NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Phenylephrine-AFT 10 mg/mL solution for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 10 mg Phenylephrine Hydrochloride in 1 mL (1%) solution for injection. It is for use in one patient on one occasion only. Discard any residue.

Excipients with known effects: Sodium metabisulfite

For the full list of excipients, see Section 6.1 List of excipients.

3. PHARMACEUTICAL FORM

Solution for injection.

Phenylephrine -AFT, is a clear, colourless, sterile, nonpyrogenic solution for intravenous use. It must be diluted before administration as an intravenous bolus injection or continuous intravenous infusion, is supplied as 1 mL vials containing 10 mg/1 mL Phenylephrine hydrochloride.

It has a pH of between 4.5 and 5.0. Phenylephrine -AFT contains no antimicrobial preservative.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Phenylephrine -AFT is indicated for the maintenance of an adequate level of blood pressure during spinal and inhalation anaesthesia and for the treatment of vascular failure in shock, shock-like states, and drug-induced hypotension, or hypersensitivity. It is also employed to overcome paroxysmal supraventricular tachycardia, to prolong spinal anaesthesia, and as a vasoconstrictor in regional analgesia.

4.2 Dose and method of administration

Method of administration

Phenylephrine hydrochloride is generally injected subcutaneously, intramuscularly, slowly intravenously, or in dilute solution as a continuous intravenous infusion. In patients with paroxysmal supraventricular tachycardia and, if indicated, in case of emergency, phenylephrine hydrochloride is administered directly intravenously. The dose should be adjusted according to the pressor response.

Dosage Calculations	
Dose Required	**Use Phenylephrine AFT (1%)**

10 mg	1 mL
5 mg	0.5 mL
1 mg	0.1 mL

For convenience in intermittent intravenous administration, dilute 1 mL Phenylephrine AFT (1%) with 9 mL Sterile Water for Injection, to yield 0.1% phenylephrine hydrochloride.

Dose Required	**Use Diluted Phenylephrine AFT (0.1%)**
0.1 mg	0.1 mL
0.2 mg	0.2 mL
0.5 mg	0.5 mL

Dose

Mild or Moderate Hypotension:

Subcutaneously or Intramuscularly:

Usual dose, from 2 mg to 5 mg. Range, from 1 mg to 10 mg. Initial dose should not exceed 5 mg.

Intravenously:

Usual dose, 0.2 mg. Range, from 0.1 mg to 0.5 mg. Initial dose should not exceed 0.5 mg.

Injections should not be repeated more often than every 10 to 15 minutes. A 5 mg intramuscular dose should raise blood pressure for one to two hours. A 0.5 mg intravenous dose should elevate the pressure for about 15 minutes.

Severe Hypotension and Shock - Including Medicine-Related Hypotension:

Blood volume depletion should always be corrected as fully as possible before any vasopressor is administered. When, as an emergency measure, intra-aortic pressures must be maintained to prevent cerebral or coronary artery ischemia, phenylephrine hydrochloride can be administered before and concurrently with blood volume replacement.

Hypotension and occasionally severe shock may result from overdosage or idiosyncrasy following the administration of certain drugs, especially adrenergic and ganglion blocking agents, rauwolfia and veratrum alkaloids, and phenothiazine tranquilizers. Patients who receive a phenothiazine derivative as preoperative medication are especially susceptible to these reactions. As an adjunct in the management of such episodes, phenylephrine hydrochloride is a suitable agent for restoring blood pressure.

Higher initial and maintenance doses of phenylephrine hydrochloride are required in patients with persistent or untreated severe hypotension or shock. Hypotension produced by powerful peripheral

adrenergic blocking agents, chlorpromazine, or phaeochromocytomectomy may also require more intensive therapy.

