

► limb defects. Cranial nerve defects are difficult to detect by sonography, however thorough.

Note that misoprostol has a negative risk-benefit balance in the prevention and treatment of gastroduodenal ulcers in young women, and that better alternatives are available (antacids, omeprazole, etc.).

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Telithromycin: visual disorders, myasthenia

● **Case fatalities: this macrolide has a negative risk-benefit balance; its use not justified.**

After issuing an alert in the summer of 2006 concerning a risk of potentially fatal liver damage and torsades de pointes associated with telithromycin, the US Food and Drug Administration (FDA) reviewed the adverse effects of this macrolide antibiotic (1). Fifteen cases of aggravated myasthenia were reported up to October 2006. Six patients were intubated and four died (2-4).

Between April 2004 and July 2006, 390 cases of visual disorders were reported, 71 of which were severe (3). They appeared to involve accommodation problems. During a comparative study, 12 volunteers reported visual disorders while taking telithromycin, versus only one case with placebo. Ophthalmologic findings were normal.

In addition, the risk of cardiac and hepatic adverse effects was confirmed.

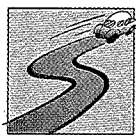
In February 2007 the FDA restricted the use of telithromycin to certain forms of pneumonia (2). The European authorities were slower to react, and the measures they took were too lenient.

It is best to simply avoid using telithromycin and to choose a macrolide with a better risk-benefit balance instead.

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Adverse drug effects: in children too

● **Despite treatment in line with the summary of product characteristics.**

A French regional pharmacovigilance centre (Caen in Normandy) has analysed adverse effects among children aged from 0 to 18 years that were reported between 2000 and 2005 (1).

During this 6-year period, 215 adverse effects affecting 126 children were reported in the region. Hospital physicians reported 65% of cases, and 35% of the children were under two years of age. Adverse effects were considered serious in 54% of cases. The reactions included a worsened condition, and neurological and cutaneous disorders. The drugs most frequently implicated were anti-infectives and vaccines (40%), drugs acting on the central nervous system (28%), metabolic agents and gastrointestinal drugs (8%).

Medication errors or off-licence use were associated with 11% of reports.

Adverse drug effects are a frequent cause of morbidity in children (2). The incidence of adverse effects in hospitalised children has been estimated at 4% to 17%, and about 2% of paediatric admissions are linked to adverse drug reactions. This is similar to the incidence reported in adults.

In summary, children, like adults, are at risk of adverse drug reactions, even when the drug is given in accordance with the summary of product characteristics.

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