PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

PL 18157/0223

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted Beacon Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Phenylephrine 10mg/ml Solution for Injection or Infusion (PL 18157/0223) on 3rd March 2011. This is a prescription-only medicine (POM) and is used to treat low blood pressure, which may be caused by circulatory failure, spinal anaesthesia or certain medicines.

Phenylephrine 10mg/ml Solution for Injection or Infusion contains the active ingredient phenylephrine hydrochloride, which belongs to a group of medicines known as adrenergic cardiac stimulants. It raises blood pressure by constricting blood vessels.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Phenylephrine 10mg/ml Solution for Injection or Infusion outweigh the risks; hence a Marketing Authorisation has been granted.
PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a Marketing Authorisation for the medicinal product Phenylephrine 10mg/ml Solution for Injection or Infusion (PL 18157/0223) to Beacon Pharmaceuticals Limited on 3rd March 2011. This product is a prescription-only medicine.

This application was submitted as an abridged application according to Article 10(1) of Directive 2001/83/EC. The application refers to the innovator product, Phenylephrine Injection BP 10 mg/ml, licensed to Knoll Pharma Limited, on the 1st April 1993 (PL 13530/0045). The licence subsequently underwent a change of ownership on 17th November 1999 and is currently licensed to Waymade plc. The reference product has been authorised in the EEA for over 10 years.

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.

The pharmacovigilance system, as described by the MAH, fulfils the requirements and provides adequate evidence that the MAH has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The MAH has provided adequate justification for not submitting a Risk Management Plan (RMP). As the application is for a generic version of an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active is well established.

No new pre-clinical or clinical studies were performed, which is acceptable given that the proposed product is a generic medicinal product of the reference product that has been licensed for over 10 years.

No new or unexpected safety concerns arose during the review of information provided by the Marketing Authorisation Holder (MAH) and it was, therefore, judged that the benefits of taking product Phenylephrine 10mg/ml Solution for Injection or Infusion outweigh the risks; hence a Marketing Authorisation has been granted.
**PHARMACEUTICAL ASSESSMENT**

**DRUG SUBSTANCE**

**Phenylephrine Hydrochloride**

INN: Phenylephrine hydrochloride

Chemical name: (1R0-1-(3-Hydroxyphenyl)-2-(methylamino)ethanol hydrochloride

Structure:

```
   O
  / \  
N   O
   \  
   CH₃ , HCl
```

Molecular mass: 203.7

Molecular formula: C₉H₁₃NO₂.HCl

**General Properties**

Description: White or almost white crystalline powder.

Solubility: Freely soluble in water and in ethanol.

Phenylephrine hydrochloride is the subject of a European Pharmacopoeia monograph (Ph Eur).

**Manufacture**

All aspects of the manufacture and control of the active substance phenylephrine hydrochloride are covered by a European Directorate for the Quality of Medicines (EDQM) Certificate of Suitability.

**DRUG PRODUCT**

**Description and Composition**

Phenylephrine 10mg/ml Solution for Injection or Infusion is presented as a clear colourless sterile solution. Each 1ml ampoule contains 10mg of phenylephrine.

Other ingredients consist of pharmaceutical excipients, namely N/1 sodium hydroxide (for pH adjustment), N/1 hydrochloride (pH adjustment) acid and water for injections. Appropriate justification for the inclusion of each excipient has been provided. All excipients used comply with their relevant European Pharmacopoeia (Ph. Eur) monographs. Satisfactory Certificates of Analysis have been provided for all excipients.

The applicant has provided a declaration confirming that there are no materials of human or animal origin contained in or used in the manufacturing process of the proposed product. None of the excipients are sourced from genetically modified organisms.
**Pharmaceutical Development**  
Suitable pharmaceutical development data have been provided for this application.

The physico-chemical properties of the drug product have been compared with the originator product. These data demonstrate that the proposed product can be considered a generic medicinal product to Phenylephrine Injection BP 10mg/ml (Wayamde PLC).

Compatibility studies have been carried with water for injection, 0.9% isotonic saline solution and 5% glucose solution. Dilution studies show that the product is chemically stable.

**Manufacture**  
A description and flow-chart of the manufacturing method has been provided.

In-process controls were considered appropriate considering the nature of the product and the method of manufacture. Process validation studies have been conducted and are accepted.

**Finished Product Specification**  
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Satisfactory batch analysis data are provided and comply with the release specification. Certificates of Analysis have been provided for any reference standards used.

