packaging Working Group, free from any influence from packaging manufacturers.

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YELLOW CARDS

Vogalib° oral lyophilisate **(*metopimazine*)** Procter & Gamble Pharmaceuticals (Rev Prescrire n° 403)
For not giving due prominence on the box or blister packs to the INN, whereas every possible effort should be made to help patients and health professionals identify the presence of *metopimazine*, a drug with neuroleptic properties.

Bactérix° hard capsules **(*nifuroxazide*)** Gifrer Barbezat (Prescrire Int n° 187)
For not displaying the INN on the blister pack, which makes it difficult for patients and health professionals to identify the presence of *nifuroxazide*, a drug that can provoke severe allergic reactions and immunological adverse effects.

Skudexum° tablets **(*tramadol* 75 mg + *dexketoprofen* 25 mg)** Menarini (Rev Prescrire n° 409)
For giving insufficient prominence on the box and blister pack to the INNs and the quantity of *tramadol* present. The labelling therefore makes it difficult to understand the composition of the tablets, yet patients and health professionals ought to be able to easily identify the presence of opioids in medicines to avoid any confusion, and in particular the risk of unwitting concomitant use of several opioid-containing medicines.

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RED CARDS

DANGEROUSLY LIMITED INFORMATION IN THE LABELLING OR PATIENT LEAFLET, INCLUDING UMBRELLA BRANDS

Drill Maux de Gorge° tablets and syrup (***alfa-amylase***), **MucoDrill°** effervescent tablets (***acetylcysteine***) Pierre Fabre Médicament (Rev Prescrire n° 399) • **Lysopaïne Maux de Gorge Ambroxol°** oromucosal spray, solution (***ambroxol***) Sanofi Aventis (Prescrire Int n° 184) **Humex Mal de Gorge°** lozenges (***lidocaine + dichlorobenzyl alcohol + amylmetacresol***) Urgo Healthcare (Rev Prescrire n° 399) • **Clarix état Grippal°** powder for oral solution in sachets (***paracetamol + chlorphenamine + vitamin C***) Coopération Pharmaceutique Française (Rev Prescrire n° 400)
The principle of an umbrella brand is to sell various medicines containing different active substances, with different dangers, under the same trademark. This marketing strategy, based on brand recognition, can lead to confusion between drugs of the same umbrella brand and unawareness of certain risks, such as drug interactions. The risk of error is increased by the visual resemblance between medicines, which all display the umbrella brand name in large, bold characters and share the same typographic style and graphics. INNs are often barely readable. Umbrella brands are still not prohibited in France as of early 2018.

Activox Rhume Pélargonium° oral solution (***Pelargonium root extract***) Arkopharma (Rev Prescrire n° 399)
For being part of an umbrella brand and for including the falsely reassuring statement in the patient leaflet that "*no interactions have been reported*", whereas *Pelargonium root extracts* contain coumarin derivatives and a risk of increasing the effect of oral anticoagulants has not been ruled out.

Delprim° tablets (***trimethoprim***) DB Pharma (Rev Prescrire n° 406)
For not giving due prominence to the INN on blister packs or sufficient information in the patient leaflet about the risks during pregnancy. The patient leaflet does not explain the risk of teratogenicity when *trimethoprim* is taken during the first trimester (neural tube closure defects, oral clefts, urinary tract abnormalities and congenital heart defects), and does not warn patients that exposure during the 3 months before pregnancy also seems to be associated with a higher incidence of congenital malformations.

Epclusa° tablets (***sofosbuvir + velpatasvir***) Gilead Sciences (Rev Prescrire n° 410)
For the bulk bottle and for providing insufficient information in the patient leaflet about adverse effects. The patient leaflet omits the known harms of *sofosbuvir* (arrhythmias, neutropenia, etc.) and most of the adverse effects that occurred during the clinical development of the *sofosbuvir + velpatasvir* combination, in particular: irritability, insomnia, rash, and depression.

PACKAGING THAT POSES A RISK OF DOSING ERRORS

Cosimprel° 5 mg/10 mg and 10 mg/5 mg tablets (***bisoprolol + perindopril***) Servier (Rev Prescrire n° 408)
For the strong visual resemblance between the labelling of the boxes and bulk bottles of these two combinations with "mirror-image" dose strengths (5 mg/10 mg and 10 mg/5 mg), which could cause dosing errors.

Kayexalate° powder for oral or rectal suspension (***sodium polystyrene sulfonate***) Sanofi Aventis (Rev Prescrire n° 407)
For failing to provide the means necessary for accurate dose preparation: multidose bulk jar with a spoon instead of single-dose sachets for adults; and no dosage form or dosing device suitable for children, necessitating extemporaneous preparation by a pharmacist. And for the lack of a child-proof closure on a jar containing such a large quantity of drug.

PACKAGING THAT POSES A RISK OF POISONING IN CHILDREN WHO INGEST THE CONTENTS UNNOTICED BY THEIR CARERS

Biocalyptol° **Biocalyptol Sans Sucre°** Zambon, **Dimétane°** Biocodex, **Hexapneumine Adultes°** **Hexapneumine Enfants°** Bouchara-Recordati, syrups (***pholcodine***) (Prescrire Int n° 184)
For the absence of a child-proof cap on the bottle of these 5 *pholcodine*-containing medicines, exposing children to the risk of serious adverse effects, in particular respiratory depression, if they accidentally ingest the contents.

Ferrostrane° syrup (***sodium feredetate***) Teofarma, **Fumafer°** chocolate-flavoured oral powder (***iron***) Sanofi Aventis (Rev Prescrire n° 405)
For marketing in France these two medicines for five decades in a bottle without a child-proof cap, exposing children to the risk of accidental ingestion of *iron* and its serious and potentially fatal adverse effects. As of early 2018, a child-proof cap has finally been added to Ferrostrane° bottles in France.

Nausicalm° syrup (***dimenhydrinate***) Nogues (Rev Prescrire n° 410)
For the absence of a child-proof cap on the bottle, exposing children to the risk of accidental ingestion of this antihistamine and its serious and potentially fatal adverse effects. In response to our query, the company informed us that a child-proof cap is planned for late 2018.

Colchicine Opocalcium° tablets (***colchicine***), **Colchimax°** tablets (***colchicine + opium powder + tiemonium***) Mayoly-Spindler (Rev Prescrire n° 402, Prescrire Int n° 187)
For lacking any specific safety features to make it harder for children to gain access to the tablets, which could result in a potentially fatal *colchicine* overdose. The box could have a safety catch, or the blister pack could have a child-resistant film, combined if necessary with a tool to help remove tablets.

▶ Translated from *Rev Prescrire* **February 2018**
Volume 38 N° 412 • Pages 86-87

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