Continuous Infusion:

Add 10 mg of the drug (1 mL of 1 % solution) to 500 mL of dextrose 5% injection, or sodium chloride 0.9% injection (providing a 1:50,000 solution equivalent to 20 micrograms per mL). To raise the blood pressure rapidly, start the infusion at about 100 micrograms to 180 micrograms per minute (based on 20 drops per mL this would be 100 to 180 drops per minute). When the blood pressure is stabilised (at a low normal level for the individual), a maintenance rate of 40 micrograms to 60 micrograms per minute usually suffices (based on 20 drops per mL this would be 40 to 60 drops per minute). If the drop size of the infusion system varies from the 20 drops per mL, the dose must be adjusted accordingly.

If a prompt initial pressor response is not obtained, additional increments of phenylephrine hydrochloride (10 mg or more) are added to the infusion bottle. The rate of flow is then adjusted until the desired blood pressure level is obtained. (In some cases, a more potent vasopressor, such as norepinephrine bitartrate, may be required.) Hypertension should be avoided. The blood pressure should be checked frequently. Headache and/or bradycardia may indicate hypertension. Arrhythmias are rare.

Spinal Anaesthesia-Hypotension:

Routine parenteral use of phenylephrine hydrochloride has been recommended for the prophylaxis and treatment of hypotension during spinal anaesthesia. It is best administered subcutaneously or intramuscularly three or four minutes before injection of the spinal anaesthetic. The total requirement for high anaesthetic levels is usually 3 mg, and for lower levels, 2 mg. For hypotensive emergencies during spinal anaesthesia, phenylephrine hydrochloride may be injected intravenously, using an initial dose of 0.2 mg. Any subsequent dose should not exceed the previous dose by more than 0.1 mg to 0.2 mg and no more than 0.5 mg should be administered in a single dose. To combat hypotension during spinal anaesthesia in children, a dose of 0.5 mg to 1 mg per 25 pounds (approx. 11 kg) body weight, administered subcutaneously or intramuscularly, is recommended.

Prolongation of Spinal Anaesthesia:

The addition of 2 mg to 5 mg of phenylephrine hydrochloride to the anaesthetic solution increases the duration of motor block by as much as approximately 50 percent without any increase in the incidence of complications such as nausea, vomiting, or blood pressure disturbances.

Vasoconstrictor for Regional Analgesia:

Concentrations about ten times those employed when adrenaline is used as a vasoconstrictor are recommended. The optimum strength is 1:20,000 (equivalent to 50 micrograms per mL) made by adding 1 mg of phenylephrine hydrochloride to every 20 mL of local anaesthetic solution. Some pressor responses can be expected when 2 mg or more are injected.

Paroxysmal Supraventricular Tachycardia:

Rapid intravenous injection (within 20 to 30 seconds) is recommended; the initial dose should not exceed 0.5 mg, and subsequent doses, which are determined by the initial blood pressure response, should not exceed the preceding dose by more than 0.1 mg to 0.2 mg, and should never exceed 1 mg.

Paediatric use

To combat hypotension during spinal anaesthesia in children, a dose of 0.5 mg to 1 mg per 25 pounds (approx. 11 kg) body weight, administered subcutaneously or intramuscularly, is recommended.

For storage conditions after dilution of the medicine, see section 6.3.

4.3 Contraindications

Phenylephrine hydrochloride should not be used in patients with severe hypertension, ventricular tachycardia, or in patients who are hypersensitive to it.

4.4 Special warnings and precautions for use

If used in conjunction with oxytocic medicines, the pressor effect of sympathomimetic pressor amines is potentiated (see section 4.5). The obstetrician should be warned 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.

Contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

General

Phenylephrine hydrochloride should be employed only with extreme caution in elderly patients or in patients with hyperthyroidism, bradycardia, partial heart block, myocardial disease, or severe arteriosclerosis.

Use in Labour and Delivery

If vasopressor drugs are either used to correct hypotension or added to the local anaesthetic solution, 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.

4.5 Interaction with other medicines and other forms of interaction

Vasopressors, particularly metaraminol, may cause serious cardiac arrhythmias during halothane anaesthesia and therefore should be used only with great caution or not at all.

Oxytocic medicines: The pressor effect of sympathomimetic pressor amines is potentiated (see section 4.4 Special warnings and precautions for use).

