PROFESSIONAL INFORMATION

SCHEDULING STATUS

S4

1 NAME OF THE MEDICINE
PHENPRESSOR 10 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each vial contains 10 mg/ml phenylephrine hydrochloride.
Contains sodium hydroxide: q.s. to pH adjustment
Sugar free.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Solution for injection.
A clear colourless solution with a pH range of 3,5 to 5,0.

4 CLINICAL PARTICULARS
Therapeutic indications
PHENPRESSOR 10 mg/ml is indicated for increasing the blood pressure in adults with clinically significant hypotension resulting primarily from vasodilation in such settings as septic shock or anaesthesia.
The duration of action is short-lived (minutes) and repeat injections are frequently required.

Posology and method of administration
Posology
Patients receiving PHENPRESSOR 10 mg/ml should be closely monitored. Treatment with PHENPRESSOR 10 mg/ml is not a substitute for replacement of blood, plasma, fluids and/or electrolytes. Prior to administration of therapy, hypovolaemia should be corrected. Acidosis may reduce the effectiveness of phenylephrine.
Dosage must be adjusted to meet the individual requirements of each patient, on the basis of clinical response. Some patients may need higher than usual recommended doses for a time.
Dosing for perioperative setting
In adult patients undergoing surgical procedures with either neuraxial anaesthesia or general anaesthesia:
- 50 µg to 250 µg by intravenous bolus administration. The most frequently reported initial bolus dose is 50 µg or 100 µg.
- 0,5 µg/kg/min to 1,4 µg/kg/min by intravenous continuous infusion, titrated to blood pressure goal.

Dosing for septic or other vasodilatory shock
In adult patients with septic or other vasodilatory shock:
- 0,5 µg/kg/min to 6 µg/kg/min by intravenous continuous infusion, titrated to blood pressure goal. Doses above 6 µg/kg/min do not show significant incremental increase in blood pressure.

Method of administration
PHENPRESSOR 10 mg/ml is not for intramuscular or subcutaneous use.
Caution is recommended to avoid extravasation, which may cause tissue necrosis and sloughing of surrounded tissues (see section 4.4). When discontinuing therapy, the dosage should be reduced gradually, since sudden cessation of therapy may result in severe hypotension. Intravascular fluid should be replaced if necessary, to avoid hypotension.
PHENPRESSOR 10 mg/ml must be diluted before administration as slow intravenous bolus injection or intravenous infusion or continuous intravenous infusion.
An infusion pump or other suitable metering device should be used to control the rate of infusion in order to avoid unintended administration of a bolus dose. Infusion of PHENPRESSOR 10 mg/ml should be given into a large vein, or preferably, directly into the central venous line. Inspect the solution for particulate matter and discolouration prior to administration. The diluted solution should not be kept for more than 4 hours at room temperature or for more than 24 hours under refrigerated conditions. Discard any unused portion.
For preparation of the solution for injection, see section 6.6.

Contraindications
- Hypersensitivity to phenylephrine or to any of the excipients of PHENPRESSOR 10 mg/ml (see section 6.1).
- Patients taking monoamine oxidase inhibitors, or within 14 days of ceasing such treatment (see section 4.4 and 4.5).
- Paediatric use.
- Severe uncontrolled hypertension.
- Severe hyperthyroidism.
- Severe heart-block with or without bradycardia.
- Severe bradycardia (less than 50 bpm).
- Uncontrolled cardiac failure.
- Severe impaired coronary circulation.
- Prostatic enlargement.

Special warnings and precautions for use
Sustained IV infusion may result in diminished effect.

Cardiovascular effects
Great care should be exercised in administering PHENPRESSOR 10 mg/ml to patients with pre-existing cardiovascular disease such as ischaemic heart disease, dysrhythmias, occlusive vascular disease including arteriosclerosis, hypertension or aneurysms.
Severe bradycardia and decreased cardiac output may occur.
Excessive peripheral and visceral vasoconstriction with ischaemia to vital organs may occur, especially in patients with extensive peripheral vascular disease, e.g. Raynaud's phenomenon. Increased blood pressure may occur and precipitate underlying heart failure, angina in patients with severe arteriosclerosis or past history of angina and increased pulmonary arterial pressure.
In patients with reduced cardiac output or coronary vascular disease, vital organ functions should be closely monitored, and dose reduction should be considered when systemic blood pressure is near the lower end of the target range.