**Container Closure System**  
The finished product is licensed for marketing in 1ml neutral Type I glass ampoules with a snap-off neck. Each 1ml ampoule contains phenylephrine hydrochloride equivalent to 10mg phenylephrine.

The ampoules are packaged with the patient information leaflet into outer cardboard cartons. Ampoule sizes of 1ml are available in packs of 10 ampoules.

Satisfactory specifications and Certificates of Analysis for all packaging components used have been provided. All primary product packaging complies with EU legislation, Directive 2002/72/EC (as amended), and is suitable for parenteral preparations.

**Stability**  
Finished product stability studies have been conducted in accordance with current guidelines and results were within the proposed specification limits. Based on the results, a shelf-life of 36 months has been set, which is satisfactory. Storage conditions are ‘Keep out of sight and reach of children’ and ‘Store below 25°C’ and ‘Store in original package’.

**Bioequivalence Study**  
Bioequivalence studies are not necessary to support this application for a parenteral product.
Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels
The approved SmPCs, PILs and labelling are pharmaceutically acceptable. Mock-ups of the package leaflet and labelling have been provided.

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

Expert Report
The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical dossier. The CV of the expert has been provided.

Conclusion
It is recommended that a Marketing Authorisation is granted for this application.
PRECLINICAL ASSESSMENT

This application was submitted as an abridged, standard application, according to Article 10.1 of Directive 2001/83/EC, as amended.

The pharmacodynamic, pharmacokinetic and toxicological properties of phenylephrine hydrochloride are well-known. Therefore, no further studies are required and the applicant has provided none.

The pre-clinical overview was written by a suitably qualified person and is satisfactory. The *curriculum vitae* of the expert has been provided.

A suitable justification has been provided for the non-submission of an environmental risk assessment.
CLINICAL ASSESSMENT

Pharmacokinetics
No new data have been submitted and none are required for an application of this type.

Phenylephrine 10mg/ml Solution for Injection or Infusion is a generic version of Phenylephrine Injection BP 10 mg/ml, Waymade Plc, UK (PL 06464/0902). The use of the reference product is well-established in the UK. Both products contain the same quantitative and qualitative composition of the active ingredient, phenylephrine. Thus, in accordance with the “Guideline on the Investigation of Bioequivalence” (CPMP/EWP/QWP/1401/98 rev.1/Corr*), the applicant is not required to submit a bioequivalence study, if the product is to be administered as an aqueous intravenous solution containing the same active substance, in the same concentration as the currently authorised product.

Pharmacodynamics
No new data have been submitted and none are required for an application of this type.

Clinical efficacy
No new data have been submitted and none are required for an application of this type.

Clinical safety
No new safety data have been submitted or required for this generic application. As phenylephrine is a well-known product with an acceptable adverse event profile, this is satisfactory.

Expert Report
A satisfactory clinical overview is provided, and has been prepared by an appropriately qualified physician. The curriculum vitae of the expert has been provided.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), Labels
The SmPC and PIL are medically acceptable, and consistent with those for the reference product. The labelling is medically acceptable and in-line with current requirements.

MAA form
The MAA form is medically satisfactory.

Conclusion
There are no objections to approval of Phenylephrine 10mg/ml Solution for Injection or Infusion from a clinical point of view.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The important quality characteristics of Phenylephrine 10mg/ml Solution for Injection or Infusion are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

EFFICACY
The applicant’s Phenylephrine 10mg/ml Solution for Injection or Infusion has been demonstrated to be a generic version of the reference product, Phenylephrine Injection BP 10 mg/ml, initially licensed to Knoll Pharma Limited on the 1st April 1993 (PL 13530/0045) and subsequently underwent a change of ownership on 17th November 1999 and is currently licensed to Waymade plc (PL 06464/0902).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The SmPC and PIL are acceptable, and consistent with those for the reference product. The labelling is acceptable and in-line with current requirements.

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

BENEFIT/RISK ASSESSMENT
The quality of the product is acceptable, and no new preclinical or clinical safety concerns have been identified. The qualitative and quantitative assessment supports the claim that the applicant’s Phenylephrine 10mg/ml Solution for Injection or Infusion and the reference product Phenylephrine Injection BP 10 mg/ml (Waymade plc) are interchangeable.

