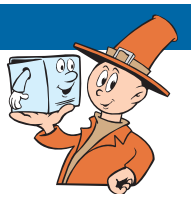
2013 Prescrire Packaging Awards



The Packaging Awards focus on the quality of packaging for drugs evaluated in 2013 in the New Products section of our French edition.

Throughout the year, we systematically examine the packaging of 150 to 250 pharmaceutical products. This provides us with an opportunity to identify high-quality packaging and to detect dangerous packaging that is a potential source of confusion and errors, in order to inform our readers (see the annual packaging review, to be published in our May issue). Every aspect of the packaging that could have an impact on the harm-benefit balance is examined, including the labelling (legibility of international nonproprietary names (INNs) and dosages, the appropriateness of dosing schedules or pictograms, and storage conditions); any devices provided for drug preparation or administration; the performance of tamper-proof devices such as stoppers and blister pack films; and the legibility and thoroughness of the patient leaflets, including dose preparation, adverse effects, and contraindications.

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

2013: some progress, but dangers continue to accumulate. Some improvements were observed in 2013: three drugs were considered worthy of a Packaging Award, a number that had not been reached since 2008.

However, the number of pharmaceuticals with substandard or dangerous packaging increased in 2013, with 33 products receiving a Yellow or Red Card.

Packaging Awards

- **BCG-Medac° powder and solvent for intravesical suspension** Medac (BCG) (*Prescrire Int* n° 146)
  Contains all the materials required for patient care (solvent pouch, urinary probes) and reduces the risk of contamination (closed system for dose preparation, bag for waste disposal).
- **Suboxone° (*buprenorphine + naloxone*) and Subutex° (*buprenorphine*) sublingual tablets**
  Reckitt Benckiser Pharmaceuticals (*Rev Prescrire* n° 362)
  Reduction in the risk of accidental ingestion of these tablets by children, thanks to the addition of an effective tamperproof film to the blister packs (**a**).

a- Our tests show that it is almost impossible to break the tamperproof film with one's bare hands. To remove a tablet, it is first necessary to tear off a blister unit along the perforated lines, then to peel off the safety film, starting at the only corner where the film is not glued down.

Yellow Cards

- **Oralair° sublingual tablets** Stallergènes (***allergenic extract of five grass pollens***) (*Rev Prescrire* n°352) • **Quinofree° eye drops** Théa (***ofloxacin***) (*Rev Prescrire* n° 356) • **Voltarènophta° eye drops** Théa (***diclofenac***) (*Rev Prescrire* n° 354) • **Zalerg° eye drops** Théa (***ketotifen***) (*Rev Prescrire* n° 354)
  The primary packaging (blister packs, single-dose units) of these four products fails to mention the international nonproprietary names.
- **Tamiflu° powder for oral suspension** Roche **(*oseltamivir*)** (*Rev Prescrire* n° 354)
  The syringe is insufficiently precise for measuring a dose for a newborn, and it is graduated in millilitres, requiring the user to convert the prescribed dose from milligrams into millilitres, thus creating a risk of error and overdose.
- **Bromocriptine Zentiva inhibition de la lactation° tablets** Sanofi Aventis (*bromocriptine*) (*Rev Prescrire* n° 352)
  The dosing schedule printed on the box ("morning", "midday", "evening") is inappropriate, as the dose regimen recommended by the SPC is between one-half and two tablets a day; this creates a risk of overdose.

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Red Cards

Dangerous lack of information on the labelling or patient leaflet

- **Antalnox° Ge tablets** Pierre Fabre Médicament (*naproxen*) (*Rev Prescrire* n° 359) • **Rhinadvil Rhume Ibuprofène/pseudoéphédrine° tablets** Pfizer Santé Familiale (*ibuprofen + pseudoephedrine*) (*Rev Prescrire* n° 352). The patient leaflets fail to adequately warn patients of the dangers posed by these nonsteroidal anti-inflammatory drugs (NSAIDs). They do not mention the possible increased risk of miscarriage and malformations when used during the first trimester of pregnancy, or the potentially life-threatening renal and cardiovascular effects on the unborn child following exposure from the second trimester. Instead, they simply mention a contraindication from the 6th month of pregnancy. Finally, they fail to mention converging data that suggest *pseudoephedrine* may be teratogenic.
- **Jakavi° tablets** Novartis Pharma (*ruxolitinib*) (*Prescrire Int* n° 137). The patient leaflet describes adverse effects as mild or moderate and usually transient, yet *ruxolitinib* can cause severe bleeding and other serious adverse effects such as confusion.
- **Clarix toux sèche dextrométhorphane Adultes° sachets of oral solution** Coopération pharmaceutique française (*dextromethorphan*) (*Rev Prescrire* n° 354). The INN, which would allow users to identify this opioid, is not clearly printed on the box, even though the Clarix° umbrella line includes various other active substances.