Dermatological effects
Avoid extravasation as this can cause necrosis or sloughing of tissue.

Endocrine and metabolic effects
Use extreme caution in patients with hyperthyroidism. Care is also required when given to patients with diabetes mellitus.

Monoamine oxidase (MAO) inhibitors
Concurrent use may prolong and intensify cardiac stimulation and vasopressor effects because of the release of catecholamines which accumulate in intraneuronal storage sites during MAO inhibitor therapy; this may result in headache, cardiac dysrhythmias, vomiting or sudden and severe hypertensive or hyper-pyretic crises. For patients who have been receiving MAO inhibitors 2 to 3 weeks prior to administration of sympathomimetic medicines, the initial dosage should be reduced to be no more than one-tenth of the usual dose (see section 4.3 and 4.5).

Immunologic effects
Allergic reactions, including anaphylactic symptoms, may occur in patients with sulfite-sensitivity.

Neurologic effects
Blood pressure response to PHENPRESSOR 10 mg/ml may be increased in patients with autonomic disfunction.

Renal toxicity
PHENPRESSOR 10 mg/ml can increase the need for renal therapy in patients with septic shock. Monitor renal function.

Effects on the eye
Care is required when given to patients with closed angle glaucoma.

Interaction with other medicines 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 dysrhythmias may also occur if phenylephrine injection is given to patients receiving cardiac glycosides (such as digoxin), quinidine or tricyclic antidepressants (such as imipramine) and nor adrenergic-serotonergic antidepressants (such as minalcipram, venlafaxine).

Phenylephrine is a hypertensive medicine and may consequently reverse the action of many antihypertensive and diuretic medicines. The patient should be carefully monitored to confirm the desired effect is obtained.

Interactions of phenylephrine with alpha and beta receptor blocking medicines may be complex. Medicines which have an effect on α1 adrenoceptors could potentiate (such as clonidine) the vasopressive action of phenylephrine and may result in profound bradycardia, or inhibit (such as doxazosin, labetalol, prazosin, haloperidol, phenothiazines) 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 or other 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 (such as selegiline, moclobemide, linezolid, nialamide, pargyline, phenelzine) or reversible inhibitors of monoamine oxidase (see section 4.3 and 4.4). This interaction is still possible 15 days after discontinuation of the MAO.

Concurrent use with ergot alkaloids (such as bromocriptine, lisuride, carbergoline, pergolide dihydroergotamine, ergotamine, methylergometrine, methylsergide) increases the risk of vasoconstriction and/or hypertensive crisis.

Concomitant use with reserpine and other sympatholytic medicines causes a substantial increase in blood pressure (hyperreactivity linked to the reduction in sympathetic tone and/or to the inhibition of adrenaline (epinephrine) or noradrenalin (norepinephrine) entry in sympathetic fibres). Use with caution if the combination cannot be avoided.

Fertility, pregnancy and lactation
Pregnancy
The safety of PHENPRESSOR 10 mg/ml during pregnancy has not been established. Due to the vasoconstrictive properties of phenylephrine, PHENPRESSOR 10 mg/ml should be used with caution in patients with a history of pre-eclampsia. Administration of PHENPRESSOR 10 mg/ml in late pregnancy or labour may cause foetal hypoxia and bradycardia.
Breastfeeding
The safety of PHENPRESSOR 10 mg/ml during lactation has not been established. Excretion of phenylephrine in breast milk appears to be minimal.

Fertility
No data is available on fertility.

