

## **Package leaflet: Information for the patient**

### **Phenylephrine Unimedic 10 mg/ml, concentrate for solution for injection/infusion**

phenylephrine

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Phenylephrine Unimedic is and what it is used for
2. What you need to know before you use Phenylephrine Unimedic
3. How to use Phenylephrine Unimedic
4. Possible side effects
5. How to store Phenylephrine Unimedic
6. Contents of the pack and other information

#### **1. What Phenylephrine Unimedic is and what it is used for**

This drug belongs to a group called adrenergic or dopaminergic agents. Phenylephrine Unimedic is used to treat low blood pressure that can occur during different types of anesthesia.

#### **2. What you need to know before you use Phenylephrine Unimedic**

##### **Do not use Phenylephrine Unimedic if:**

- you are allergic (hypersensitive) to phenylephrine or any of the other ingredients of this medicine (listed in section 6).
- you suffer from hypertension (increased blood pressure)
- you are suffering from a peripheral vascular disease (poor blood circulation)
- you take a non-selective monoamine oxidase inhibitor (MAOI) (or within 2 weeks of their withdrawal) for treatment of depression (iproniazide, nialamide).
- you suffer from a severe overactive thyroid gland (hyperthyroidism)

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before using Phenylephrine Unimedic;

- if you are elderly
- if you have an overactive thyroid gland
- if you suffer from heart problems as a slow pulse, heart block (partial), heart muscle disease, poor blood circulation in the heart, non-severe peripheral vascular insufficiency, heart rhythm disorders, tachycardia (high heart rate), bradycardia (low heart rate), angina pectoris
- if you have poor blood circulation in the brain
- if you have atherosclerosis (hardening and thickening of the blood vessel walls)
- if you have diabetes mellitus
- if you are treated with oxytocin as the effect on the blood vessels can be enhanced and cause very high blood pressure and stroke in the period immediately after childbirth

- if you suffer from arterial hypertension
- if you suffer from a closed angle glaucoma

In patients with serious heart failure phenylephrine may worsen the heart failure as a consequence of blood vessel constriction.

The blood pressure in your arteries will be monitored during treatment. If you have heart disease, additional monitoring of vital functions will be performed.

### **Children**

The medicine is not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations.

### **Other medicines and Phenylephrine Unimedic**

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Do not use Phenylephrine Unimedic with:

- iproniazide, nialamide (for depression)

The following medicines may affect or be affected by concomitant use:

- dihydroergotamine, ergotamine, methylergometrine, methysergide (for migraine)
- linezolid (an antibiotic)
- bromocriptine, cabergoline, lisuride, pergolide (for Parkinson's disease)
- desipramine, imipramine, nortriptyline, moclobemide, toloxatone, minalcipram, venlafaxine (for depression)
- anaesthetics that are inhaled (desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane)
- medicine used to treat high blood pressure (guanethidine)
- medicines used to treat heart failure and certain irregular heartbeats (cardiac glycosides)
- medicine used to treat abnormal heart rhythm (quinidine)
- medicine used during labour (oxytocin)

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine.

#### Pregnancy

This medication should not be used during pregnancy unless absolutely necessary.

#### Breast-feeding

This medication should not be used during breast-feeding unless it is absolutely necessary. However, in the event of a single administration during childbirth, breast-feeding is possible.

### **Driving and using machines**

Not relevant.

### **Phenylephrine Unimedic contains sodium**

Each 2 ml ampoule (containing 1 ml solution) contains 0,2 mmol (3,7 mg) sodium. This means that it contains less than 1 mmol sodium (23 mg), that is to say essentially "sodium-free".

## **3. How to take Phenylephrine Unimedic**

The administration will be performed by a health-care professional with appropriate training and relevant experience.

#### Use in Adults

Your doctor or nurse will give you Phenylephrine Unimedic into a vein (intravenously). Your doctor will decide the right dose for you and when and how it should be injected.

#### Use in patients with impaired renal function

Lower doses of phenylephrine may be needed in patients with impaired renal function.

#### Use in patients with impaired liver function

Higher doses of phenylephrine may be needed in patients with cirrhosis of the liver.

#### Use in older people

Treatment in older people should be carried out with care.

#### Use in children

It is not recommended for use in children due to insufficient data on efficacy, safety and dosage recommendations.

#### **If you use more Phenylephrine Unimedic than you should**

Signs that indicates that you have received too much Phenylephrine Unimedic is a faster and irregular heart beat, headache, nausea, vomiting, paranoid psychosis, hallucinations and hypertension (headache, shortness of breath, tiredness).

It is unlikely that this will happen because you will get this medicine at a hospital.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following adverse reactions, with the frequencies not known, have been reported:

Some side effects may be serious.

#### **Tell your doctor straight away if you get any of the following:**

- chest pain or pain due to the angina
- irregular heartbeat
- feeling the heart pumping in the chest
- bleeding in the brain (speech disorder, dizziness, paralysis of one side of the body)
- psychosis (loosing contact with reality)

Other side effects may include (frequencies are not known):

- reaction of hypersensitivity (allergy)
- excessive dilation of the pupils
- increased pressure in the eye (aggravation of glaucoma)
- excitability (excessive sensitivity of an organ or body part)
- agitation (restlessness)
- anxiety
- confusion
- headache
- nervousness,
- insomnia (difficulty falling or staying asleep)
- shaking (tremor)
- burning of the skin
- prickling of the skin
- itching or tingling skin sensation (paraesthesia)
- slow or high heart rate
- high blood pressure (headache, shortness of breath, tiredness)
- difficulty in breathing
- fluids in the lung
- nausea

- vomiting
- sweating
- pallor or skin blanching (pale colour of the skin)
- goose flesh
- tissue damage at the site of the injection
- muscle weakness
- difficulty in passing urine or urine retention

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V\\*](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Phenylephrine Unimedic**

Keep the ampoules in the outer carton in order to protect from light.

### *Storage condition after dilution*

Chemical and physical in-use stability has been demonstrated for 7 days 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°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Phenylephrine Unimedic contains**

- The active substance is phenylephrine. Phenylephrine Unimedic contains phenylephrine hydrochloride equivalent to 10 mg/ml phenylephrine.
- The other ingredients are sodium chloride, sodium citrate, citric acid, water for injection and hydrochloric acid and sodium hydroxid for pH adjustment

### **What Phenylephrine Unimedic looks like and contents of the pack**

Clear and colourless solution.

Phenylephrine Unimedic 10 mg/ml, concentrate for solution for injection/infusion is available in glass ampoules of 2 ml (containing 1 ml solution).

The ampoules are packaged in trays of plastic and then in cartons of 5, 10, 20, 50 and 100 ampoules.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder**

To be completed nationally

### **Manufacturer**

Unimedic AB  
Storjordenvägen 2  
SE-864 31 Matfors  
Sweden

### **This leaflet was last revised in**

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The following information is intended for healthcare professionals only:

*Solution with a high concentration and that must be diluted before the administration.*

#### Reconstitution/dilution:

Phenylephrine Unimedic 10 mg/ml will be administered as an injection or infusion after dilution in sodium chloride 9 mg/ml (or glucose 50 mg/ml).

- Dilution to a concentration of 100 micrograms/ml: 1 ml of the 10 mg/ml solution is diluted in 100 ml sodium chloride 9 mg/ml (or glucose 50 mg/ml).
- Dilution to a concentration of 50 micrograms/ml: 1 ml of the 10 mg/ml solution is diluted in 200 ml sodium chloride 9 mg/ml or glucose 50 mg/ml.

Other concentrations may also occur.