Packaging that poses a risk for children

- **Revatio° power for oral suspension** Pfizer **(*sildenafil*)** (*Rev Prescrire* n° 352). There is a risk of massive overdose with the measuring device provided: the graduations on the syringe exceed the maximum dose; its graduation in millilitres (ml) requires the user to convert the dose from milligrams to millilitres; the dual graduation of the syringes in "ml" and "tsp" (teaspoon) is confusing; and the 30-ml cup provided to reconstitute the suspension could be confused with the dose measuring device.
- **Dolstic° 10% oral solution** Bioprojet Pharma (***paracetamol***) (*Rev Prescrire* n° 359). The two presentations of this product are not sufficiently distinct, as they contain measuring devices of different capacities, one for children up to 3 years of age, and the other for children from 3 to 10 years. Use of the latter device to treat infants could result in serious overdose.
- **Théralène° 4% oral solution and 0.05% syrup** Erempharma (***alimemazine***) (*Rev Prescrire* n° 362). The two products are too similar in appearance. However, the concentration of the oral solution is 80 times that of the syrup, and children would be exposed to a risk of severe adverse effects from this neuroleptic in case of confusion. In addition, the bottles of syrup lack a child-proof cap.
- **Codoliprane° 500 mg/30 mg divisible effervescent tablets** Sanofi Aventis **(*paracetamol + codeine*)** (*Rev Prescrire* n° 351). This type of tablet and the dosage are inappropriate for a product intended for children as young as three years; in addition, the lack of a child-proof cap on the tube creates a risk of overdose.
- **Trophirès composé enfants° suppositories** Sanofi Aventis **(*paracetamol + eucalyptus essential oil + tenoate sodium*)** (*Rev Prescrire* n° 353). The presence of *paracetamol* is not highlighted on the front of the box, which is similar to that of the *paracetamol*-free product belonging to this product line, creating a risk of confusion and overdose if another product containing *paracetamol* is used concomitantly.
- Five **suppositories** containing **terpene derivatives: • Biquinol enfants°** Merck Médication familiale • **Bronchodermine enfants°** S.E.R.P. • **Bronchorectine au citral enfants°** Mayoly Spindler • **Coquelusedal enfants°** Élerté • **Ozothine enfants°** Zambon (*Rev Prescrire* n° 353). The labelling on the front the boxes and the blister packs fails to mention the names of the terpene derivatives, which should be avoided in children because of the risk of seizures.
- **Huvanof° sachets of powder for oral solution** Sanofi Aventis **(*acetylsalicylic acid*)** (*Rev Prescrire* n° 361). The labelling on the boxes and sachets fails to highlight the presence of *aspirin,* and it is difficult to differentiate between the various dose strengths, creating a risk of overdose in children.
- **Ritaline° LP 10 mg capsules** Novartis Pharma **(*methylphenidate*)** (*Rev Prescrire* n° 357). The use of bulk bottles is inappropriate for this amphetamine psychostimulant intended for "hyperactive" children, and trivialises the risk associated with handling these drugs.
- **Imeth°** Nordic Pharma, **Méthotrexate Bellon°** Sanofi Aventis, **Novatrex°** Pfizer, **tablets (*methotrexate*)** (*Prescrire Int* n° 126) • **Clarix toux sèche dextrométhorphane mépyramine adultes° syrup** Coopération pharmaceutique française **(*dextromethorphan + mepyramine*)** (*Rev Prescrire* n° 357) • **Bricanyl° LP tablets** AstraZeneca **(*terbutaline*)** (*Rev Prescrire* n° 362) • **Rivotril° drops of oral solution** Roche **(*clonazepam*)** (*Rev Prescrire* n° 354). The bottles for these six products all lack a child-proof cap, creating a risk of accidental ingestion by a child, who would be exposed to the potentially severe adverse effects of these drugs.

Risk of dosing errors in adults

- **Januvia°** Merck Sharp & Dohme, **Xelevia°** Pierre Fabre Medicament, **tablets (*sitagliptin*)** (*Rev Prescrire* n° 352). The resemblance between the two dose strengths (50 mg and 100 mg) on the boxes and blister packs is a source of confusion, since patients with moderate renal failure must not ingest more than 50 mg per intake.
- **Maginjectable° IV or IM solution** Coopération pharmaceutique française **(*magnesium*)** (*Rev Prescrire* n° 362). The printing on the vials is poorly legible, especially regarding the hypertonic nature of the solution. In addition, the route of administration and the mode of IV injection are not mentioned, the dosage is expressed in two ways on the front of the box, and the information in the patient leaflet on the signs and treatment of hypermagnesaemia is inadequate.
- **Zyloric° tablets** H.A.C. Pharma **(*allopurinol*)** (*Rev Prescrire* n° 356). The INN and dosages are poorly legible on the blister packs, which also have a similar appearance, creating a risk of confusion; yet this drug can cause serious, dose-dependent, cutaneous hypersensitivity reactions.
- **Vimpat° syrup** UCB Pharma **(*lacosamide*)** (*Rev Prescrire* n° 352). The measuring cup is imprecise and graduated in millilitres (ml), requiring the user to convert milligrams to millilitres, thus creating a risk of underdosing or overdosing.