Extensive clinical experience with phenylephrine hydrochloride is considered to have demonstrated the therapeutic value of the active substance. The benefit:risk is, therefore, considered to be positive.
PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

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STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the marketing authorisation application on 16th February 2009.</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 20th February 2009.</td>
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<td>Following assessment of the applications the MHRA requested further information relating to the quality dossiers on 26th August 2009 and 14th January 2011.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 23rd March 2010 and 14th February 2011.</td>
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<td>The application was determined on 3rd March 2011.</td>
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STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

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SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Phenylephrine 10mg/ml Solution for Injection or Infusion (PL 18157/0223) is as follows:

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.
Patients taking monoamine oxidase inhibitors, or within 14 days of ceasing such treatment.
Severe hypertension and hyperthyroidism.

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 or closed-angle glaucoma. Keep all medicines out of the reach of children.

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 may increase blood pressure and consequently reverse the action of many antihypertensive agents. Interactions of phenylephrine with alpha and beta receptor blocking drugs may be complex. Drugs which have an effect on α₁-adrenoreceptors could potentiate (such as ganisetron) or inhibit (such as doxazosin or buspirone) the vasopressive action of phenylephrine.

4.6 Pregnancy and lactation
The safety of phenylephrine during pregnancy and lactation has not been established. Administration of phenylephrine in late pregnancy or labour may cause foetal hypoxia and bradycardia. Excretion of phenylephrine in breast milk appears to be minimal.

4.7 Effects on ability to drive and use machines
No adverse effects known.

4.8 Undesirable effects
Extravasation of Phenylephrine injection may cause tissue necrosis. Phenylephrine will cause a rise in blood pressure with headache and vomiting and this may produce cerebral haemorrhage and pulmonary oedema. There may also be a reflex bradycardia or tachycardia, other cardiac arrhythmias, anginal pain, palpitations and cardiac arrest, hypotension with dizziness, and fainting and flushing may occur. Phenylephrine may induce difficulty in micturition and urinary retention, mydriasis, dyspnoea, altered metabolism including disturbances of glucose metabolism, sweating, hypersalivation, transient tingling and coolness of the skin and temporary fullness of the head. Phenylephrine is without significant stimulating effects on the central nervous system at usual doses.

4.9 Overdose
Symptoms of overdosage include headache, vomiting, hypertension and reflex bradycardia and other cardiac arrhythmias. 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 myocytes 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 breakring.
Pack size: 10 ampoules

6.6 Special precautions for disposal
Not applicable.

7 MARKETING AUTHORISATION HOLDER
Beacon Pharmaceuticals Ltd.
85, High Street, Tunbridge Wells
Kent TN1 1YG, UK

8 MARKETING AUTHORISATION NUMBER(S)
PL 18157/0223

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
03/03/2011

10 DATE OF REVISION OF THE TEXT
03/03/2011
PATIENT INFORMATION LEAFLET

PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION
(Referred to as Phenytoin Injection in this leaflet)

Read all of this leaflet carefully before you are given this medicine:
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or nurse.
• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:
1. What Phenytoin Injection is and what it is used for
2. Before you are given Phenytoin Injection
3. How Phenytoin Injection will be given
4. Possible side effects
5. How to store Phenytoin Injection
6. Further information

1. WHAT PHENYLEPHRINE INJECTION IS AND WHAT IT IS USED FOR

Phenytoin Injection contains phenylephrine hydrochloride, which belongs to a group of medicines known as adrenergic cardiotonic agents. It raises blood pressure by constricting blood vessels.

Phenytoin Injection is used to treat low blood pressure, which may be caused by circulatory failure, spinal anaesthesia or certain medicines.

2. BEFORE YOU ARE GIVEN PHENYLEPHRINE INJECTION

You should NOT be given Phenytoin Injection if any of the following apply to you:
• you are allergic (hypersensitive) to phenylephrine hydrochloride or any of the other ingredients listed in section 6
• you suffer from high blood pressure
• you have an overactive thyroid
• you are taking Monoamine Oxidase Inhibitors (MAOIs) used to treat depression, or have taken them in the last 14 days.

Special care should be taken with Phenytoin Injection if any of the following apply to you:
• Tell your doctor if you have:
  • any heart problems or disease, including arrhythmias or angina
  • a disease of your blood vessels, such as arteriosclerosis or aneurysms
  • diabetes mellitus
  • closed-angle glaucoma (increased pressure in the eye)
  • you are pregnant or breast-feeding.