MAO Inhibitors: The pressor effect of sympathomimetic pressor amines is markedly potentiated in patients receiving monoamine oxidase inhibitors (MAOI). Therefore, when initiating pressor therapy in these patients, the initial dose should be small and used with due caution. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants.

4.6 Fertility, pregnancy, and lactation

Effects on fertility

No data available.

Use in pregnancy

Animal reproduction studies have not been conducted with phenylephrine hydrochloride. It is also not known whether phenylephrine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Phenylephrine hydrochloride should be given to a pregnant woman only if clearly needed.

Use in lactation

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.

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Headache, reflex bradycardia, excitability, restlessness, and rarely arrhythmias.

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose

Overdosage may induce ventricular extrasystoles and short paroxysms of ventricular tachycardia, a sensation of fullness in the head and tingling of the extremities.

Should an excessive elevation of blood pressure occur, it may be immediately relieved by an α-adrenergic blocking agent, e.g., phentolamine.

The oral LD50 in the rat is 350 mg/kg, in the mouse 120 mg/kg.

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Mechanism of action

Phenylephrine hydrochloride injection is a vasoconstrictor and pressor drug chemically related to adrenaline and ephedrine.

Phenylephrine hydrochloride produces vasoconstriction that lasts longer than that of adrenaline and ephedrine. Responses are more sustained than those to adrenaline, lasting 20 minutes after intravenous and as long as 50 minutes after subcutaneous injection. Its action on the heart contrasts sharply with that of adrenaline and ephedrine, in that it slows the heart rate and increases the stroke output producing no disturbance in the rhythm of the pulse.

Phenylephrine hydrochloride is a powerful postsynaptic alpha-receptor stimulant with little effect on the beta-receptors of the heart. In therapeutic doses, it produces little if any stimulation of either the spinal cord or cerebrum. A singular advantage of this drug is the fact that repeated injections produce comparable effects.

The predominant actions of phenylephrine hydrochloride are on the cardiovascular system. Parenteral administration causes a rise in systolic and diastolic pressures in man and other species. Accompanying the pressor response to phenylephrine hydrochloride is a marked reflex bradycardia that can be blocked by atropine; after atropine, large doses of phenylephrine hydrochloride increase the heart rate only slightly. In man, cardiac output is slightly decreased, and peripheral resistance is considerably increased. Circulation time is slightly prolonged, and venous pressure is slightly increased; venous constriction is not marked. Most vascular beds are constricted; renal splanchnic, cutaneous, and limb blood flows are reduced but coronary blood flow is increased. Pulmonary vessels are constricted, and pulmonary arterial pressure is raised.

The drug is a powerful vasoconstrictor, with properties very similar to those of norepinephrine but almost completely lacking the chronotropic and inotropic actions on the heart. Cardiac irregularities are seen only very rarely even with large doses.

5.2 Pharmacokinetic properties

Absorption

No data available.

Distribution

No data available.

Metabolism

No data available.

Excretion

No data available.

5.3 Preclinical safety data

Genotoxicity/ Carcinogenicity

No long-term animal studies have been done to evaluate the potential of phenylephrine hydrochloride in these areas.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Sodium chloride
- Sodium citrate dihydrate
- Citric acid monohydrate
- Sodium metabisulfite
- Sodium hydroxide
- Hydrochloric acid
- Water for injection

6.2 Incompatibilities

No data available.

6.3 Shelf life

24 Months

To reduce microbiological hazard, use as soon as practicable after dilution in 5 % glucose or 0.9 % sodium chloride. If storage is necessary, hold at 2-8 °C for not more than 24 hours.

6.4 Special precautions for storage

Store below 25°C.

For storage conditions after dilution of the medicine, see section 6.3.

6.5 Nature and contents of container

Phenylephrine -AFT contains 10 mg/1 mL phenylephrine hydrochloride and is available in 2-mL type I

clear glass vial with rubber stopper and aluminium-plastic overseal.

Pack size: Cartons contain 10 vials.

6.6 Special precautions for disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine.

8. SPONSOR

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9. DATE OF FIRST APPROVAL

25 June 2026

10. DATE OF REVISION OF THE TEXT

24 November 2025