DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC) IN AGREEMENT WITH ITALIAN HEALTH AUTHORITY (AIFA)

08 July 2024

CHENPEN® (Adrenaline)
Information on the shortage of the medicinal product

Dear Healthcare Professional,
the MAH Bioprojet Pharma, in agreement with the Italian Health Authority (AIFA), would like to inform you on the following.

Because of a temporary interruption of production due to a delay in the Technology Transfer at the new manufacturer specialized in filling adrenaline syringes, the medicinal product Chenpen® in all authorized packaging, will be in shortage.

In particular:
- Chenpen® "150 micrograms/0,3 ml solution for injection" 1x 0,3 ml pre-filled glass syringe (MA n. 040864011) will presumably be in shortage starting from February 2025;
- Chenpen® "300 micrograms/0,3 ml solution for injection" 1x 0,3 ml pre-filled glass syringe (MA n. 040864023) will presumably be in shortage starting from the end of July 2024;
- Chenpen® "500 micrograms/0,3 ml solution for injection" 1x 0,3 ml pre-filled glass syringe (MA n. 040864050) will presumably be in shortage starting from the end of July 2024.

The return of availability of all the 3 strengths of Chenpen® on the European market is expected by the second quarter of 2025.
For any updates, please refer to the Lists of medicinal products in shortage, updated periodically and published at the following link: https://www.aifa.gov.it/farmaci-carenti

The supply shortage is not related to any quality defects of the medicinal product or safety issues.

Summary and background
Chenpen® contains adrenaline and is authorized for emergency treatment for acute allergic reactions (anaphylaxis) caused by peanuts or other foods, drugs, insect bites or stings, and other allergens as well as exercise-induced or idiopathic anaphylaxis.
Chenpen® 150 mcg and Chenpen® 300 mcg are indicated in adults and in children and the appropriate dosage changes, depending on bodyweight and doctor's clinical evaluation.
For individuals over 60 kg bodyweight, the recommended dose is 300-500 micrograms, depending on doctor’s clinical evaluation.
Chenpen® 500 mcg is not recommended in children.

It should be noted that unjustified improper use of the medicine could be unsafe. Therefore, in order to allow a correct and safe use of the medicine, compliance with the information contained in the Summary of Product Characteristics is requested.

Mitigation actions and further information for specialists
Healthcare Professionals are encouraged to ensure that patients using Chenpen® are informed of this availability issue and, in the event of use or expiration of the autoinjector in their possession, to safely transition patients to an alternative therapy.
For the 150 mcg and 300 mcg dosages, doctors are advised to use alternatives to Chenpen®, marketed in Italy. Switching from one type of medicine to another should only be carried out in consultation with a doctor and requires a close medical supervision in relation to their different use. The main risk from a safety point of view is represented by dosing errors and treatment interruptions due to the need to learn how to use a new device.
To mitigate the above risks, an accurate training to patients is required until Chenpen® becomes available again on the market.

For the 500 mcg dosage, no other autoinjectors marketed in Italy are available, therefore in this case the assessment on how to proceed must be carried out based on the clinical picture of each individual patient, by the relevant specialist doctor.

Healthcare Professionals are invited to reserve the use of auto-injectors for patients during the shortage period; therefore, in case of need, in environments where the presence of a Healthcare Professional is expected (hospitals, nursing homes, clinics, dental practices, etc.), the use of adrenaline injectable solution in vials, regularly available on the market, is strongly recommended.

Reporting of adverse reactions
Doctors and other Healthcare Professionals are required to report any suspected adverse reactions associated with the use of Chenpen. Doctors and other Healthcare Professionals, in accordance with the law, must transmit, within 2 days or within 36 hours in the case of biological medicines, to the Pharmacovigilance Manager of the healthcare facility to which they belong or, if operating in private healthcare facilities, through the Health Management, to the Pharmacovigilance Manager of the competent local health authority, the reports of suspected adverse reactions, using the appropriate forms (paper or electronic) available at the following link: https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool for confirming a positive benefit/risk ratio in real conditions of use. Reports of Suspected Adverse Drug Reactions must be sent to the Pharmacovigilance Manager of the Structure to which the Operator belongs. This Information Note is also published on the AIFA website (www.agenziafarmaco.it) whose regular consultation is recommended for the best professional information and citizen service.

Company's contact points
Further information on the temporary unavailability of medicines and medical information can be obtained by contacting Bioprojet Italia srl, via Giovanni Battista Pirelli, 11 - 20124 Milano
Tel +39 02 84254830
Email: info@bioprojet.it; Web site www.bioprojet.it
Pharmacovigilance reports: Tel +39 339 6966566 or by email to farmacovigilanza@bioprojet.it