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Orodispersible paracetamol tablets: danger of poisoning in children

● **Paracetamol overdose can cause serious and sometimes fatal liver damage. Children are at particular risk of overdose with the orodispersible tablet form. A study conducted by a Swiss poison control centre showed that children ingested twice the dose of paracetamol in cases involving the orodispersible tablet form.**

● **In practice, it is better to keep drugs, including commonly used medicines such as paracetamol, out of reach of children and to warn their relatives and carers that paracetamol is highly toxic in case of overdose.**

● **In France, as of 1 March 2012, a number of orodispersible paracetamol tablets are sold in bulk tubes without a child-proof cap, packaging that is particularly dangerous for children. Blister packs sealed with a safety film are safer because it takes longer to remove the tablets. When choosing a drug, the safety of its packaging will remain a key factor to take into consideration until the pharmaceutical industry and drug regulatory agencies place more importance on protecting patients and their relatives.**

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Paracetamol is the drug of choice for relieving pain or fever in children. Serious adverse effects are extremely rare at therapeutic doses, and mainly involve allergic reactions. It is highly toxic in overdose however, provoking sometimes fatal liver damage (1,2). It is therefore extremely important to prevent its accidental ingestion by children. One crucial preventive measure is to use packaging that is difficult for young children to open.

Some formulations present a greater risk to children than others: for example, paediatric oral liquid paracetamol preparations without a child-proof cap (3).

A Swiss poison control centre conducted a retrospective study of 203 cases of accidental paracetamol ingestion, which highlights the dangers of tablets, including orodispersible tablets (4).

Almost twice as much paracetamol ingested with orodispersible tablets. This retrospective study analysed all cases of poisoning reported to the centre between June 2003 and August 2009, in which children under the age of 6 years had accidentally ingested orodispersible or solid 500 mg paracetamol tablets. In these cases, paracetamol was the only drug implicated and the ingested dose was known (4).

The mean ingested dose of paracetamol was twice as high with orodispersible tablets. Solid 500 mg tablets were implicated in 187 cases in which children, whose mean age was about 2 years, ingested 2.5 tablets on average, corresponding to about 100 mg/kg of paracetamol. Orodispersible 500 mg tablets were implicated in 16 cases in which children with a mean age of 3 years ingested an average of 4.6 tablets, corresponding to about 150 mg/kg of paracetamol. The authors suggest that the rapid disintegration of orodispersible tablets on contact with saliva and their more pleasant taste that masks the bitterness of paracetamol encourage higher consumption (4).

In practice: keep paracetamol out of reach of children and demand suitable packaging. As of 1 March 2012, several orodispersible paracetamol products are marketed in France, at dose strengths of 250 mg or 500 mg. To protect children from accidental overdose with serious consequences, drugs should be kept out of their reach. Their relatives and carers should be warned about each drug's toxicity, including commonplace drugs whose dangers are often overlooked.

It is the responsibility of pharmaceutical companies to provide packaging designed for patient safety, and it is up to drug regulatory agencies to safeguard patients and their relatives (see inset opposite).

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Orodispersible paracetamol: the packaging makes all the difference

As of 1 March 2012, 5 orodispersible products containing paracetamol are marketed in France.

Efferalganodis° in France, Dafalgan° Odis in Belgium, and Dafalganodis° in Switzerland expose children in particular to the risk of accidental overdose. These orodispersible tablets are packaged in a bulk tube without a child-proof cap, providing easy access to 4 g of paracetamol in the form of sweet, pleasantly tart, fruit-flavoured tablets that fizz in the mouth; some of these tablets resemble mint candy.

The other products available in France are packaged in transparent or opaque,

plastic or foil blister packs, making it more difficult for children to rapidly remove the tablets. DolipraneOro°, Paratabs° and Paralyoc° 500 mg contain between 6 g and 8 g of paracetamol per box. Each box of Paralyoc° 250 mg contains 2.5 g of paracetamol.

Paratabs° orodispersible paracetamol tablets are supplied in blister packs sealed with a safety film that delays access to the tablets even more. According to our packaging analysis, this is the orodispersible paracetamol product with the safest packaging.

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Selected references from Prescrire's literature search.

- 1- Prescrire Rédaction "Douleur ou fièvre chez les enfants: préférer le paracétamol" Infos-Patients Prescrire mises à jour décembre 2011: 1 page.
- 2- Prescrire Rédaction "Fiche E6A. Hépatites aiguës médicamenteuses en bref" *Rev Prescrire* 2011; 31 (338 suppl. interactions médicamenteuses).
- 3- Prescrire Editorial Staff "Safety of paracetamol packaging in the United Kingdom" *Prescrire Int* 2001; 10 (56): 189.
- 4- Ceschi A et al. "Paracetamol orodispersible tablets: a risk for severe poisoning in children?" *Eur J Clin Pharmacol* 2011; 67: 97-99.