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

Undesirable effects
a. Summary of the safety profile
A tabulated list of undesirable effects is outlined below:
The undesirable effects are listed according to organ systems and following frequency: Frequent, Less frequent, Frequency unknown (cannot be estimated from the available data).
b. Tabulated summary of adverse reactions

MedDRA system organ class	Frequency	Adverse reactions
Immune system disorders	Less frequent	Hypersensitivity
Metabolism and nutrition disorders	Frequency unknown	Metabolic disorders
Psychiatric disorders	Less frequent	Nervousness, insomnia, anxiety, excitability, agitation, psychotic states, confusion
Nervous system disorders	Frequent	Headache
	Less frequent	Paraesthesia, tremor
	Frequency unknown	Cerebral haemorrhage
Eye disorders	Less frequent	Mydriasis, angle-closure glaucoma
Cardiac disorders	Less frequent	Bradycardia, tachycardia, ventricular dysrhythmia, angina pectoris
	Frequency unknown	Palpitations, cardiac arrest
Vascular disorders	Less frequent	Hypotension, hypertension, cerebral haemorrhage, hypertensive crisis
	Frequency unknown	Dizziness, syncope, flushing
Respiratory, thoracic and mediastinal disorders	Less frequent	Dyspnoea, pulmonary oedema
Gastrointestinal disorders	Less frequent	Nausea, vomiting
	Frequency unknown	Salivary hypersecretion
Skin and subcutaneous tissue disorder	Less frequent	Sweating, pallor or skin blanching, piloerection, skin necrosis with extravasation
Musculoskeletal disorders	Less frequent	Muscle weakness
Renal and urinary disorders	Less frequent	Dysuria, urinary retention
General disorders and administration site conditions	Frequency unknown	Extravasation, infusion site necrosis, hyperhidrosis
Investigations	Frequency unknown	Increased blood pressure, abnormal blood glucose

c. Description of selected adverse reactions
Phenylephrine is without significant stimulating effects on the central nervous system at usual doses. PHENPRESSOR 10 mg/ml may cause a transient tingling and coolness of the skin and a temporary sensation of fullness in the head. Extravasation of the injection may cause local necrosis (see section 4.4). Peripheral vasoconstriction, possibly leading to necrosis or gangrene, may occur with prolonged use of PHENPRESSOR 10 mg/ml in high doses or low doses in the presence of peripheral vascular disease.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8

Overdose
Symptoms
Symptoms of overdosage include headache, vomiting, hypertension and reflex bradycardia and other cardiac dysrhythmias. In severe cases confusion, hallucinations and seizures may occur.
Management
Treatment should consist of symptomatic and supportive measures. For excessive hypertensive effects, the administration should be reduced or the medicine temporarily discontinued until the blood pressure is decreased. If the measures fail to lower the blood pressure, a short acting alpha-adrenergic blocking medicine may be administered.

5 PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: adrenergic and dopaminergic medicine. ATC code: C01CA6.
Pharmacological classification: 7.2 Vasoconstrictors, pressor medicines.

Phenylephrine is an alpha 1 adrenergic receptor agonist. After injection phenylephrine produces peripheral vasoconstriction and an increase in arterial pressure; it also produces reflex bradycardia. Beta 1 adrenergic effects are insignificant.

Pharmacokinetic properties
Distribution
Following intravenous infusion of phenylephrine hydrochloride, the effective half-life is approximately 5 minutes. The steady-state volume of distribution (340 l) exceeds the body volume by a factor of 5, suggesting a high distribution into certain organ compartments. The average total serum clearance (2 095 ml/min) is close to one-third of the cardiac output.

Metabolism and elimination
A mass balance study showed that phenylephrine is extensively metabolised by the liver with only 12 % of the dose excreted unchanged in the urine. Deamination by monoamine oxidase is the primary metabolic pathway resulting in the formation of the major metabolite (m-hydroxymandelic acid) which accounts for 57 % of the total administered dose.

Preclinical safety data
Not applicable.

6 PHARMACEUTICAL PARTICULARS
List of excipients
Citric acid monohydrate (E330)
Hydrochloric acid (for pH adjustment) (E507)
Sodium chloride
Sodium citrate dihydrate (E331)
Sodium hydroxide (for pH adjustment) (E524)
Sodium metabisulfite (E223)
Water for injection

Incompatibilities
PHENPRESSOR 10 mg/ml has been stated to be incompatible with alkalies, ferric salts, phenytoin sodium and oxidising medicines.

