17th March 2025

Direct Healthcare Professional Communication (DHPC)

Supply termination of Promixin 1MIU Powder for Nebuliser Solution (colistimethate sodium), I-neb AAD device and I-neb consumables - advice to transition patients

Dear Healthcare Professional,

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

Summary

Despite extensive efforts, Zambon UK have been unable to secure the ongoing supply of I-nebs, discs and consumables from its external manufacturer. Additionally, supply disruptions of alternatives on the market have led to an increase in demand for Promixin, accelerating the depletion of available stock sooner than anticipated.

As a result, Zambon UK regrets to announce that **Promixin (colistimethate sodium) is due to become unavailable by May 2025.** I-nebs and consumables are also due to become unavailable.

To minimise disruption, healthcare professionals should be prepared for stock to potentially run out earlier and are **urged to support existing patients in transitioning to an alternative nebuliser and treatment.**

Background

Promixin is indicated for the management in adult and paediatric of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis.

Zambon UK offers a package service whereby the annual treatment cost of Promixin includes the supply and ongoing maintenance of the I-neb nebuliser, associated consumables and enrolment into the I-nhale Patient Support Programme.

Despite extensive efforts and due to circumstances outside of its control, Zambon UK have been unable to secure ongoing supply due to its external manufacturer ceasing the supply of I-nebs and

Zambon UK Limited
Ground Floor, Suite F, Breakspear Park,
Breakspear Way, Hemel Hempstead,
HP2 4TZ United Kingdom
Company number 04005203

T: +44 (0) 1243 859 000
infoUK@zambongroup.com

consumables. Consequently, I-nebs are no longer provided to new patients prescribed Promixin and new patient registrations for the I-nhale Patient Support Programme ceased as of 31 October 2024.

The provision of Promixin 1MIU Powder for Nebuliser Solution (colistimethate sodium), I-neb consumables and Promixin discs to existing patients is projected to continue only until May 2025.

Information for healthcare professionals

We strongly urge healthcare professionals to support patients currently prescribed Promixin and using the I-neb device in transitioning to an alternative nebuliser and treatment. Promixin can be administered via any nebuliser suitable for delivering nebulised antibiotics. Details regarding drug delivery characteristics with different nebulisers are available in the Promixin Summary of Product Characteristics.

Delays in addressing this situation could result in patients being unable to access their medication, which may have clinical consequences.

The I-nhale Patient Support Programme (provided via an external provider), including access to the I-nhale Portal, I-adhere online adherence software, and ongoing telephone and logistical support, will continue to assist registered patients and healthcare providers until December 2025.

Please ensure that all relevant staff and colleagues are made aware of the contents of this communication.

Call for reporting:

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life- threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼.

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Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card scheme. You can report via:

- The Yellow Card website- https://yellowcard.mhra.gov.uk/
- The free Yellow Card app available from the Apple Apple App Store or Google Play Store
- Some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.
When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point:

If you have any questions, please contact Zambon UK at infoUK@zambongroup.com.

Yours Sincerely,

Alex Black
Country Lead
Zambon UK Ltd

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