

Applicant/HCR	:	Umsebe Healthcare	V8 (10.05.2024)
Product name, strength and dosage form	:	Hypopress 0,1 mg/ml (solution for injection or infusion) Hypopress 10 mg/ml (solution for injection or infusion)	

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS **S4**

**HYPOPRESS 0,1 mg/ml**

**HYPOPRESS 10 mg/ml**

**Solution for injection or infusion**

Phenylephrine hydrochloride

Sugar-free

### Read all of this leaflet carefully before you are given HYPOPRESS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- HYPOPRESS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

1. What HYPOPRESS is and what it is used for
2. What you need to know before you are given HYPOPRESS
3. How you will be given HYPOPRESS
4. Possible side effects
5. How to store HYPOPRESS

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## 6. Contents of the pack and other information

### 1. What HYPOPRESS is and what it is used for

HYPOPRESS contains phenylephrine hydrochloride, which raises blood pressure by constricting blood vessels.

HYPOPRESS is used to treat low blood pressure:

- due to septic shock.
- during anaesthesia.

### 2. What you need to know before you are given HYPOPRESS

**HYPOPRESS should not be given to you:**

- if you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of HYPOPRESS (listed in section 6).
- if you are a child.
- if you suffer from uncontrolled blood pressure or peripheral vascular disease (poor blood circulation, particularly in the limbs).
- if you have one of the following serious heart conditions: heart-block, uncontrolled heart failure, poor blood circulation in the heart.
- if you have a very slow heartbeat (called bradycardia).
- if you have an overactive thyroid gland.
- if you are taking medicines causing narrowing of the blood vessels (ephedrine, pseudoephedrine, methylphenidate).
- if you are taking medicines given by mouth or via the nose causing narrowing of the blood vessels (etilefrine, midodrine, naphazoline, oxymetazoline, synephrine, tetryzoline, tuaminoheptane, tymazoline).

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- if you are taking monoamine oxidase inhibitors (MAOI's) (iproniazid, nialamide) used to treat depression, or have taken them in the last 14 days.

### Warnings and precautions

Tell your doctor or healthcare professional before being given HYPOPRESS if you have:

- diabetes.
- arterial hypertension (high blood pressure).
- weakening of the walls of the blood vessels.
- an uncontrolled overactive thyroid.
- any heart problems or disease, such as slow or fast heart rate, irregular heartbeat, chest pains.
- poor blood circulation in the brain.
- any blood circulation disease or condition.
- autonomic dysfunction (a nerve disfunction that regulates your heart rate and blood pressure).
- kidney or liver problems.
- closed angle glaucoma (increased pressure in the eye).

HYPOPRESS can cause severe bradycardia (slowing of the heart rate) and decreased cardiac output (decrease in amount of blood pumped by the heart). HYPOPRESS can also result in excessive narrowing of the blood vessels of the extremities and those leading to organs, which could result in reduced blood rich oxygen reaching vital organs. This is more likely to happen in patients with peripheral vascular disease (a blood circulation disease causing the narrowing of blood vessels outside the heart and brain), e.g., the condition called Raynaud's phenomenon. An increase in blood pressure may occur, which could cause heart failure, angina (chest pain) in patients with severe arteriosclerosis (a disease of the small arteries,

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which reduces the amount of oxygen rich blood that flows through them), or past history of angina and increased pulmonary arterial pressure (high blood pressure in the lungs).

In patients with serious heart failure, HYPOPRESS may worsen the heart failure as a consequence of blood vessel constriction (blood vessels becoming smaller).

Special care should be taken with HYPOPRESS, if you are elderly.

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:**

HYPOPRESS should not be used in children due to insufficient data on efficacy, safety and dose recommendations.

**Other medicines and HYPOPRESS**

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

HYPOPRESS is not to be used in combination with (see section 2):

- non-selective monoamine oxidase inhibitors (MAOIs) (iproniazid, nialamide) used to treat depression.
- medicines causing narrowing of the blood vessels (ephedrine, pseudoephedrine, methylphenidate).

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- medicines given by mouth or via the nose causing narrowing of the blood vessels (etilefrine, midodrine, naphazoline, oxymetazoline, synephrine, tetrazoline, tuaminoheptane, tymazoline).

Interactions are possible with the following medicines:

- bromocriptine, cabergoline, lisuride, pergolide (used to treat Parkinson's disease).
- dihydroergotamine, ergotamine, methylergotamine, methylsergide (used for the treatment of migraine).
- linezolid (an antibiotic).
- desipramine, imipramine, nortriptyline, moclobemide, pargyline, selegiline, toloxatan, venlafaxine (medicines used to treat depression).
- guanethidine, labetalol, prazosin, reserpine and related products (medicines used to treat high blood pressure).
- quinidine, digoxin (medicines used to treat heart failure and certain irregular heartbeats).
- desflurane, enflurane, halothane, isoflurane, methoxyflurane, sevoflurane (anaesthetics that are inhaled).
- oxytocin (medicine used during labour).
- doxazosin (used for the treatment of enlarged prostates in men).
- haloperidol, phenothiazine (used for the treatment of certain mental conditions).