Shelf life
24 months.

Special precautions for storage
Store at or below 25 °C. Protect from light.
After dilution with 5 % Dextrose Injection or 0,9 % Sodium Chloride Injection, the diluted solution can be stored at or below 25 ºC for 4 hours or at 2 – 8 ºC for 24 hours.

Nature and contents of container
1 ml solution for injection filled in a 2 ml USP Type-I Clear glass tubular vial closed with 13 mm grey chlorobutyl rubber stoppers and 13 mm aluminium flip-off seals with green colour button.
5 vials packed in an outer carton
5 ml solution for injection filled in a 5 ml USP Type-I Clear glass tubular vial closed with 20 mm grey chlorobutyl rubber stoppers and 20 mm aluminium flip-off seals with blue colour button.
1 vial packed in an outer carton
10 ml solution for injection filled in a 10 ml USP Type-I Clear glass tubular vial closed with 20 mm grey chlorobutyl rubber stoppers and 20 mm aluminium flip-off seals with orange colour button.
1 vial packed in an outer carton

Special precautions for disposal and other handling
Preparing a 50 µg/ml solution of bolus intravenous administration
For bolus intravenous administration, add 10 mg (1 ml of a 10 mg/ml concentration) of PHENPRESSOR 10 mg/ml to 200 ml of 5 % Dextrose Injection or 0,9 % Sodium Chloride Injection. This will yield a final concentration of 50 µg/ml. Withdraw an appropriate dose from the 50 µg/ml solution prior to bolus intravenous administration of the diluted solution.

Preparing a solution for continuous intravenous infusion
For continuous intravenous infusion, withdraw 10 mg (1 ml of 10 mg/ml concentration) of PHENPRESSOR 10 mg/ml and add 500 ml of 5 % Dextrose Injection or 0,9 % Sodium Chloride Injection (providing a final concentration of 20 µg/ml).

7 HOLDER OF CERTIFICATE OF REGISTRATION
Juno Pharma SA (Pty) Ltd
3 Gwen Lane, 4th Floor, Sandton, 2031
Contact No.: +27 (0)10 594 5610. PV Email Address: pv@trinitypharma.co.za

8 REGISTRATION NUMBER
55/7.2/0361

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
18 April 2023

10 DATE OF REVISION OF THE TEXT
N.A

400 mm

170 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PHENPRESSOR 10 mg/ml Solution for injection
Phenylephrine hydrochloride
Sugar free

Read all of this leaflet carefully before you receive PHENPRESSOR 10 mg/ml
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What PHENPRESSOR 10 mg/ml is and what it is used for
The active ingredient in PHENPRESSOR 10 mg/ml is phenylephrine hydrochloride.
Phenylephrine belongs to a group of medicines called anti-hypotensive medicines. PHENPRESSOR 10 mg/ml is used in adults to relieve low blood pressure which may occur during an operation or after an injury.

2. What you need to know before you receive PHENPRESSOR 10 mg/ml
PHENPRESSOR 10 mg/ml should not be administered to you:
- if you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of PHENPRESSOR 10 mg/ml (listed in section 6).
- if you are taking a group of medicines called monoamine oxidase inhibitors (MAOIs) or have stopped taking them within the last 14 days.
- if you have severe uncontrolled high blood pressure.
- If you have an overactive thyroid (hyperthyroidism).
- if you have a slow heart rate.
- if you have uncontrolled heart failure.
- if you have prostatic enlargement.
- if you have heart or circulatory problems.

Use in children is not recommended.

Warnings and precautions
Talk to your doctor or nurse before receiving PHENPRESSOR 10 mg/ml:
- if you have heart conditions such as the following: ischaemic heart disease, dysrhythmia, heart failure, angina pectoris, occlusive vascular disease, high blood pressure or aneurysms.
- if you have diabetes mellitus, diabetic autonomic neuropathy (a complication of diabetes mellitus).
- if you have closed angle glaucoma.
- if you have kidney problems.
- if you have autonomic dysfunction.
- if you are allergic to sulfites.

