Prescrire's Red Cards for drug packaging, 1991-2012: some improvements, but many dangers persist

Since 1991, as part of its annual Prescrire Awards, *Prescrire* has issued more than 100 Red Cards for poor-quality packaging. The reasons were varied:
- Dangers, especially for children, due to the lack of a child-proof cap on bulk bottles, easily peeled blister packs, or an attractive flavour or shape;
- Incomplete or misleading information in the labelling or patient leaflet;
- Lack of a suitable dosing device;
- Similar appearance of different products marketed under an umbrella brand, creating a risk of confusion between products with very different compositions;
- Presentations that trivialise a drug or increase the risk of overdose.

In October 2013, we re-examined the packaging of these drugs to see if there had been any improvements (**a**).

Some products more secure. Some companies have made efforts to prevent accidental exposure of children. This is the case for Sectral° oral solution 40 mg/ml (*acebutolol*), whose bottles are now equipped with a child-proof cap (*Rev Prescrire* n° 266), and also Suboxone° tablets (*buprenorphine + naloxone*), which have been marketed since 2013 in unit blister packs equipped with a tamper-proof film that restricts access by children (*Rev Prescrire* n° 342; n° 362). The *quinine*-containing combination (Okimus°), authorised for cramps, has been sold since late 2012 in blister packs rather than bulk bottles, although it remains a drug to avoid (*Rev Prescrire* n° 297; n° 352).

In contrast, no improvements were made in the packaging of tablets containing *methotrexate* (Imeth°, Méthotrexate Bellon°, Novatrex°) or that of Quinimax° tablets (*quinidine + quinine + cinchonidine + cinchonine*), which are still sold in bulk bottles without a child-proof cap, even though the bottles contain enough tablets to kill a child (*Rev Prescrire* n° 352; n° 231).

Vials of Dolko° oral *paracetamol* solution, as well as Toplexil° syrup (*oxomemazine*) and Zarontin° (*ethosuximide*, an antiepileptic drug) are still not equipped with a child-proof cap (*Rev Prescrire* n° 284; n° 309; n° 359).

Some improvements in patient information. The labelling of certain drugs has improved. This is the case for Renaudin° vials of *adrenaline* and *atropine*, following harmonisation of the labelling on vials of several injectable solutions by the French drug regulatory agency in 2007. The dose strengths of *fosphenytoin* and *phenytoin* equivalent can now be more clearly distinguished on boxes of Prodilantin° (*Rev Prescrire* n° 201). And the total amount of *ziconotide* has been added to the front of boxes of Prialt° solution for infusion 100 micrograms/ml, while the international nonproprietary name (INN) has been added to the vials, albeit in small print (*Rev Prescrire* n° 316).

In contrast, no improvements were made to two products containing *isotretinoin* (Procuta° and Curacné°): the brand name still overshadows the INN of this highly teratogenic drug (*Rev Prescrire* n° 267). Similarly, boxes of Nurofentabs° and Nurofenflash° (formerly Nuroflash°) do not sufficiently highlight the INN (*ibuprofen*). This creates a risk of accidental exposure during pregnancy, and also a risk of overdose, particularly during concomitant self-medication with other products containing *ibuprofen* (*Rev Prescrire* n° 264, n° 319).

Some instructions for use are now more informative, such as those for Monuril° (*fosfomycin*) (*Rev Prescrire* n° 103) (1). In contrast, the patient leaflets for the nonsteroidal anti-inflammatory drugs (NSAIDs) we examined in 2013 fail to highlight the risks to the fetus during the first two trimesters of pregnancy (*Rev Prescrire* n° 352; n° 340; n° 328; n° 304; n° 292).

The two-box dosing schedule printed on boxes of Flixovate° (*fluticasone*) cream and ointment, which exposed infants to a risk of overdose, has been removed.

Ease of use: we can and must do better. The results of our analysis of dosing devices are disappointing. One questionable improvement is the inclusion of a measuring cup graduated in millilitres for *ethosuximide* (Zarontin°). This is better than using a household spoon, but the cups are imprecise and unreliable, which is unacceptable for an antiepileptic drug (*Rev Prescrire* n° 309; n° 338).

The oral syringes provided with oral *levetiracetam* 100 mg/ml (Keppra°) are still graduated in millilitres, requiring the user to convert the dose; this is a proven source of serious dosing errors (2) (*Rev Prescrire* n° 327).

Vials of BCG SSI° vaccine still contain a volume equivalent to 10 or 20 doses and a syringe of inappropriate capacity, even though abscesses at the injection site have been reported following overdose (*Rev Prescrire* n° 267; n° 285).

Confusing packaging: slight improvements. The oral solution and syrup of *valproic acid* (Dépakine°) are easier to distinguish, with the use of different-coloured boxes and syringe plungers (*Rev Prescrire* n° 231; n° 257).

Although the packaging for Atacand° (*candesartan*) and Hytacand° (*candesartan + hydrochlorothiazide*) was slightly improved, the graphics used for these two products remain similar and are easily confused (*Rev Prescrire* n° 226183).

Presentations that trivialise drugs. The appearance of some packaging remains inappropriate. Ketum° 120 g gel (*ketoprofen*) still resembles a toothpaste tube (*Rev Prescrire* n° 202). Lozenges containing *flurbiprofen* (Strefen°), an NSAID for self-medication, still resemble candy (*Rev Prescrire* n° 281). Most *methylphenidate* tablets and capsules are still sold in bulk bottles (Concerta° LP, Ritalin° LP), making it more difficult to teach children of the need to carefully respect the prescribed dose of this amphetamine (*Rev Prescrire* n° 258).

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a- *About twenty drugs that received a Red Card since 1991 are no longer marketed in France.*

1- ANSM "Notice-Monuril° 3 g, granulés pour solution buvable en sachets" 25 October 2010: 5 pages.
2- European Commission "Leaflet-Keppra° 100 mg/ml, oral solution" 26 August 2013: 8 pages.

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