Safeguarding public health

MHRA

21st April 2009

Dear Colleague,

New advice on oral salicylate gels in under 16s

Issue

The Commission on Human Medicines (CHM) 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.

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 (April 2009), we have received a total of three suspected serious Adverse Drug Reactions (ADR) reports in association with the use of topical oral gels in children containing choline salicylate. 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, CHM concluded that they should be contraindicated in children and young people under the age of 16 years. This advice brings these products in line with other oral salicylate containing products which were contraindicated in children and young people under the age of 16 years of age in 2002. It should be emphasised that this is a precautionary measure to remove what is a theoretical risk of Reye's syndrome if these products are overused in children and young people.

Products Affected

- Bonjela
- Bonjela Cool Mint

Medicines and Healthcare products Regulatory Agency
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These two products are currently the only gels containing choline salicylate which are available for use in children and young people and are on general sale in the UK. Other Bonjela branded products are not affected as they do not contain salicylate.

- Pyralvex

This is a pharmacy only product, containing salicylic acid which is also affected. Pyralvex is an oral paint indicated for denture pain and the relief of pain associated with mouth ulcers and is currently available for children and young people over the age of 12 years. It is now recommended that this should only be used in adults and young people over the age of 16 years.

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.

For pain associated with orthodontic devices, salt water mouthwashes are recommended for sore areas. For discomfort arising from tooth movement a paracetamol based painkiller is recommended.

The communications issued to the general public will emphasise that if parents/carers or young people are in doubt over which treatment to use then they should consult their pharmacist, dentist, GP or health visitor.

Timing

We have worked closely with the company to re-design the packaging and patient information of Bonjela and Bonjela Cool Mint to reflect the above advice. The new packaging is expected to be available week commencing May 18th. In the meantime Bonjela and Bonjela Cool Mint with the older labelling will continue to be available and can be supplied for use by adults and children over the age of 16 years.

This information will be made publically available via a press release which will be embargoed until midnight on Wednesday 22nd April 2009. The information is

being provided to health care professionals in advance of the press release so that healthcare professionals are able to answer any questions that may arise.

Further information

For further information on this advice please contact the MHRA Information Centre on 020 7084 2000, email info@mhra.gsi.gov.uk, web address http://www.mhra.gov.uk.

Yours faithfully,

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