Other medicines and PHENPRESSOR 10 mg/ml
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Do not use PHENPRESSOR 10 mg/ml with:
- Monoamine oxidase (MAO) inhibitors used for depression, (such as selegiline, moclobemide, linezolid, nialamide, pargyline, phenelzine).

The following medicines may affect or be affected by concomitant use:
- Digoxin (medicine used to treat heart problems).
- Imipramine, minalcipram, venlafaxine (medicines used for depression).
- Cyclopropane and halothane (medicines that are inhaled as anaesthetics).
- Atomoxetine (medicine used to treat attention-deficit hyperactivity disorder (ADHD)).
- Clonidine (medicine used to treat high blood pressure)
- Quinidine (medicine used to treat abnormal heart rhythm).
- Doxazosin, labetalol, prazosin (medicines used to treat high blood pressure).
- Haloperidol, phenothiazines (medicines used to treat mental illness).
- Atropine (medicine used for slow heart rate or pesticide poisoning).
- Lithium (medicine used for depression or aggression).
- Ergot alkaloids, such as bromocriptine, lisuride, carbergoline, pergolide dihydroergotamine, ergotamine, methylergometrine, methylsergide (medicines to treat migraine).

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 receiving PHENPRESSOR 10 mg/ml. The safety of PHENPRESSOR 10 mg/ml during pregnancy and breastfeeding has not been established.

Driving and using machines
There are no known adverse effects. It is not always possible to predict to what extent PHENPRESSOR 10mg/ml 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 PHENPRESSOR 10 mg/ml affects you.

3. How to receive PHENPRESSOR 10 mg/ml
Do not share medicines prescribed for you with any other person. You will not be expected to give yourself PHENPRESSOR 10 mg/ml. It will be given to you by a person who is qualified to do so. Your doctor will work out the dosage that is correct for you and will adjust this dosage to meet your individual requirement. If you have the impression that the effect of PHENPRESSOR 10 mg/ml is too strong or too weak, tell your doctor or pharmacist.

If you receive more PHENPRESSOR 10 mg/ml than you should
Since your doctor will administer PHENPRESSOR 10 mg/ml, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Symptoms of overdose include headache, feeling sick, high blood pressure, a fast or irregular heartbeat, confusion, hallucinations and fits.

If you miss a dose of PHENPRESSOR 10 mg/ml
Since your doctor will administer PHENPRESSOR 10 mg/ml, it is unlikely that the dose will be missed.

4. Possible side effects
PHENPRESSOR 10 mg/ml can have side effects.
Not all side effects reported for PHENPRESSOR 10 mg/ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PHENPRESSOR 10 mg/ml, please consult your health care provider for advice.
If any of the following happens, stop receiving PHENPRESSOR 10 mg/ml and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to PHENPRESSOR 10 mg/ml. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequent
- headache.

Less frequent
- numbness or a burning feeling that occurs most often in the extremities, such as the hands, arms, legs, or feet,
- tremor,
- nervousness,
- difficulty sleeping,
- anxiety and confusion,
- angle closure glaucoma (when pressure rises quickly inside the eye),
- shortness of breath,
- enlarged pupils, which may make your vision blurry,
- increased or decreased blood pressure,
- dizziness,
- feeling sick, vomiting,
- tingling and coolness of the skin, sweating,
- muscle weakness,
- difficulty in passing urine.

Frequency unknown
- bleeding in the brain,
- fluid on the lungs,
- a drop in blood pressure may occur with dizziness, fainting and flushing,
- changes in heart rate and rhythm, anginal pain, heart block,
- an increase in saliva,
- a feeling of fullness in the head,
- changes in blood sugar levels,
- occasional skin reactions.

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 PHENPRESSOR 10 mg/ml.

