

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (SAFETY)

AGREED WITH THE ITALIAN MEDICINES AGENCY (AIFA)

15 October 2025

Nifedikor 20 mg/ml oral drops, solution (nifedipine):

modification of the dropper that varies the amount of medicine dispensed

Dear Healthcare Professional

The Marketing Authorisation Holder (MAH) Viatris Italia S.r.l., in agreement with the Italian Medicines Agency, intends to inform you of the following:

Summary:

- **following the change in the dropper, the medicine Nifedikor 20 mg/ml oral drops, solution has a new MA number 024608061, and a different drop volume.**
- **The new dropper dispenses a new volume, double the previous one, so each single drop now contains 1 mg of nifedipine.**
- **Previous dropper: Each drop contained 0.5 mg of nifedipine (20 drops = 10 mg).**
- **New dropper: Each drop contains 1 mg of nifedipine (10 drops = 10 mg).**

Following the change in the dropper, the volume of the single drop has changed. This has led to a change in the amount of active substance present in each drop, leading to a potential risk of therapeutic error.

Prescribers are advised to pay attention to the new information on dosing reported in the Summary of Product Characteristics for each indication.

Further information

Nifedikor 20 mg/ml oral drops, solution, is a nifedipine-based medicine, authorized for the following therapeutic indications:

Treatment of ischemic heart disease

- chronic-stable angina pectoris (angina from exertion)
- vasospastic angina pectoris (Prinzmetal's angina, variant angina)

Treatment of arterial hypertension

Treatment of hypertensive crises

Treatment of Raynaud's syndrome (primary and secondary)

Request for safety reports

AIFA takes this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an essential tool to confirm a favorable benefit-risk ratio in the actual conditions of use.

Reports of suspected adverse drug reactions can be made

- *by filling out the reporting form and sending it by email to the Pharmacovigilance Manager (<https://www.aifa.gov.it/responsabili-farmacovigilanza>) or alternatively to the company*
- *directly online on the AIFA website. (<https://servizionline.aifa.gov.it/schedasegnalazioni/>)*

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