SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Phenylephrine 10 mg/ml Solution for Injection or Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenylephrine hydrochloride Ph Eur 1.0% w/v

Each 1 ml ampoule contains 10 mg phenylephrine.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection, or concentrate for solution for injection or infusion.

Clear, colourless, sterile, solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For subcutaneous, intramuscular or slow intravenous injection or by intravenous infusion.

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

Adults

Phenylephrine injection may be administered subcutaneously or intramuscularly in a dosage of 2 to 5 mg with further doses of 1 to 10 mg if necessary according to response, or in a dose of 100 to 500 micrograms by slow intravenous injection as a 0.1% solution, repeated as necessary after at least 15 minutes.

Alternatively, 10 mg in 500 ml of glucose 5% injection or sodium chloride 0.9% injection may be infused intravenously, initially at a rate of up to 180 micrograms per minute, reduced according to response to 30-60 micrograms per minute.

Children

100 micrograms/kg bodyweight subcutaneously or intramuscularly.

Elderly

There is no need for dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to phenylephrine or to any of the excipients listed in section 6.1.
Patients taking monoamine oxidase inhibitors, or within 14 days of ceasing such treatment.
Severe hypertension and hyperthyroidism.
Avoid in patients with prostatic enlargement.

4.4 Special warnings and precautions for use

Great care should be exercised in administering Phenylephrine Injection to patients with pre-existing cardiovascular disease such as ischaemic heart disease, arrhythmias,occlusive vascular disease including arteriosclerosis, hypertension or aneurysms.
Anginal pain may be precipitated in patients with angina pectoris.

Care is also required when given to patients with diabetes mellitus.

Phenylephrine is not recommended in subjects with a shallow anterior chamber or a history of acute narrow angle glaucoma. Use of Phenylephrine 10 mg/ml Injection in patients with shallow anterior chamber, a history of acute narrow angle glaucoma and/or insufficient pupil dilation can increase the risk of both iridocele and floppy iris syndrome.

Keep all medicines out of the reach of children.

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Phenylephrine may interact with cyclopropane and halothane and other halogenated inhalational anaesthetics, to induce ventricular fibrillation.

An increased risk of arrhythmias may also occur if phenylephrine injection is given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

Phenylephrine is a hypertensive agent and may consequently reverse the action of many antihypertensive drugs. Interactions of phenylephrine with alpha and beta receptor blocking drugs may be complex.

Drugs which have an effect on α_1- adrenoreceptors could potentiate (suchas clonidine) or inhibit (such as doxazosin) the vasopressive action of phenylephrine.

Caution should be applied when administering atomoxetine concurrently, as there is potential for synergistic pharmacological effects.

Severe hypertension may occur following the use of phenylephrine and atropine orother antimuscarinics.

The pressor effects of phenylephrine may be slightly reduced by lithium carbonate.

The effects of phenylephrine may be potentiated by the use of monoamine oxidase inhibitors or reversible inhibitors of monoamine oxidase.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of phenylephrine during pregnancy has not been established.Due to the vasoconstrictive properties of phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Administration of phenylephrine in late pregnancy or labour may cause foetal hypoxia and bradycardia.

Breast-feeding

The safety of phenylephrine during lactation has not been established. Excretion of phenylephrine in breast milk appears to be minimal.

Fertility

No data available

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

A tabulated list of undesirable effects is outlined below:

The undesirable effects are listed according to organ systems and following frequency:

Not known (cannot be estimated from the available data)

Immune system disorders

Hypersensitivity

Metabolism and nutrition disorders

Metabolic disorders

Psychiatric disorders

Nervousness, insomnia

Nervous system disorders

Headache, cerebral haemorrhage, paraesthesia

Eye disorders

Mydriasis, angle-closure glaucoma

Cardiac disorders

Pulmonary oedema, bradycardia, tachycardia, arrhythmia, angina pectoris, palpitations, cardiac arrest

Vascular disorders

Hypotension, dizziness, syncope, flushing

Respiratory, thoracic and mediastinal disorders

Dyspnoea

Gastrointestinal disorders

Vomiting, salivary hypersecretion

Renal and urinary disorders

Dysuria, urinary retention

General disorders and administration site conditions

Extravasation, infusion site necrosis, hyperhidrosis

Investigations

Increased blood pressure, abnormal blood glucose

Phenylephrine is without significant stimulating effects on the central nervoussystem at usual doses.

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 balanceof the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Symptoms of overdosage include headache, vomiting, hypertension and reflex bradycardia and other cardiac arrhythmias. In severe cases confusion, hallucinationsand seizures may occur.

Management

Treatment should consist of symptomatic and supportive measures. The hypertensive effects may be treated with an alpha-adrenoceptor blocking drug, such as phentolamine, 5 to 60 mg i.v. over 10-30 minutes, repeated as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Adrenergic and dopaminergic agents.

ATC code: C01C A06

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. After injection it produces peripheral vasoconstriction and increased arterial pressure. It also causes reflex bradycardia.

5.2 Pharmacokinetic properties

When injected subcutaneously or intramuscularly, phenylephrine takes 10 to 15 minutes to act. Subcutaneous and intramuscular injections are effective for up to about one and up to two hours respectively. Intravenous injections are effective for up to about 20 minutes. Phenylephrine is metabolised in the liver by monoamine oxidase. The metabolites, their route and rate of excretion have not been identified.

5.3 Preclinical safety data

Phenylephrine has been used to induce cardiac myocyte hypertrophy in cultures of rat neonatal mycocytes at doses of 100 µM and 10 µM. To the best of our knowledge there have been no human studies associating therapeutic phenylephrine use with the development of cardiac myocyte hypertrophy.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N/1 Sodium Hydroxide

N/1 Hydrochloric Acid

Water for Injections Ph Eur

6.2 Incompatibilities

Phenylephrine Injection has been stated to be incompatible with alkalis, ferric salts, phenytoin sodium and oxidising agents.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Keep out of sight and reach of children.

Store below 25°C. Store in the original package.

6.5 Nature and contents of container

1 ml neutral glass ampoule with ceramic break ring.

Pack size: 10 ampoules

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Kent Pharma UK Limited,
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1, Dover Place, Ashford, Kent,
England,
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8 MARKETING AUTHORISATION NUMBER(S)

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