5. How to store PHENPRESSOR 10 mg/ml
Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light.
- Do not use after the expiry date stated on the label/ carton

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 PHENPRESSOR 10 mg/ml contains
- The active substance is phenylephrine hydrochloride. Each 1 ml of PHENPRESSOR 10 mg/ml contains 10 mg of phenylephrine hydrochloride. Sugar free.
- The other ingredients are citric acid monohydrate, hydrochloric acid, sodium chloride, sodium citrate dihydrate, sodium hydroxide, sodium metabisulfite, water for injection.

What PHENPRESSOR 10 mg/ml looks like and contents of the pack
A clear colourless solution with a pH range of 3,5 to 5,0.
PHENPRESSOR 10 mg/ml is packed as follows:
- 1 ml solution for injection filled in a 2 ml USP Type-I Clear glass tubular vial closed with 13 mm grey chlorobutyl rubber stoppers and 13 mm aluminium flip-off seals with green colour button.
  5 vials packed in an outer carton
- 5 ml solution for injection filled in a 5 ml USP Type-I Clear glass tubular vial closed with 20 mm grey chlorobutyl rubber stoppers and 20 mm aluminium flip-off seals with blue colour button.
  1 vial packed in an outer carton
- 10 ml solution for injection filled in a 10 ml USP Type-I Clear glass tubular vial closed with 20 mm grey chlorobutyl rubber stoppers and 20 mm aluminium flip-off seals with orange colour button.
  1 vial packed in an outer carton

Holder of Certificate of Registration
Juno Pharma SA (Pty) Ltd
3 Gwen Lane, 4th Floor, Sandton, 2031
Contact No.: +27 (0)10 594 5610. PV Email Address: pv@trinitypharma.co.za

This leaflet was last revised in
26 July 2023

Registration number
55/7.2/0361

Access to the corresponding Professional Information
www.trinitypharma.co.za

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

PHENPRESSOR 10 mg/ml Oplossing vir inspuiting
Fenielefrienhidrochloried
Suikervry

Lees hierdie inligtingstuk sorgvuldig voordat jy PHENPRESSOR 10 mg/ml ontvang
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorg verskaffer indien jy verdere vrae het

Wat in hierdie inligtingstuk is

1. Wat PHENPRESSOR 10 mg/ml is en waarvoor dit gebruik word
Die aktiewe bestanddeel in PHENPRESSOR 10 mg/ml is fenielefrienhidrochloried.
Fenielefrien behoort aan 'n groep medisynes wat antihipotensiewe medisyne genoem word. PHENPRESSOR 10 mg/ml word gebruik by volwassenes om lae bloeddruk te verlig wat mag voorkom tydens 'n operasie of 'n besering.

2. Wat jy behoort te weet voordat jy PHENPRESSOR 10 mg/ml ontvang
PHENPRESSOR 10 mg/ml behoort nie aan jou toegedien te word:
- indien jy hipersensitief (allergies) vir fenielefrienhidrochloried of enige van die ander bestanddele van PHENPRESSOR 10 mg/ml is nie (gelys in afdeling 6).
- indien jy 'n groep medisyne neem wat monoamienoksidase inhibeerders (MAOIs) genoem word of indien jy hulle ophou neem het binne die laaste 14 dae.
- indien jy ernstige onbeheerde hoë bloeddruk het.
- indien jy 'n ooraktiewe skildklier het (hipertireose).
- indien jy 'n stadige hartklop het.
- indien jy onbeheerde hartversaking het.
- indien jy prostaatvergroting het.
- indien jy hart- of bloedsomloop probleme het.

Gebruik by kinders word nie aanbeveel nie.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of verpleegster voordat jy PHENPRESSOR 10 mg/ml ontvang:
- indien jy harttoestande soos die volgende het: ischemiese hartsiekte, disritmieë, hartversaking, angina pectoris, okklusiewe vaskulêre siekte, hoë bloeddruk of aneurismes.
- indien jy diabetes mellitus het, diabetiese outonomiese neuropatie ('n komplikasie van diabetes mellitus).
- indien jy nouhoek gloukoom het.
- indien jy nier probleme het.
- indien jy outonomiese disfunksie het.
- indien jy vir sulfiete allergies is.

