Direct Healthcare Professional Communication

April 2021

Shortage of Colomycin (Colistimethate Sodium), 1 million IU, Powder for solution for injection, infusion or inhalation, in the UK: replacement with Spanish Colomycin 1 million IU vials over-labelled with the UK label during the supply shortage

Dear Healthcare Professional,

Teva UK Limited in agreement with the Medicines & Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **Due to delays in finalising the new batch release site post Brexit and delays in bulk supply of Colomycin, a shortage is anticipated in UK market of Colomycin (Colistimethate Sodium), 1million IU, Powder for solution for injection, infusion or inhalation - PL 00289/2255 from April 2021 for a period of 3 to 4 weeks.**

- **In order to mitigate the impact of this shortage, Teva has decided to import 6610 pcs (batch number: non serialised: 021466 and serialised: 021467) in the UK containing Colomycin 1 million IU from Spain. This will cover approximately one week of UK supply.**

- **The imported product vials from Spain will be over-labelled with a UK label and repacked into UK cartons with a UK Patient Information Leaflet. This product is considered licensed in the UK. You are being informed to provide assurance that the packs have not been tampered with and the over-labelling is for a short period stated in the above paragraph.**

- **The UK and Spanish vials contain the same active ingredient, Colistimethate Sodium, in the same concentration in Type I, 10 ml nominal capacity glass vial with red 'flip-off' cap supplied in cartons of ten vials.**

- **This matter does not affect the safety and efficacy of the product.**

Teva UK Limited
☐ Head office | Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX | +44 (0) 1977 628 500
☐ Eastbourne | Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG| +44 (0) 1323 501 111
✓ Harlow | Field House, Station Approach, Harlow, Essex, CM20 2FB | +44 (0) 20 7540 7000

www.tevauk.com

Further information

Colomycin is indicated for intravenous and inhalation use in adults and children including neonates;

Colomycin by intravenous administration is indicated in adults and children including neonates for the treatment of serious infections due to selected aerobic Gram-negative pathogens in patients with limited treatment options.

Colomycin by inhalation is also indicated for the management of adult and paediatric chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from https://itunes.apple.com/us/app/apple-store/id990237487?pt=117756671&ct=EYC&mt=8 Apple App Store or https://play.google.com/store/apps/details?id=uk.org.mhra.yellowcard&referrer=utm_source%3DEYC%26utm_medium%3Dcpc%26anid%3Dadmob Google Play Store, and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals.

Suspected side effects can also be reported by calling 0800 731 6789 for free. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point

All adverse events should also be reported to Teva UK Limited at: www.tevauk.com. If you have any additional questions about Colomycin, please contact Teva UK Medical Information on 0207 540 7117 or *via* email at: medinfo@tevauk.com.

Yours Sincerely,

Tahir Saleem
Senior Medical Director Cluster Lead UK & IE

Teva UK Limited
☐ Head office | Ridings Point, Whistler Drive, Castleford, West Yorkshire, WF10 5HX | +44 (0) 1977 628 500
☐ Eastbourne | Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG| +44 (0) 1323 501 111
✓ Harlow | Field House, Station Approach, Harlow, Essex, CM20 2FB | +44 (0) 20 7540 7000

www.tevauk.com