2023 Prescrire Packaging Awards

When Prescrire evaluates a drug's harm-benefit balance or its ease of use, its packaging is an important factor to take into consideration. 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, and in particular can the doses required be measured accurately?

Our packaging analyses take many factors into account: the clinical situation in which the drug will be used; the patients liable to receive it, especially pregnant women, children or older people; whether family members, carers or nurses will prepare and administer the drug; and whether it will be used in an emergency setting, in hospitals or in the community, obtained on prescription, on the advice of a community pharmacist, or bought by the patient from an internet retailer.

Every aspect of the packaging is analysed for its impact on quality of care and the safety of users 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, dosing schedules, symbols or pictograms;
– The devices provided for preparing, measuring and administering doses;
– The risk that someone other than the patient, especially children, could ingest the drug, unnoticed by their carers;
– The quality and clarity of the information provided in the patient leaflet, especially information on how to use the product, its adverse effects, and the situations and patient groups in which the drug poses a particular risk, as well as any information made available through a QR code on the box.

The 2023 Prescrire Packaging Awards pertain to the packaging of drugs evaluated in our French edition in 2023. Two products have earned an award for their particularly well-designed packaging. However, various products received a "Red Card" because their packaging is liable to cause medication errors or poses other dangers.

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Packaging well-designed for the oral administration of high doses of dexamethasone

Dexliq° oral solution (***dexamethasone***) - Theravia (French authorisation) (*Rev Prescrire* n° 473)

Packaging that made intranasal fentanyl safer to use

Instanyl° DoseGuard° nasal spray solution (***fentanyl***) - Takeda (EU centralised procedure) (*Prescrire Int* n° 257)

Intranasal *fentanyl* is authorised for the relief of breakthrough pain in cancer patients, as an add-on to well-conducted maintenance opioid therapy. *Fentanyl* nasal spray was initially marketed under the brand name Instanyl° in a multidose spray bottle enclosed in a child-resistant box, with no lock-out mechanism to prevent overdoses. Single-dose spray containers, in secondary packaging protected by a child-resistant film, were subsequently marketed alongside these multidose bottles but, in France at least, they were only available in hospitals.

Fentanyl nasal spray was marketed in new packaging in 2023, under the brand name Instanyl° DoseGuard°, consisting of a multidose spray bottle with a child-proof cap and a button on the side to unlock the device. An electronic dose management system limits the number of successive doses to 2, in accordance with the recommendation in the SmPC to treat each episode of breakthrough pain with no more than 2 doses, administered at least 10 minutes apart.

In practice, when 2 successive doses are administered within a 60-minute period, an automatic lock-out mechanism prevents any further administrations for 2 hours. This system is designed to limit accidental overdoses, which can be fatal. The priming procedure is complex, and patients must learn how the lock-out system works, but Instanyl° DoseGuard° succeeds in making opioid use safer for patients and the people around them, especially children, while at the same time allowing some flexibility in adjusting the dose to the level of pain experienced by patients, both in the community and in hospitals.

Red Cards

39 drugs authorised in the European Union or France in poor-quality packaging received a "Red Card" for various reasons:

– Dry oral forms supplied in multidose bottles: difficult to identify the drug once removed from the bottle, and risk of accidental drug exposure, especially in children;
– Oral liquid forms supplied in bottles with no child-proof cap: risk of accidental drug exposure, especially in children;
– An oral solution supplied in a dropper container, with a recommended dose of up to 60 drops: risk of wrong-dose errors;
– Look-alike packaging: risk of wrong-drug errors;
– Insufficient prominence given to INNs: difficult to identify the drug substance(s) present;
– Incomplete information concerning risks during pregnancy: risk of embryotoxicity, fetotoxicity or pregnancy complications.

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