Ander medisyne en PHENPRESSOR 10 mg/ml
Vertel altyd vir jou gesondheidsorg verskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Moet nie PHENPRESSOR 10 mg/ml gebruik saam met:
- Monoamienoksidase (MAO) inhibeerders wat gebruik word vir depressie, (soos selegilien, moklobemied, linesolied, nialamied, pargilien, fenelsien).

Die volgende medisyne mag gepaardgaande gebruik beïnvloed of deur dit beïnvloed word:
- Digoksien (medisyne wat gebruik word om hart probleme te behandel).
- Imipramien, minalsipram, venlafaksien (medisyne wat vir depressie gebruik word).
- Siklopropaan en halotaan (medisyne wat as narkose ingeasem word).
- Atomoksetien (medisyne wat gebruik word om aandag-afleibaarheid hiperaktiwiteitsversteuring te behandel (AAHV)).
- Klonidien (medisyne wat gebruik word om hoë bloeddruk te behandel).
- Kinidien (medisyne wat gebruik word om abnormale hartritme te behandel).
- Doksasosien, labetalol, prasosien (medisyne wat gebruik word om hoë bloeddruk te behandel).
- Haloperidol, fenotiasiene (medisyne wat gebruik word om geestesversteurings te behandel).
- Atropien (medisyne wat gebruik word vir stadige hartklop of plaagdodervergiftiging).
- Litium (medisyne wat gebruik word vir depressie of aggressie).
- Ergot-alkaloïede, soos bromokriptien, lisuried, karbergolien, pergolied-dihidro-ergotamien, ergotamien, metielergometrien, metielsergied (medisyne om skeelhoofpyn te behandel).

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy dalk swanger mag wees of beplan om swanger te raak, raadpleeg jou dokter, apteker of ander gesondheidsorg verskaffer vir advies voordat jy PHENPRESSOR 10 mg/ml ontvang. Die veiligheid van PHENPRESSOR 10 mg/ml tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie
Daar is geen nadelige effekte nie. Dit is nie altyd moontlik om te voorspel tot watter mate PHENPRESSOR 10 mg/ml mag inmeng met jou daaglikse aktiwiteite nie. Jy moet verseker dat jy nie deelneem aan die bogenoemde aktiwiteite totdat jy bewus is van die mate waartoe PHENPRESSOR 10mg/ml jou affekteer nie.

3. Hoe om PHENPRESSOR 10 mg/ml te ontvang
Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Daar sal nie van jou verwag word om vir jouself PHENPRESSOR 10 mg/ml toe te dien nie. Dit sal aan jou gegee word deur 'n persoon wat gekwalifiseerd is om dit te doen. Jou dokter sal die dosering uitwerk wat reg is vir jou en sal hierdie dosering aanpas om aan jou individuele behoeftes te voldoen. Indien jy onder die indruk is dat die effek van PHENPRESSOR 10 mg/ml te sterk of te swak is, sê vir jou dokter of apteker.

Indien jy meer PHENPRESSOR 10 mg/ml ontvang as wat jy behoort
Aangesien jou dokter PHENPRESSOR 10 mg/ml vir jou gaan toedien, sal hy/sy die dosering kontroleer. In die geval van oordosering, sal jou dokter egter die oordosis bestuur. Simptome van oordosering sluit hoofpyn, siek gevoel, hoë bloeddruk, 'n vinnige of onreëlmatige hartklop, verwarring, hallusinasies en aanvalle in.

Indien jy 'n dosis van PHENPRESSOR 10 mg/ml oorslaan
Aangesien jou dokter PHENPRESSOR 10 mg/ml vir jou sal toe dien, is dit onwaarskynlik dat 'n dosis oorgeslaan sal word.

