SUMMARY OF PRODUCT CHARACTERISTICS

1. PRODUCT NAME

Phenylephrine Altan 10 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains: phenylephrine hydrochloride 10 mg. 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 monoamine-oxidase inhibitors or 14 days after discontinuing treatment with this medicinal product.
- Severe hypertension.
- Hyperthyroidism.

4.4 Special warnings and precautions for use

Special caution should be exercised when administering Phenylephrine Altan 10 mg/ml to patients with pre-existing cardiovascular disease such as ischemic heart disease, arrhythmias, occlusive vascular disease including arteriosclerosis, hypertension or aneurysms. Angina patients can experience angina pain.

Caution should also be taken when Phenylephrine Altan 10 mg/ml is administered to patients with diabetes mellitus or angle-closure glaucoma.

4.5 Interaction with other medicinal products and other forms of interaction

Phenylephrine may interact with cyclopropane and halothane and other halogenated inhalation anaesthetics, and may induce ventricular fibrillation. An increased risk of arrhythmias may also occur if Phenylephrine Altan 10 mg/ml is given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

Phenylephrine can increase blood pressure and therefore reverse the action of many antihypertensive agents. Interaction of phenylephrine hydrochloride with α- and β-receptor-blocking drugs can be complex.

4.6 Pregnancy, labor and lactation

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.

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 (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1.000 to < 1/100); rare (≥ 1/10.000 to < 1/1.000); very rare (< 1/10.000), not known (frequency cannot be estimated from the available data).

Some side effects have been observed during treatment with Phenylephrine; however, its frequency has not been established accurately:

Cardiac disorders
Reflex bradycardia, reflex tachycardia, cardiac arrhythmias, angina pain, palpitations, cardiac arrest.

Vascular disorders
Hypertension, hypotension, flushing

Nervous system disorders:
Headache, cerebral haemorrhage, vertigo, fainting, dullness.
Phenylephrine lacks significant stimulant effects on the central nervous system at the usual doses.

Respiratory, thoracic and mediastinal disorders:
Dyspnoea, pulmonary oedema.

Gastrointestinal disorders:
Vomiting, sialorrhea.

Renal and urinary disorders:
Difficulty urinating, urinary retention.

Skin and subcutaneous tissue disorders:
Sweating, transient tingling, cold sensation on the skin.

Metabolism and nutrition disorders:
Alterations in glucose metabolism.

General disorders and alterations at the administration site:
Extravasation of phenylephrine hydrochloride can cause tissue necrosis.

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 hydrochloride is a sympathomimetic agent with direct effects mainly on adrenergic receptors. It has a predominantly α-adrenergic activity and lacks significant stimulant effects on the central nervous system at usual doses. After injection, it produces peripheral vasoconstriction and increased blood pressure. It also causes reflex bradycardia.

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 metabolized 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 oxidizing 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 AUTHORIZATION 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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