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

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The safety of HYPOPRESS during pregnancy and breastfeeding has not been established.

### **Driving and using machines**

HYPOPRESS can cause side effects (including low blood pressure with dizziness, fainting, breathing difficulty, muscular weakness), which may affect your ability to drive or operate a motor vehicle or other heavy machinery.

It is not always possible to predict to what extent HYPOPRESS may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which HYPOPRESS affects them.

### **HYPOPRESS contains sodium**

HYPOPRESS 0,1 mg/ml contains 3,54 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,2 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

HYPOPRESS 10 mg/ml contains 2,36 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0,1 % of the recommended maximum daily dietary intake of 2 g sodium for an adult.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **3. How HYPOPRESS will be given**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself HYPOPRESS. It will be given to you by a person who is qualified to do so.

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### **If you are given more HYPOPRESS than you should**

Since a health care provider will administer HYPOPRESS, he / she will control the dosage.

However, in the event of overdosage your doctor will manage the overdosage.

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

HYPOPRESS can have side effects.

Not all side effects reported for HYPOPRESS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking HYPOPRESS, please consult your health care provider for advice.

If any of the following happens, stop taking / using HYPOPRESS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction (swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing; rash or itching, fainting).
- An irregular heartbeat (dysrhythmias).
- Very slow heartbeat (bradycardia).
- Chest pain or pain due to angina.
- Your heart stops beating (cardiac arrest).
- Feeling the heart pumping in the chest (palpitations).
- Bleeding in the brain (speech disorder, dizziness, paralysis of one side of the body).
- Psychosis (loosing contact with reality and hear or see things that do not exist).

These are all very serious side effects. If you have them, you may have had a serious reaction to HYPOPRESS. You may need urgent medical attention or hospitalisation.

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**Frequent side effects:**

- Headache

**Less frequent side effects:**

- Euphoria (feeling very happy/excited)
- Agitation (restlessness)
- Anxiety
- Confusion
- Tingling of the skin
- A feeling of fullness of the head
- Nervousness
- Insomnia (difficulty falling or staying asleep)
- Pins and needles (paresthesia)
- Shaking uncontrollably (tremor)
- Excessive dilation of the pupils (pupils of the eyes become very large)
- Increased pressure in the eye (aggravation of glaucoma)
- High blood pressure
- Low blood pressure with dizziness
- Pallor or skin blanching (pale colour of the skin)
- Difficulty in breathing
- Fluids in the lung
- Vomiting
- Nausea
- Goose flesh
- Sweating

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- Skin blanching (whitening of the skin)
- Muscular weakness
- Difficulty in passing urine or urine retention
- Tissue damage at the site of the injection

**Other side effects (frequencies are not known):**

- Change in the metabolism of glucose (sugar)
- Fainting
- Flushing of skin
- Cold skin
- Excessive production of saliva
- Excessive sweating

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of HYPOPRESS.

**5. How to store HYPOPRESS**

Store at or below 30 °C in the outer carton.

Do not refrigerate or freeze.

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Use immediately after opening.

Maintain strict aseptic standards during dilution for administration by intravenous infusion.

Do not use after the expiry date, which is stated on the carton and ampoule. The expiry date refers to the last day of that month.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

### What HYPOPRESS contains

HYPOPRESS 0,1 mg/ml contains 0,1 mg/ml phenylephrine hydrochloride. One ampoule of 5 ml contains 0,5 mg of phenylephrine hydrochloride.

The other ingredients are hydrochloric acid, sodium chloride and water for injections.

HYPOPRESS 10 mg/ml contains 10 mg/ml phenylephrine hydrochloride. One ampoule of 1 ml contains 10 mg of phenylephrine hydrochloride.

The other ingredients are hydrochloric acid, sodium chloride and water for injections.

### What HYPOPRESS looks like and contents of the pack

HYPOPRESS 0,1 mg/ml is a clear, colourless solution. It is presented in 5 ml one point cut clear Type I glass ampoules. Ampoules are packed into outer cardboard cartons in pack sizes of 10.

HYPOPRESS 10 mg/ml is a clear, colourless, sterile solution. It is presented in 2 ml (1 ml fill) one point cut clear Type I glass ampoules. Ampoules are packed into outer cardboard cartons in pack sizes of 10.

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**Holder of Certificate of Registration**

Umsebe Healthcare

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21 Dreyer Street, Claremont

Cape Town

7708

South Africa

**Name of Manufacturer:** Sintetica SA

**This leaflet was last revised in**

10 May 2024

**Registration numbers**

HYPOPRESS 0,1 mg/ml: 55/6.1/0352

HYPOPRESS 10 mg/ml: 55/6.1/0353

**Access to the corresponding Professional Information**

10 May 2024

**NAMIBIA:**

HYPOPRESS 0,1 mg/ml: Reg. No.: 21/7.2/0002 NS2

HYPOPRESS 10 mg/ml: Reg. No.: 21/7.2/0003 NS2