

# Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years

July 2021



Recently the licensing for Chloramphenicol eye drop products which contain borax or boric acid buffers were amended to state that, the use in children under the age of two years is contraindicated. This was in response to the advice not to exceed the maximum daily limit to boron exposure due to the risk of impaired fertility.

Following review of the evidence available and on the advice of independent experts, the MHRA has concluded that **the benefits of Chloramphenicol eye drops containing borax or boric acid buffers outweigh any potential risks to children under the age of two years.**

The MHRA has stated that:

***‘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’***

The product information for affected chloramphenicol products is being updated in response to the MHRA’s updated advice and restrictions will be removed for UK Chloramphenicol eye drop products.

Prescribers are reminded that Public Health England and NICE advise self-care as first line treatment for conjunctivitis: Bath/clean eyelids with cotton wool dipped in sterile saline or boiled (cooled) water, to remove crusting.

Where second line treatment with Chloramphenicol is indicated, healthcare professionals should reassure parents and carers that these products can be safely administered to children under two years of age as prescribed.

***The MHRA has concluded that the benefits of Chloramphenicol eye drops which contain borax or boric acid buffers in children under the age of two years outweigh any potential risks.***

***Public Health England and NICE advise self-care as first line treatment for conjunctivitis***

***Healthcare professionals should reassure parents and carers that these products can be safely given to children under two years of age as prescribed when clinically indicated***

For further information, please contact the Medicines Management Team on 01254 282000 (BwD CCG) or 01282 644799 (EL CCG)