

SUMMARY OF PRODUCT CHARACTERISTICS

1. PRODUCT NAME

Phenylephrine Altan 10 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 10 mg phenylephrine hydrochloride.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Colourless, clear, solution for injection/infusion.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of hypotensive states, e.g. septic shock, circulatory failure, during spinal anaesthesia or drug-induced hypotension.

4.2 Posology and method of administration

Administer by subcutaneous, intramuscular, slow IV injection or IV infusion.

Whenever solution and container permit, parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration.

Adults

Phenylephrine Altan 10 mg/ml can be administered subcutaneously or intramuscularly at 2-5 mg doses with additional 1-10 mg doses, if necessary depending on the response, or in 100-500 microgram doses by slow intravenous injection 0.1% solution, repeated as necessary after at least 15 minutes.

Alternatively, dilute the content of a 10-mg ampoule in 500 ml, 5% glucose solution for injection or 0.9% sodium chloride solution for injection; then, infuse it intravenously, initially at 180 micrograms per minute max. rate, reducing it according to response to 30-60 micrograms per minute.

Children

100 micrograms/kg body weight by subcutaneous or intramuscular route.

Elderly

Dosage in elderly does not require any changes

4.3 Contraindications

- Hypersensitivity to phenylephrine, or to any of the excipients.

- Patients on treatment with non-selective monoamine-oxidase inhibitors (MAOIs) or 14 days after discontinuing treatment with this medicinal product due to the risk of paroxysmal hypertension and potentially fatal hyperthermia (see section 4.5).
- Severe hypertension or peripheral vascular disease, due to the risk of ischaemic gangrene or vascular thrombosis.
- Severe hyperthyroidism.

4.4 Special warnings and precautions for use

Blood pressure should be monitored during treatment.

Phenylephrine should be administered with caution to patients with:

- diabetes mellitus;
- high blood pressure;
- uncontrolled hyperthyroidism
- coronary heart disease and chronic heart conditions;
- non-severe peripheral vascular disease;
- bradycardia;
- partial heart block;
- tachycardia;
- arrhythmias;
- angina pectoris (phenylephrine may trigger or exacerbate angina in patients with coronary artery disease and a history of angina);
- aneurysm;
- angle-closure glaucoma.

Phenylephrine may cause a reduction in cardiac output. It should therefore be administered with extreme caution to patients with arteriosclerosis, elderly patients and patients with impaired cerebral or coronary circulation.

In patients with reduced cardiac output or coronary artery disease, vital organ function should be closely monitored, and a reduction in dose should be considered when systemic blood pressure approaches the lower end of the target range.

In patients with severe heart failure or cardiogenic shock, phenylephrine may cause a worsening of heart failure as a result of the induced vasoconstriction (increased afterload).

Special care must be taken when administering the phenylephrine injection to avoid extravasation, as this can cause tissue necrosis.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated combinations (see section 4.3)

- Non-selective monoamine oxidase inhibitors (MAO)

Paroxysmal hypertension, potentially life-threatening hyperthermia. Due to the long duration of action of MAOIs, this interaction remains possible 15 days after discontinuing the MAOI.

Combinations to be avoided (see section 4.4)

- Dopaminergic ergot alkaloids (bromocriptine, cabergoline, lisuride, pergolide):

Risk of vasoconstriction and/or hypertensive emergency.

Vasoconstrictive ergot alkaloids (dihydroergotamine, ergotamine, methylergometrine, methylergide):
Risk of vasoconstriction and/or hypertensive emergency.

- Tricyclic antidepressants (e.g. imipramine):

Paroxysmal hypertension with a risk of arrhythmias (inhibition of the entry of adrenaline or noradrenaline into the sympathetic fibres).

- Noradrenergic-serotonergic antidepressants (milnacipran, venlafaxine):

Paroxysmal hypertension with a risk of arrhythmias (inhibition of the entry of adrenaline or noradrenaline into the sympathetic fibres).

- Selective type A MAO inhibitors

Risk of vasoconstriction and/or hypertensive emergency.

- Linezolid:

Risk of vasoconstriction and/or hypertensive emergency.

- Guanethidine and related products:

A substantial increase in blood pressure (hyperreactivity linked to a reduction in sympathetic tone and/or inhibition of the uptake of adrenaline or noradrenaline in the sympathetic fibres). If this combination cannot be avoided, use lower doses of sympathomimetic agents with caution.

- Cardiac glycosides, quinidine:

Increased risk of arrhythmias.

- Sibutramine:

Paroxysmal hypertension with a risk of arrhythmias (inhibition of the entry of adrenaline or noradrenaline into the sympathetic fibres).

- Halogenated volatile anaesthetics (desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane):

Risk of perioperative hypertensive crisis and arrhythmia.

Combinations requiring precautions for use:

- Oxytocic agents:

The effect of presynaptic sympathomimetic amines is enhanced. Consequently, some oxytocic agents can cause severe, persistent hypertension, and strokes may occur during the postpartum period.

4.6 Pregnancy, labor, lactation and fertility

The safety of phenylephrine during pregnancy and lactation has not been established.

The most common maternal adverse reactions reported in published studies of phenylephrine use during neuraxial anesthesia during Cesarean delivery include nausea and vomiting, bradycardia, reactive hypertension, and transient arrhythmias. Phenylephrine, when administered during labor or delivery, does not appear to alter either neonatal Apgar scores or umbilical artery blood-gas status.

Excretion of phenylephrine hydrochloride into breast milk appears to be minimal.

