

Ulcer Gels Warning for Children

Mouth ulcer and teething treatments containing salicylate salts should not be used by children under the age of 16.

There is a theoretical risk that these products could cause a serious condition called Reye's syndrome.

But the Medicines and Healthcare products Regulatory Agency (MHRA) said the advice was only precautionary.

The main products affected are Bonjela and Bonjela Cool Mint Gel, but Bonjela Teething Gel is not affected.

Salicylate salts have the same effect on the body as aspirin, which experts have already warned should not be used by children.

The MHRA has received reports of three children being hospitalised after using oral gels containing choline salicylate.

However, Reye's syndrome was not confirmed in any of the cases.

In a further four cases children experienced vomiting or diarrhoea after using Bonjela for teething pain, but all made a full recovery.

The MHRA stressed there were a number of alternative treatments for pain associated with teething and mouth ulcers.

It advised parents to seek advice from a GP, dentist or pharmacist if unsure what to do.

Dr June Raine, MHRA director of vigilance and risk management of medicines, said the new advice brings these products into line with others containing aspirin.

She said: "Any risk from these oral gel products is theoretical. We are not aware of any confirmed cases, but when there are alternatives available, any risk is not worth taking."

Remote risk

David Pruce, of the Royal Pharmaceutical Society of Great Britain (RPSGB) stressed the risk was purely theoretical.

"There is a very remote risk for young children using this product and it is always best to err on the side of caution.

"There are other products on the market which have the same soothing effect, but which do not contain salicylate salts and are therefore safe to use on children younger than 16."

Reye's syndrome is a rare but potentially fatal disease that causes damage to many of the body's organs.

In particular it causes swelling of the brain, and problems with fat in the liver.

The initial symptoms include persistent vomiting, listlessness, loss of energy, and drowsiness.

Without treatment this can progress to extreme irritability, agitation, delirium, and coma.

Most children who have developed Reye's syndrome were recovering from a viral infection, usually either flu or chickenpox, and had taken aspirin to treat their symptoms.

A statement from Reckitt Benckiser, which makes Bonjela, said it had redesigned packaging to make it easier for consumers to choose the right gel.

Bonjela is designed to relieve the pain and swelling caused by mouth ulcers, denture sores and brace sores.

Bonjela Cool does the same thing but is formulated as a cool mint gel.

Bonjela Teething Gel for young children contains a different formula and is unaffected.