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**Important information for Healthcare Professionals:**

***Chloromycetin (Chloramphenicol) 0.5% w/v Redidrops Eye Drops, Solution. PA1142/021/001***

**Further revision to recommendations for use in children.**
**Change from 'Contraindication' to 'Prescribe with Caution' for children under 2 years.**

Dear Healthcare Professional,

Amdipharm Ltd. would like to inform you of the following:

- *This product contains boron (borax and boric acid) as an excipient. In December 2019, a contraindication to the use of* ***Chloromycetin 0.5% w/v Redidrops Eye Drops*** *in children under 2 years was introduced. This contraindication was introduced because the estimated exposure to boron with maximal dosing exceeded the daily safety limit of 1mg Boron per day for children in this age group (<2 years), as was outlined in the Annex to EMA's 'Excipients in the labelling and package leaflet of medicinal products for human use' ( EMA guideline on excipients). The daily safety limit for this age group is calculated conservatively using the most sensitive effect in toxicity studies in rodents, which is developmental toxicity. Dose-dependent toxicity to fertility was also reported in the adult rat studies, but the relevance for human fertility, or future human fertility in the case of children is unknown.*

- *Subsequently, there has been further consideration and revision of the EMA guideline on excipients with respect to boron.* ***The revision makes clear that even where the daily safety limit of boron is exceeded chloramphenicol eye drops can be prescribed with caution in the relevant age group.***

- *HPRA have considered the revision of the EMA guideline on excipients with respect to boron, and also other factors such as the small conjunctival sac in children under 2 years of age (meaning that exposure is likely less than estimated), the unknown relevance of the animal fertility data, and the short term nature of treatment.* ***HPRA have concluded that the balance between the benefits and risks of Chloromycetin 0.5% w/v Redidrops is positive for children aged 0 to 2 years when antibiotic topical treatment is considered necessary. Therefore the contraindication in children under 2 years has been removed from the product information, and instead the following cautions apply:***

*SmPC Section 4.4:*

*This medicine contains boron which has been shown to impair fertility in animals. While the potential for effect on fertility in humans is not known, it should be prescribed with caution to a child younger than 2 years, as the exposure to boron may exceed the daily safety limit when used in line with the maximum recommended posology in this age group.*

*Patient information leaflet: Section 2*

*This medicine should not be given to a child younger than 2 years without medical advice, as it contains boron and may impair fertility in the future.*

- *Additionally, a minor clarification has been added to dosing/posology sections of the product information (see bold text). The amended posology states that 'The recommended dosage for adults and children is two drops to be applied to the affected eye every 3 hours **during waking hours**, or more frequently if required. Treatment should be continued for at least 48 hours after the eye appears normal.'*

- *This update is consistent with advice issued by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) concerning the use of chloramphenicol eye drops in children under 2 years.*

Please ensure that all relevant staff are made aware of the content of this letter and that the information is communicated to health care professionals

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

**References:**

1. Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668)

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance. Website: www.hpra.ie.

Adverse events should also be reported to medicalinformation@advanzpharma.com.
If you have any questions, please contact Medical Information at:
Tel No.: +353 1890 25 24 73 Fax +44 (0) 20 8588 9200

Yours sincerely,
Dr. Anju Agarwal
Director, Global Patient Safety

Signature: Anju Agarwal
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