Noradrenaline (Norepinephrine) 0.08 mg/ml (4 mg in 50 ml) solution for infusion in a vial and potential risk of medication errors

January 2019

Dear Healthcare Professional,

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

Summary

Laboratoire Aguettant received marketing approval for a new Noradrenaline product: namely Noradrenaline (base) 0.08 mg/ml solution for infusion (equivalent to Noradrenaline Tartrate 0.16mg/ml) presented in a 50 ml vial.

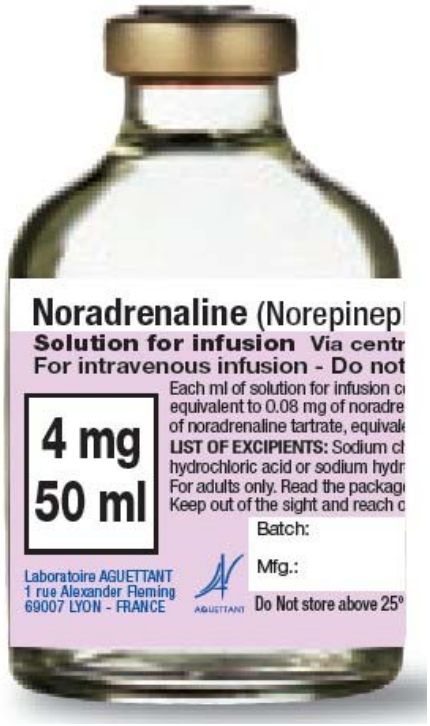
This product differs from existing Noradrenaline products in both strength and presentation.

There is a potential risk of medication errors should healthcare professionals not recognise these new features.

	NEW PRODUCT **NORADRENALINE (NOREPINEPHRINE) SOLUTION FOR INFUSION** **0.08 MG/ML (AS BASE)**	**EXISTING PRODUCTS** **NORADRENALINE (NOREPINEPHRINE) CONCENTRATE FOR SOLUTION FOR INFUSION** **1MG/ML (AS BASE)**
Presentation	50 ml Glass Vial (4 mg in 50 ml as base)	Glass Ampoules (typically 2 ml)
Strength	0.08 mg/ml as Noradrenaline (Norepinephrine) base	1 mg/ml as Noradrenaline (Norepinephrine) base
Dilution to provide 0.08 mg/ml as base	**Ready to use (should NOT be diluted before use)**	**Dilution required before use**

- Failure to differentiate the ready to use Noradrenaline 0.08 mg/ml solution for infusion from the concentrates requiring dilution before use could lead to inappropriate dilution of Noradrenaline 0.08 mg/ml solution for infusion.
- Inadvertent dilution of Noradrenaline 0.08 mg/ml solution for infusion **could lead to under-dosing of the patient** and persistent life-threatening hypotension.

Further information on the safety concern

Noradrenaline (Norepinephrine) **0.08 mg/ml** (4 mg in 50 ml) solution for infusion in a vial
Each 50 ml vial contains 4 mg Noradrenaline base.


Noradrenaline 0.08 mg/ml solution for infusion is indicated in adults weighing over 50kg for the on-going treatment of hypotensive emergencies with escalating noradrenaline dose requirements.

It should not be used for initiating vasopressor treatment. It may be considered for use in patients already established on noradrenaline therapy whose dose requirements are clinically confirmed to be escalating, such that Noradrenaline 0.08 mg/ml solution for infusion may be commenced at a flow rate of 2 ml/hour.

Blood pressure should be monitored carefully for the duration of therapy and preferably controlled by arterial blood pressure monitoring.

Noradrenaline should only be administered as an intravenous infusion via a central venous catheter to minimise the risk of extravasation and subsequent tissue necrosis. Noradrenaline 0.08 mg/ml solution for infusion should be infused at a controlled rate using a syringe driver pump.

Noradrenaline 0.08 mg/ml solution for infusion is not approved for use in children.

Please read the enclosed Summary of Product Characteristics for full details.

Reporting of suspected adverse reactions

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 the national reporting system:

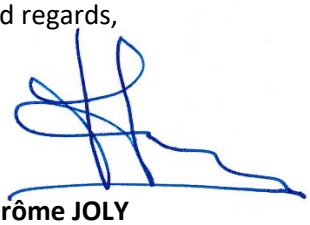
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

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 question 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

Kind regards,



Jérôme JOLY
Global Qualified Person and Quality Director
Laboratoire Aguettant

Annie-Claude BENICHOU
Global QPPV
Laboratoire Aguettant