4. Moontlike newe-effekte
PHENPRESSOR 10 mg/ml kan newe-effekte hê.
Nie al die newe-effekte wat vir PHENPRESSOR 10 mg/ml gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige onaangename gevolge ondervind terwyl jy PHENPRESSOR 10 mg/ml ontvang, kontak jou gesondheidsorg verskaffer vir advies.
Indien enige van die volgende gebeur, hou op om PHENPRESSOR 10 mg/ml te ontvang en sê vir jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of gejeuk.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie teen PHENPRESSOR 10 mg/ml gehad het. Jy mag dringende mediese aandag of hospitalisering nodig hê.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereeld
- hoofpyn.

Minder gereeld
- gevoelloosheid of 'n brand gevoel wat die meeste in die ledemate voorkom, soos die hande, arms, bene of voete,
- bewing,
- senuweeagtigheid,
- sukkel om te slaap,
- angstigheid en verwarring,
- nouhoek gloukoom (wanneer druk vinnig in die oog styg),
- kort van asem,
- vergrote pupille, wat jou visie mag verdof,
- verhoogde of verlaagde bloeddruk,
- duiseligheid,
- siek gevoel, braking,
- tinteling en koelheid van die vel, sweet,
- spierswakheid,
- probleme met urinering.

Frekwensie onbekend
- bloeding in die brein,
- vog op die longe,
- 'n daling in bloeddruk mag voorkom met duiseligheid, floute en blosing,
- veranderinge in hartklop en ritme, anginapyn, hartblok,
- 'n verhoging in speeksel,
- 'n gevoel van volheid in die kop,
- veranderinge in bloedsuiker vlakke,
- vel reaksies af en toe.

Lig asseblief jou dokter of apteker in indien jy enige newe-effek ervaar wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8 Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van PHENPRESSOR 10 mg/ml.

5. Hoe om PHENPRESSOR 10 mg/ml te bewaar
Bewaar alle medisyne buite bereik van kinders
- Bewaar by of benede 25°C. Beskerm teen lig.
- Moenie na die vervaldatum op die etiket/karton gebruik nie.

Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting
Wat PHENPRESSOR 10 mg/ml bevat
- Die aktiewe bestanddeel is fenielefrienhidrochloried. Elke 1 ml van PHENPRESSOR 10 mg/ml bevat 10 mg fenielefrienhidrochloried. Suikervry.
- Die ander bestanddele is sitroensuur monohidraat, soutsuur, natriumchloried, natriumsitraat dihidraat, natriumhidroksied, natriummetabisulfiet, water vir inspuiting.

Hoe PHENPRESSOR 10 mg/ml lyk en inhoud van die pak
'n Helder kleurlose oplossing met 'n pH reeks van 3,5 tot 5,0.
PHENPRESSOR 10 mg/ml word soos volg verpak:
- 1 ml oplossing vir inspuiting gevul in 'n 2 ml USP Tipe-I Helder glas buisvormige flessie toegemaak met 13 mm grys chlorobutiel rubberproppe en 13 mm aluminium afwip seëls met 'n groen kleur doppie.
  5 flessies verpak in 'n buite karton.
- 5 ml oplossing vir inspuiting gevul in 'n 5 ml USP Tipe-I Helder glas buisvormige flessie toegemaak met 20 mm grys chlorobutiel rubberproppe en 20 mm aluminium afwip seëls met 'n blou kleur doppie.
  1 flessie verpak in 'n buite karton.
- 10 ml oplossing vir inspuiting gevul in 'n 10 ml USP Tipe-I Helder glas buisvormige flessie toegemaak met 20 mm grys chlorobutiel rubberproppe en 20 mm aluminium afwip seëls met 'n oranje kleur doppie.
  1 flessie verpak in 'n buite karton.

Houer van die Registrasiesertifikaat
Juno Pharma SA (Edms.) Bpk
Gwen Laan 3, 4de Vloer, Sandton, 2031
Kontaknommer: +27 (0)10 594 5610. PV E-posadres: pv@trinitypharma.co.za

Hierdie inligtingstuk was hersien in
26 Julie 2023

Registrasienommer
55/7.2/0361

Toegang tot die ooreenstemmende Professionele Inligting
www.trinitypharma.co.za