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Athlone Laboratories
Ballymurray
Co. Roscommon
Ireland
F42 EW02

11th November 2022

Important Information for Healthcare Professionals

New Method of Administration

Phenylephrine Hydrochloride 10 mg/ml Solution for Injection or Infusion

PA0298/027/001

Dear Sir/Madam,

Athlone Laboratories in agreement with the Health Products Regulatory Authority (HPRA) would like to inform you about a number of key differences between our product and alternative authorised products to ensure the safe use of the product for your patients.

The key differences are highlighted in bold in the table below.

Product name	Phenylephrine **Hydrochloride 10mg/mL** Solution for Injection of Infusion	Phenylephrine 100 micrograms/mL solution for injection/infusion	Phenylephrine 50 micrograms/mL**,** solution for injection in pre-filled syringe
Marketing Authorisation Holder	Athlone Laboratories	Laboratoire Aguettant	Laboratoire Aguettant
Indications	For the treatment of hypotensive states during spinal anaesthesia or **drug-induced hypotension**	Treatment of hypotension during spinal, epidural or general anaesthesia.	Treatment of hypotension during spinal, epidural or general anaesthesia.
Method of administration	For **subcutaneous, intramuscular** or intravenous bolus injection, or intravenous infusion.	Intravenous bolus injection or intravenous infusion.	Intravenous bolus injection

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Dosing units	phenylephrine **hydrochloride**	phenylephrine	phenylephrine
Adults Intravenous bolus injection dose:	**100 to 500** micrograms by slow intravenous injection as a 0.1% solution, repeated as necessary after at least 15 minutes.	50 to 100 micrograms, which can be repeated until the desired effect is obtained. One bolus dose should not exceed 100 micrograms.	50 to 100 micrograms, which can be repeated until the desired effect is obtained. One bolus dose should not exceed 100 micrograms.
Adults Continuous infusion:	**180** micrograms per minute, reduced according to response to **30-60** micrograms per minute.	Initial dose is 25 to 50 micrograms/min. Doses can be increased up to 100 micrograms/min or reduced in order to maintain systolic blood pressure close to the normal value. Doses between 25 and 100 micrograms/min have been considered effective.	

Each 1 mL ampoule of Phenylephrine Hydrochloride 10 mg/ml Solution for Injection or Infusion from Athlone Laboratories contains 10 mg phenylephrine hydrochloride (equivalent to 8.2 mg phenylephrine) and requires dilution prior to intravenous administration as per the Summary of Product Characteristics.

Dosing of this medicinal product is given in units of phenylephrine hydrochloride rather than in units of phenylephrine which differs from other similar authorised products. Recommended intravenous dosing regimens also vary between formulations.

Please take special note of the presentation and concentration of the product and adjust your administration practices accordingly.

If you require any further information, please do not hesitate to contact our medical information department as the following contacts:

Phone: 090 666 1109
Email: medical@kent-athlone.com

Yours sincerely,

DocuSigned by:
Yvonne Wilkinson
EF106A5FAFDB462...

Yvonne Wilkinson Ph.D

Head of Regulatory
Kent-Athlone Group

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