

21 October 2020

**Amdipharm Limited.**

Temple Chambers,  
3 Burlington Road,  
Dublin 4, Ireland  
Tel: 44 (0) 208 588 9396  
Email: 44 (0) 208 588 9396

**Important information for healthcare professionals  
Restriction to use in paediatric population less than 2 years**

**Chloramphenicol  
Chloromycetin 0.5% w/v Redidrops Eye Drops, Solution.**

Dear Healthcare Professional,

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

- *SmPC section 4.1, 4.2, 4.3 and 4.4 updated pertaining to the use of Chloromycetin 0.5% w/v Redidrops Eye Drops in Paediatric population.*
- *Chloromycetin 0.5% w/v Redidrops Eye Drops has been contraindicated in children less than 2 years of age since it contains boron and may impair fertility in the future.*
- *The section 6.1 of the SmPC mentions borax and boric acid as listed excipients. As per the EMA guidelines on Excipients in the labelling and package leaflet of medicinal products for human use, the MAH has updated the age group for children based on the content of boron in Chloromycetin 0.5% w/v Redidrops Eye Drops. Consequently, the Patient Information Leaflet has been updated to reflect this information.*

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).

**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](http://www.hpra.ie).

Adverse events should also be reported to [medicalinformation@advanzpharma.com](mailto: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  
Head Drug Safety

Signature: *Anju Agarwal*

Date: October 21, 2020 | 14:06 BST

**Amdipharm Limited / Suite 17 / Northwood House / Northwood Avenue / Santry / Dublin 9 / Ireland**

**T: +353 (0) 1 697 1640 / F: +353 (0) 1 697 1641 / E: [enquiries@advanzpharma.com](mailto:enquiries@advanzpharma.com)**

**[www.advanzpharma.com](http://www.advanzpharma.com)**

Company No: 364596

Registration Office: 3 Burlington Road / Dublin 4 / Ireland