DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC) AGREED WITH THE ITALIAN MEDICINES AGENCY (AIFA)

31/10/2023

Nadololo Cheplapharm (nadolol)

Information on out of stock

Dear Doctor,

The Italian Medicines Agency (AIFA), in agreement with CHEPLAPHARM Arzneimittel GmbH would like to inform you of the following:

Due to production problems, the medicinal product Nadololo Cheplapharm "80mg tablets" 30 tablets MA n. 041029012 is in shortage, as following:

- Hospital channel: quota distribution until 01/01/2024; starting from 02/01/2024 until to 08/03/2024 the medicinal product will presumably be totally out of stock
- Retail channel: the medicinal product will presumably be totally out of stock

Summary and background information

Nadololo Cheplapharm is authorised with the following indications:

- Hypertension: as monotherapy or in combination with other antihypertensive drugs, in the long-term treatment of essential hypertension. Nadolol is less effective in the treatment of acute hypertensive crises.
- Angina pectoris: long-term treatment of patients with angina pectoris who have not responded adequately to a conventional approach (for example, body weight control, resting, smoking cessation, sublingual nitroglycerin administration and trigger factors elimination).
- Arrhythmias: paroxysmal atrial tachycardia, paroxysmal atrial fibrillation, ventricular and supraventricular extrasystoles, cardiovascular manifestations in hyperthyroid patients, functional signs of obstructive cardiomyopathy.

Due to production problems (lack of the active substance), the medicinal product Nadololo Cheplapharm will be in shortage on the national territory, in particular:

- Hospital channel: quota distribution until 01/01/2024; starting from 02/01/2024 until to 08/03/2024 the medicinal product will presumably be totally out of stock
- Retail channel: the medicinal product will presumably be totally out of stock

The shortage of supply is not related to any defect in the quality of the medicine or safety concerns.

Your kind support is therefore requested in order to:

- inform patients already under treatment of the above;
- re-evaluate patients currently under treatment and switch to an appropriate alternative treatment;
- not prescribe Nadololo Cheplapharm to new patients;
- prescribe Nadololo Cheplapharm only if strictly necessary and if there are no valid therapeutic alternatives for the indication in question or if, for the patients in treatment, it is not possible to switch to other medicinal products; this is to ensure that the available packs, in limited quantity, are used for indications for which the medicinal product is not substitutable.

For any updates on the shortage status, please refer to the list of medicinal products in shortage, which is updated periodically and published at the following link: https://www.aifa.gov.it/farmaci-attualmente-carenti

Reporting of side effects

Side effects related to Nadololo Cheplapharm (nadolol) should be reported to CHEPLAPHARM Arzneimittel GmbH and to the Italian Medicines Agency (AIFA) via the following link: https://www.aifa.gov.it/web/guest/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 to confirm a favorable risk-benefit ratio in real conditions of use.

Reports of Suspected Adverse Reaction from medicinal products must be sent to the Pharmacovigilance Responsible of the operator's facility.

This Information Note is also published on the AIFA website (www.aifa.gov.it) whose regular consultation is recommended for the best professional information and service to the citizen.

Sincerely yours,

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