

Safety Alert

July 2021

Restriction to use Chloramphenicol in paediatric population less than 2 years since it contains boron and may impair fertility in the future

EDA performs label update to include the following:

Posology and method of administration

Paediatric population

Chloramphenicol is not recommended to be used in children less than 2 years of age.

Contraindications

Children less than 2 years of age as this medicine contains boron which impairs fertility

Special warnings and precautions for use

Paediatric population

This medicine should not be used in children less than 2 years as this contains boron and may impair fertility in the future.

Background on the safety concerns

Chloramphenicol eye drops are indicated for the treatment of infections of the eye. Some products contain boron in the excipients (boric acid and borates), which could be associated with reproductive toxicity (based on animal studies).

Boric acid is used as an antimicrobial preservative and is used as a buffering agent to control the pH. Additionally, it can have the function as tonicity-adjusting agent.

Boron compounds are classified as toxic to reproduction. Therefore, it is considered necessary to include appropriate information in the package leaflet of boron-containing medicinal products especially for the most sensitive populations, i.e. pregnant women and children.

References:

1. HPRA ([Click here](#))
2. EMA ([Click here](#))