Taking other medicines
Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, tell your doctor or nurse if you are taking any of the following:
• anaesthetics given as a gas that you inhale, such as cyclopropane or halothane
• tricyclic antidepressants
• medicines used to treat heart conditions including cardiac glycosides or quinidine
• medicines used to treat high blood pressure
• medicines known as alpha blockers (used to treat Raynaud's syndrome or tumour of the adrenal gland) or beta blockers (used to treat heart conditions or reduce blood pressure)
• gabapentin used to prevent nausea and vomiting
• oxycodone used to treat high blood pressure or symptoms of an enlarged prostate
• buspirone used to treat anxiety.

Pregnancy and breast-feeding
Tell your doctor or nurse if you are pregnant or breast-feeding.

The safety of phenylephrine during pregnancy and breast-feeding has not been established. Giving phenylephrine in late pregnancy or labour may reduce the foetal heart rate and oxygen levels.

Continued overleaf....
3. HOW PHENYLEPHRINE INJECTION WILL BE GIVEN

You will normally be given Phenylephrine injection in a hospital or clinic.
Phenylephrine injection can be given by an injection under the skin, into a muscle, or
injected into veins. Phenylephrine can also be given by slow injection or infusion
(drip) into a vein.

Dose for adults, including the elderly:
When given under the skin or into a muscle, the usual dose is 2 to 6 mg with further doses
of 1 to 10 mg if necessary.
When given as a drip solution by slow injection into a vein the dose is 100 to 500
micrograms, repeated as necessary after at least 10 minutes.
Alternatively, it may be infused as a diluted solution into a vein (drip) and the dose
adjusted according to the response.

Dose for children:
The usual dose is 100 micrograms/kg bodyweight given as an injection under the
skin or into a muscle.

If you are given more Phenylephrine injection than you should
As you will be given Phenylephrine injection in a hospital or clinic by a qualified healthcare
provider, this will be unlikely. If you have any further questions on the use of
this product, ask your doctor or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Phenylephrine injection can cause side effects, although not everybody
gets them.

Tell your doctor or nurse if you have any of the following side effects:
- a change in your heart rate (speeding up
- slowing down or cessation, palpitations)
- an irregular heartbeat (tachycardia)
- chest pain or pain due to angina
- an increase in blood pressure with headache
- and vomiting, which may cause bleeding in
- the brain or fluid on the lungs
- a decrease in blood pressure with dizziness
- difficulty in passing urine or urine retention
- fainting or flushing
- difficulty breathing
- excessive dilation of the pupil
- tissue damage at the site of the injection.

Other side effects
- sweating
- excessive production of saliva
- a feeling of fullness in the head
- tingling or numbness of the skin
- altered metabolism including glucose
- metabolism.

If any of the side effects gets worse or you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. HOW TO STORE PHENYLEPHRINE INJECTION

Keep out of the reach and sight of children. Store below 25°C. Store in the original
package. Do not use after the expiry date, which is stated on the carton and ampoule.

6. FURTHER INFORMATION

What Phenylephrine injection contains
- Each 1ml ampoule contains 10mg of the
active substance phenylephrine hydrochloride
- The other ingredients are sodium hydroxide,
hydrochloric acid and water for injections.

What Phenylephrine injection looks like and content of the pack
Phenylephrine injection is a clear, colourless
sterile solution in a glass ampoule, available in
packs of 10 ampoules.

Marketing Authorisation Holder
Beacon Pharmaceuticals Ltd., Tunbridge Wells, Kent TN1 1YS

Manufacturer
Labana Pharmaceuticals S.L.U., 08210-
Beceite de Vallès, Barcelona, Spain.

This leaflet was last approved in MMMYYY

Children:
100 micrograms/kg bodyweight
subcutaneously or intramuscularly.

Elderly:
There’s no need for dosage reduction in the
elderly.

Pharmacokinetic properties
When injected subcutaneously or
intramuscularly, phenylephrine takes 10 to 15
minutes to act. Intravenous injections are
effective for up to about 20 minutes, whereas
subcutaneous injections are effective for up to
one hour and intramuscular injections for up to
two hours.

Incompatibilities
Phenylephrine injection has been stated to be
incompatible with alkalis, fienic salts,
phenylant sodium and oxidising agents.

For full prescribing information please refer to the Summary of Product
Characteristics.
PHENYLEPHRINE 10MG/ML SOLUTION FOR INJECTION OR INFUSION

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LABEL

Phenylephrine 10mg/ml Solution for Injection or Infusion
For sc, im, iv injection or infusion

10mg in 1ml

Batch Exp.