Fertility

No data are available regarding fertility following exposure to phenylephrine (see section 5.3).

4.7 Effects on ability to drive and use machines

Adverse effects on ability to drive and use machines are not known.

4.8 Undesirable effects

Adverse reactions may be classified per frequency as follows: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1.000$ to $< 1/100$); rare ($\geq 1/10.000$ to $< 1/1.000$); very rare ($< 1/10.000$), not known (frequency cannot be estimated from the available data).

The most common side effects of phenylephrine are bradycardia, episodes of high blood pressure, nausea and vomiting, with high blood pressure the most common at high doses.

The most commonly reported cardiovascular adverse effect appears to be bradycardia, likely due to baroreceptor-mediated vagal stimulation and consistent with the pharmacological effect of phenylephrine.

The following adverse reactions have been reported during the use of phenylephrine,; however, its frequency has not been established accurately:

Cardiac disorders

Unknown: reflex bradycardia (slow heart rate), reflex tachycardia (fast heart rate), cardiac arrhythmias (irregular heart rate), angina-like pain, palpitations, cardiac arrest.

Vascular disorders

Unknown: hypertensive crises (high blood pressure), hypotension (low blood pressure), flushing (reddening of the skin).

Nervous system disorders:

Unknown: headache, cerebral haemorrhage, vertigo, fainting, lethargy (mental or physical inactivity), insomnia, paraesthesia (abnormal skin sensation), tremor (involuntary shaking of the body or limbs).

Respiratory, thoracic and mediastinal disorders:

Unknown: dyspnoea (breathing difficulties), pulmonary oedema (swelling of the lungs).

Gastrointestinal disorders:

Unknown: nausea, vomiting, hypersalivation.

Renal and urinary disorders:

Unknown: difficulty urinating, urinary retention.

Skin and subcutaneous tissue disorders:

Unknown: sweating, transient tingling, cold sensation on the skin, pallor or blanching of the skin, goosebumps, skin necrosis with extravasation.

Metabolism and nutrition disorders:

Unknown: abnormalities in glucose metabolism.

General disorders and alterations at the administration site:

Unknown: extravasation of phenylephrine hydrochloride can cause tissue necrosis (tissue death).

Immune system disorders:

Unknown: hypersensitivity.

Psychiatric disorders:

Unknown: anxiety, irritability, agitation, psychotic states, confusion.

Eye disorders:

Unknown: mydriasis, exacerbation of pre-existing angle-closure glaucoma.

Musculoskeletal and connective tissue disorders:

Unknown: muscle weakness.

Description of selected adverse reactions

Given that phenylephrine has frequently been used in critical care settings in patients with hypotension and shock, some of the serious adverse events and deaths reported are likely to be related to the underlying condition rather than to the use of phenylephrine.

Other special populations

Elderly patients: the risk of phenylephrine toxicity is increased in elderly patients (see section 4.4).

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il>

4.9 Overdose

Overdose symptoms include headache, vomiting, hypertension and reflex bradycardia, and other cardiac arrhythmias.

Treatment should consist of symptomatic and supportive measures. Hypertensive effects can be treated with a α -adrenergic receptor blocking drug, such as phentolamine, 5-60 mg intravenously for 10-30 minutes, repeating if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: Cardiac stimulants excluding cardiac glycosides; adrenergic and dopaminergic agents.

ATC Code: C01CA06.

Phenylephrine is a potent vasoconstrictor that acts almost exclusively by stimulating alpha-1-adrenergic receptors. Such arterial vasoconstriction is also accompanied by venous vasoconstriction. This increases blood pressure and causes reflex bradycardia. Severe arterial vasoconstriction increases systemic vascular resistance (increased afterload). The overall result is a reduction in cardiac output. This is less pronounced in healthy people, but it can become more severe in cases of pre-existing heart failure. As the effects of phenylephrine are linked to its pharmacological properties, they can be counteracted by known antidotes.

5.2 Pharmacokinetic properties

When administered subcutaneously or intramuscularly, phenylephrine action takes 10 to 15 minutes. Subcutaneous and intramuscular injections are effective for about an hour and two hours respectively. Intravenous injections are effective for about 20 minutes.

Phenylephrine is metabolised in the liver by monoamine oxidase. Metabolites, route and rate of excretion have not been identified.

5.3 Preclinical safety data

Data on safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and reproductive toxicity is not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid (for pH adjustment).

Sodium hydroxide (for pH adjustment.)

Water for injections

6.2 Incompatibilities

Phenylephrine Altan 10 mg/ml is incompatible with alkalis, ferric salts, sodium phenytoin and oxidising agents.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

After dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (20-25°C).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Store below 25°C. Store in the outer package in order to protect from light.

This product is only for a single use.

6.5 Nature and contents of container

Amber-coloured type I glass ampoules.

Each pack contains 10 ampoules of 1 ml.

6.6 Special precautions for disposal and other handling

Phenylephrine Altan 10 mg/ml solution for injection/infusion can be diluted with the following solutions: Glucose 5%, sodium chloride 0.9%.

Any unused medicinal product or material that had been in contact with it, should be disposed of in

accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Propharm Ltd.
P.O.Box 4046, Ben-Gurion 23,
Zichron Yaacov, 30900

8. MARKETING AUTHORISATION NUMBER

162-16-35141-00

9. MANUFACTURER

Altan Pharmaceuticals S.A., Avda. de la Constitucion 198-199, Poligono Industrial Monte Boyal,
45950 Casarrubios del Monte (Toledo), Spain.

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