

Malta, 24 April 2009
Circular No. P08/2009

To: Medical doctors and Pharmacists

Re: New advice on oral salicylate gels in under 16s

The Medicines and Healthcare Products Regulatory Agency (MHRA), UK has recommended that topical oral pain relief products containing salicylate salts should be contraindicated in children and young people under the age of 16 years. The Medicines Authority is in agreement with the MHRA's position in relation to this measure and is, therefore, issuing this circular to provide relevant information and advice to healthcare professionals.

Background

In June 2008, the British Medical Journal published a case report of a suspected case of Reye's syndrome associated with the use of an oral gel containing choline salicylate in a 20 month old child. A risk/benefit review concluded that the symptoms reported in the case report were not consistent with Reye's syndrome and were more likely to reflect salicylate toxicity. Nevertheless, the case demonstrated that significant levels of salicylate were achievable in the blood following overuse of salicylate containing oral gels.

To date, the MHRA has received three suspected serious Adverse Drug Reaction (ADR) reports in association with the use of oral salicylate gels in children. In all cases, Reye's syndrome was suspected but in none of the cases was Reye's syndrome confirmed.

Whilst acknowledging that there is only a theoretical risk of Reye's syndrome with these oral gel products, it has been concluded that they should, nevertheless, be contraindicated in children and young people under the age of 16 years. It should be emphasised that this is a precautionary measure to remove what is a theoretical risk of Reye's syndrome when such products are overused in children and young people.

Alternative Treatments

For infant teething, gentle pressure with something cool such as a chilled teething ring may be helpful in relieving teething pain. There are a number of alternative products on the market which contain a local anaesthetic/mild antiseptic which can be used for the treatment of teething pain or mouth ulcers in children and young people and which do not contain a salicylate.

Currently there is one locally authorised oromucosal gel product containing a salicylate compound: Bonjela® Oromucosal Gel.

Dr R Busuttil
Director General (PHR)