

Phenylephrine BNM

Ready to use solution for injection against acute hypotension in the setting of spinal anaesthesia

Minimum Product Information Phenylephrine BNM (phenylephrine hydrochloride) 0.1mg/mL (0.01 %) Solution for injection

Indication: Indicated for the maintenance of an adequate level of blood pressure during spinal and inhalation anaesthesia. It is also employed to overcome paroxysmal supraventricular tachycardia. Contraindications: Patients with severe hypertension, ventricular tachycardia. In patients who are hypersensitive to it. Precautions: Should be employed only with extreme caution in patients with hyperthyroidism, bradycardia, partial heart block, myocardial disease, or severe arteriosclerosis. If used in conjunction with oxytocic medicines, the pressor effect of sympathomimetic pressor amines is potentiated. Therefore, if vasopressor drugs are used to correct hypotension, the obstetrician should be cautioned that some oxytocic drugs may cause severe persistent hypertension and that even a rupture of a cerebral blood vessel may occur during the postpartum period. Phenylephrine hydrochloride should be employed only with extreme caution in elderly patients. The safety and efficacy in children have not been established. No data are available. Phenylephrine hydrochloride should be given to a pregnant woman only if clearly needed. It is not known whether this medicine is excreted in human milk. Because many medicines are excreted in human milk, caution should be exercised when phenylephrine hydrochloride is administered to a nursing woman. Interactions: Halothane anaesthesia, oxytocic medicines, monoamine oxidase inhibitors (MAOI), tricyclic antidepressants. Adverse Effects: Headache, reflex bradycardia, excitability, restlessness, and rarely arrhythmias. Dosage and Administration: Phenylephrine BNM solution for injection 0.1mg/mL (0.01 %) is for slow intravenous injection. Phenylephrine BNM is not for subcutaneous or intramuscular administration. It should only be administered by healthcare professionals with appropriate training and relevant experience. Mild or moderate hypotension:

References

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- Kol IO, et al. The Effects of Intravenous Ephedrine During Spinal Anesthesia for Cesarean Delivery: A Randomized Controlled Trial. J Korean Med Sci. 2009;24(5):883-8.
- Chooi C, et al. Techniques for preventing hypotension during spinal anaesthesia for caesarean section. Cochrane Database Syst Rev. 2017;8:CD002251.
- 5. Kinsella SM, et al. International consensus statement on the management of hypotension with vasopressors during caesarean section under spinal anaesthesia. Anaesthesia. 2018 Jan;73(1):71-92.
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Usual dose, 0.2mg. Range, from 0.1mg to 0.5mg. Initial dose should not exceed 0.5mg. Injections should not be repeated more often than every 10 to 15 minutes. A 0.5mg intravenous dose should elevate blood pressure for about 15 minutes. Spinal anaesthesia - hypotension: For hypotensive emergencies during spinal anaesthesia, phenylephrine hydrochloride may be injected intravenously, using an initial dose of 0.2mg. Any subsequent dose should not exceed the previous dose by more than 0.1mg to 0.2mg and no more than 0.5mg should be administered in a single dose. Paroxysmal supraventricular tachycardia: Rapid intravenous injection (within 20 to 30 seconds) is recommended. The initial dose should not exceed 0.5mg, and subsequent doses, which are determined by the initial blood pressure response, should not exceed the preceding dose by more than 0.1mg to 0.2mg, and should never exceed 1mg. Schedule of medicine: Schedule 4 - Prescription Only Medicine. Sponsor: Boucher & Muir Pty Ltd (a member of the Advanz Pharma group of companies), Level 9, 76 Berry Street, North Sydney, NSW 2060. Product information is available on request from Boucher & Muir Pty Ltd. Date: Prepared November 2018 based on full Product Information (PI) dated 04 October 2018 [Con/PHL/PI/0002]

Adverse events should be reported to the local regulatory authority. Reporting forms and information can be found at <u>https://www.tga.gov.au/</u>. Adverse events should also be reported to Boucher & Muir Pty Ltd (a member of the Advanz Pharma group of companies) Medical Information via telephone on 02 9431 6333 or via e-mail at <u>medinfo.au@advanzpharma.com</u>

- Lin FQ, et al. Ephedrine versus phenylephrine for the management of hypotension during spinal anesthesia for cesarean section: an updated meta-analysis. CNS Neurosci Ther. 2012;18(7):591-7.
- Veeser M, et al. Vasopressors for the management of hypotension after spinal anesthesia for elective caesarean section. Systematic review and cumulative metaanalysis. Acta Anaesthesiol Scand. 2012;56(7):810-6.
- Tanaka M, Balki M, Parkes RK, Carvalho JCA. ED95 of phenylephrine to prevent spinal-induced hypotension and/or nausea at elective cesarean delivery. International Journal of Obstetric Anesthesia 2009; 18: 125–30.
- Van De Velde M, et al. Recommendations and guidelines for obstetric anesthesia in Belgium. Acta Anaesthesiol Belg. 2013;64(3):97-104.
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