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Benfluorex: adverse effects reviewed, 1976–2015



In 2016, the French Health Products Agency (ANSM) published a review of the adverse effects reported between 1976 and spring 2015 with the amphetamine *benfluorex* (1-3).

It includes in particular:

- 11 cases of pleural fibrosis, sometimes with heart valve disease or pulmonary hypertension;
- 6743 cases of heart valve disease, usually involving several valves, mainly the aortic and mitral valves, with regurgitation. 69 patients died following valve replacement surgery;
- 1273 cases of pulmonary arterial hypertension, with a median latency time from initiation of *benfluorex* to diagnosis of about 9 years.

In practice In late 2005, the ANSM reported being aware of 17 cases of pulmonary arterial hypertension and no cases of heart valve disease (4). So

many wasted years and so much preventable suffering.

All we can do in 2016 is help the victims, avoid drugs that are more dangerous than useful, and be watchful for signals of drug toxicity.

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3- ANSM "Rapport d'expertise. Suivi national de pharmacovigilance sur le risque d'hypertension artérielle pulmonaire sous benfluorex" 17 November 2015: 15 pages.

4- Prescire Editorial Staff "What matters most to the French regulatory agency: public health, or the health of drug companies?" *Prescire Int* 2005; **15** (81): 34-36.

NSAIDs in children: gastrointestinal bleeding



In 2016, an Italian team published a retrospective study on a series of 51 children hospitalised in eight paediatric units between 2005 and 2013. They had undergone gastrointestinal endoscopy for gastrointestinal bleeding associated with the use of a nonsteroidal anti-inflammatory drug (NSAID) (1). Their median age was 7.8 years (5 months to 18 years).

Ibuprofen was the NSAID most frequently implicated (69% of cases). The NSAID was used for pain in 57% of cases and for fever in 41% of cases. The median exposure to the NSAID before bleeding was 4 days. The NSAID had been used at appropriate doses in half of the cases.

33.3% of the children had haematemesis, 31.3% had abdominal pain, 25% had anaemia and 8% melaena, and 1.9% had nausea and vomiting. The children with haematemesis were younger on average than the children who had other symptoms.

On gastrointestinal endoscopy, 62% of the children were found to have gastric lesions, 33% duodenal lesions and 15% oesophageal lesions.

In practice This study shows that NSAIDs can provoke gastrointestinal bleeding in children, even when used for only a few days. *Paracetamol* is a better choice as first-line treatment for both pain and fever, in children as well as in adults, taking care not to exceed the maximum daily dose.

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