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IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

20th February 2026

Noradrenaline, Mykronor 5 µg/mL, solution for injection/infusion - potential risk of medication errors

Dear Healthcare Professional,

Laboratoire Aguettant, in agreement with the Health Products Regulatory Authority would like to inform you of the following:

Summary

- **There is a potential risk of medication errors related to the use of Mykronor 5 µg/mL, solution for injection/infusion, which is less concentrated than other presentations of noradrenaline (norepinephrine).**

Background on the safety concern

- Mykronor 5 µg/mL, solution for injection/infusion, is a newly introduced noradrenaline (norepinephrine) formulation that differs significantly from most noradrenaline (norepinephrine) products currently available on the market and therefore may carry a potential risk of medication errors.
- Mykronor 5 µg/mL, solution for injection/infusion, is indicated for the restoration and maintenance of perioperative blood pressure following hypotension induced by spinal or general anaesthesia in adults and is specifically intended for use in the perioperative setting.
- Mykronor 5 µg/mL, solution for injection/infusion is not suitable for the management of acute hypotensive states, such as shocks, in the critical care setting.
- This medicinal product should not be diluted before use: it is supplied ready to use and must not be mixed with other medicines. It is suitable for injection or continuous infusion through a peripheral venous line.

- There is a potential risk of underdosing or overdosing should the incorrect strength of noradrenaline be administered, as well as a risk of serious adverse drug reactions or lack of efficacy.

- Prescribers should always specify the dosage of noradrenaline on each prescription (quantities less than 1 mg should be written in micrograms and not abbreviated to mg).

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A table detailing the different presentations of noradrenaline currently on the market is provided below:

	New Product	**Existing Product**			
Name	Mykronor 5 µg/mL, solution for injection/infusion	Noradrenaline 0.08 mg/ml solution for infusion	Noradrenaline (Norepinephrine) 1:1000 Concentrate for solution for infusion	Noradrenaline (Norepinephrine) Kabi 1 mg/ml concentrate for solution for infusion	Noradrenaline (Norepinephrine) 1 mg/ml concentrate for solution for infusion
Strength	5 µg/mL as Noradrenaline (Norepinephrine) base	Noradrenaline 0.08 mg/ml solution for infusion	1 mg/ml of noradrenaline (norepinephrine) tartrate	1 mg/ml Concentrate for solution for infusion	1 mg/ml concentrate for solution for infusion
Volume & presentation	50 ml Glass Vial	50 ml Glass Vial	Glass ampoules	Glass Ampoules	Glass Ampoules
Quantity of active substance per vial/ampoule	Each 50 ml vial contains 500µg of noradrenaline tartrate corresponding to 250µg Noradrenaline base	Each 50 ml vial contains 8 mg noradrenaline tartrate, corresponding to 4 mg noradrenaline base	Each 2 ml ampoule contains 4 mg of norepinephrine tartrate equivalent to 2 mg norepinephrine base.	Each 1 ml of concentrate for solution for infusion contains 1 mg noradrenaline (norepinephrine) base equivalent to 2 mg noradrenaline (norepinephrine) tartrate.	Each ampoule containing 2 ml of concentrate for solution for infusion contains noradrenaline tartrate equivalent to 2 mg noradrenaline.
Indication	Restoration and maintenance of **perioperative** blood pressure following hypotension induced by spinal or general anaesthesia in adults.	Noradrenaline (Norepinephrine) is indicated in adults weighing over 50 kg for the treatment of hypotensive emergencies.	Norepinephrine 1:1000 is recommended for use as an emergency measure in the restoration of blood pressure in cases of acute hypotension.	Noradrenaline (Norepinephrine) Kabi is indicated in adults for use as an emergency measure in the restoration of blood pressure in cases of acute hypotension.	Noradrenaline (Norepinephrine) 1 mg/ml concentrate for solution for infusion is recommended in adults for use as an emergency measure in the restoration of blood pressure in cases of acute hypotension.
Dilution	Ready to use (should NOT be diluted before use)	Ready to use (should NOT be diluted before use)	Dilution is required before use	Dilution is required before use	Dilution is required before use

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Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare Professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Adverse reactions should also be reported to the distributor of this product, namely Aguettant Ltd on +353 (0)1 431 1350

Company contact details

If you have any questions or require further information, please contact the distributor of this product, namely Aguettant Ltd by phone on +353 (0)1 431 1350 or via email at info@aguettant.co.uk

Guillaume Sabatier
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DocuSigned by:
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