

**Direct Healthcare Professional Communication on the association of
Noradrenaline (Norepinephrine) 0.08 mg/ml (4 mg in 50 ml)
solution for infusion in a vial
with potential risk of medication errors**

November 2017

Dear Healthcare Professional,

Summary

In June 2015 Ague ttant Ltd 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.

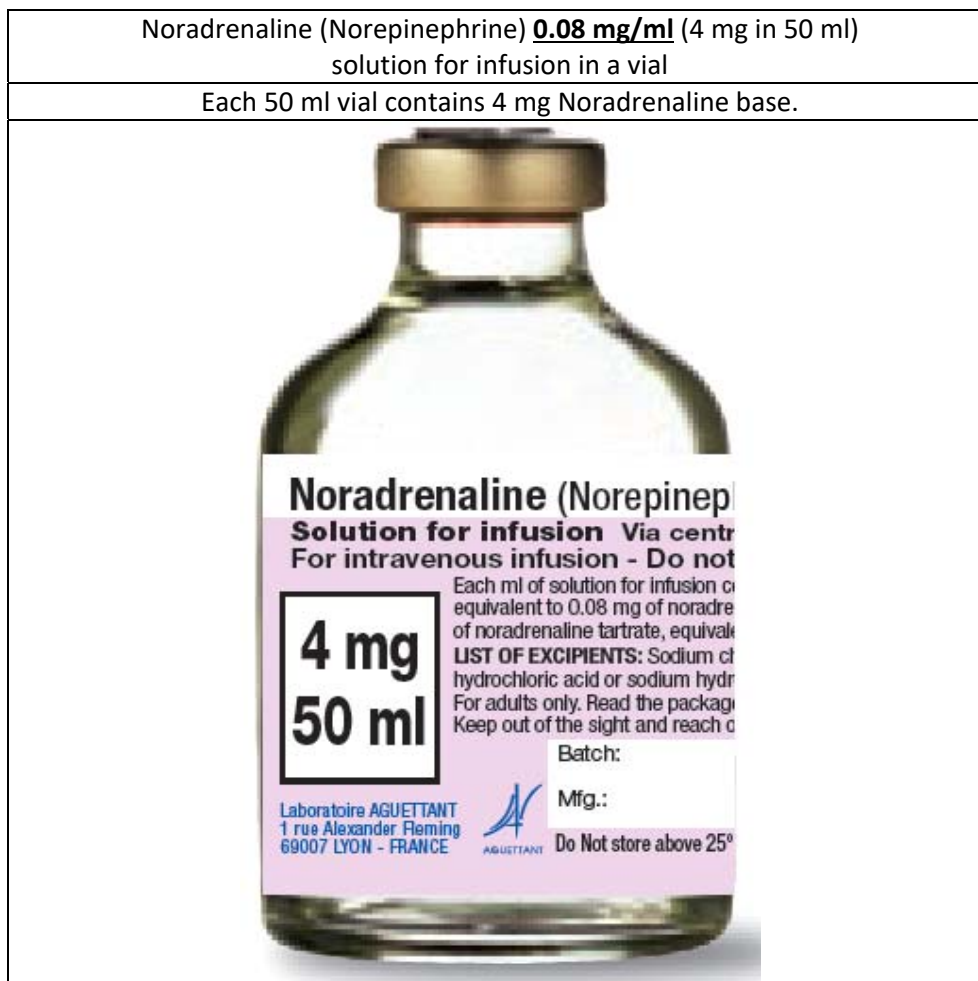
	Noradrenaline 0.08 mg/ml solution for infusion (New Product)	Noradrenaline Concentrate for solution for infusion (Existing Products)
Presentation	50 ml Glass Vial (4 mg in 50 ml as base)	Glass Ampoule in various sizes
Strength	0.08 mg/ml as Noradrenaline base	Typically 1 mg/ml as Noradrenaline base
Dilution to provide 0.08 mg/ml as base	Ready to use (should NOT be diluted before use)	Dilution required before use

- Failure to distinguish 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.

Aguettant Ltd

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Registered in England 4966231 VAT 832649416 WL 20825/1

Further information on the safety concern



Noradrenaline 0.08 mg/ml solution for infusion is indicated in adults weighing over 50kg for the ongoing 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.

Call for reporting

Please report suspected adverse drug reactions including medication errors and inadequate therapeutic effect to the MHRA through the Yellow Card Scheme.

Please report:

- All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- All suspected ADRs associated with new drugs and vaccines identified by the black triangle.

The easiest and quickest way to report ADRs is online via the Yellow Cards website –

<https://yellowcard.mhra.gov.uk/> .

Alternatively, prepaid Yellow Cards for reporting are available:

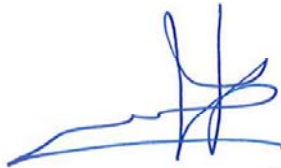
- By writing to FREEPOST YELLOW CARD (no other address details necessary)
- By emailing yellowcard@mhra.gsi.gov.uk
- At the back of the British National Formulary (BNF)
- By telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- Or by downloading and printing a form from the website <https://yellowcard.mhra.gov.uk/>

Adverse reactions should also be reported to Aguettant Ltd on 01275 463 691.

Company contact details

If you have any questions please contact Aguettant Ltd by phone on 01275 463 691 or via email at info@aguettant.co.uk

Kind regards,



Jérôme JOLY

Global Qualified Person and Quality Director



Annie-Claude BENICHOU

Global QPPV

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