

Prescribing tip for information

Boron Excipients in Chloramphenicol eye drops: Use in Children younger than 2 years

Chloramphenicol eye drops (standard and single use) contain borax or boric acid as an excipient. A [Drug Safety Update](#) was issued on 7th July 2021 by the Medicines and Healthcare products Regulatory Agency (MHRA) regarding the use of Chloramphenicol eye drops in children younger than 2 years. Following a review of the available toxicological data and calculation of daily exposure to boron from a typical dosing regime, the MHRA have concluded that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 – 2 years. **Therefore chloramphenicol eye drops can be safely administered to children aged 0 – 2 years where antibiotic eye drop treatment is indicated.**

The MHRA's Advice for healthcare professionals:

- Some licenses for chloramphenicol eye drop products were recently updated to restrict use in children younger than 2 years of age to reflect warnings on maximum daily limits for boron exposure (due to concerns around impaired future fertility)
- The MHRA have reviewed the available evidence and sought independent expert advice to understand whether there is a risk for children aged 0 to 2 years when using these products within the licensed indication, for what is likely to be a short period of time
- The MHRA review has concluded that the benefits of chloramphenicol eye drops containing borax or boric acid outweigh the potential risks for children, including those aged 0 to 2 years
- A typical Chloramphenicol eye drop regimen of one drop, applied 3 to 4 times a day, to both eyes, would result in a daily exposure well below the safety limit for children aged 0 to 2 years (Within the [Drug Safety Update](#), see notes on dosing schedule in the section on 'Findings of review')
- Advise parents and carers that chloramphenicol eye drops remain an important medicine for children when antibiotic eye treatment is indicated and that they have been used safely for many years (see below)
- The product information for affected chloramphenicol products is being updated to reflect the [revised advice](#) and remove restrictions for use in infants. In the meantime the MHRA ask that healthcare professionals reassure parents and carers that these products can be safely given to children aged 0 to 2 years as prescribed

Advice (from MHRA) for healthcare professionals to provide to parents and carers:

- Eye infections (conjunctivitis) are very common in babies and infants and it is important they are treated properly. Chloramphenicol eye drops are an important medicine for treating bacterial eye infections in children and have been used safely for many years
- Borax or boric acid are ingredients which are included in chloramphenicol eye drops and act as buffers to make sure the medicine is not too acidic or alkaline and is comfortable when administered to the eye
- Although concerns have been raised about boron and a possible effect on future fertility, these products can be safely given to children younger than 2 years as advised by a doctor or other prescriber
- Experts have advised that the amount of liquid that can be absorbed through the eyes of young children and the way these products are prescribed mean that the daily exposure to children would be well below the calculated safety limits

This Prescribing Tip is an update on Tip No: 318, circulated on 5th May 2021 and contains revised advice issued by the MHRA. Please access the most up to date guidance on this subject. For further information please see in full the [MHRA Drug Safety Update](#) .

To contact the Medicines Optimisation Team please phone 01772 214302. If you have any suggestions for future topics to cover in our prescribing tips please contact nicola.schaffel@nhs.net