AMENDED PATIENT INFORMATION LEAFLET (CLEAN COPY)

SCHEDULING STATUS

S4

PHENYLCORD 10 mg/ml

(Solution for injection)

Phenylephrine hydrochloride

Contains sodium metabisulphite: 2 mg/ml

Read all of this leaflet carefully before you are given PHENYLCORD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What PHENYLCORD is and what it is used for
2. What you need to know before you are given PHENYLCORD
3. How PHENYLCORD will be given to you
4. Possible side effects
5. How PHENYLCORD will be stored
6. Contents of the pack and other information

1. What PHENYLCORD is and what it is used for

- PHENYLCORD contains the active ingredient phenylephrine hydrochloride. It belongs to a group of medicines called adrenergic and dopaminergic medicines, which raise blood pressure by constricting blood vessels.
- PHENYLCORD is used to treat low blood pressure, which may be caused by widespread infection

or certain anaesthetic medicines.

2. What you need to know before you are given PHENYLCORD

You should not be given PHENYLCORD:

- If you are hypersensitive (allergic) to phenylephrine hydrochloride or any of the other ingredients of PHENYLCORD (listed in section 6)
- If you are a child
- If you suffer from uncontrolled high blood pressure
- If you have an overactive thyroid
- If you have any heart disease or blood circulatory problems
- If you have slower than normal heart rate
- If you taking medicines which cause a narrowing of the blood vessels, such as pseudoephedrine, methylphenidate, ephedrine
- If you are taking medicines such as etilefrine, midodrine, naphazoline, oxymetazoline, synephrine, tetryzoline, tuaminoheptane or tymazoline which also cause a narrowing of the blood vessels
- If you are taking non-selective monoamine oxidase inhibitors (MAOIs) used to treat depression (e.g. iproniazid, nialamide, linezolid, phenelzine), or have taken them in the last 14 days
- If you have an enlarged prostate

Warnings and precautions

Tell your doctor or healthcare provider before being given this injection:

- If you have diabetes
- If you have high blood pressure
- If you have been told you have a weakening of blood vessel walls, called an aneurysm
- If you have an uncontrolled overactive thyroid
- If you have any heart disease
- If you have an irregular, very slow or very fast heart rate

- If you have angina (chest pain due to reduced blood to the heart)
- If you suffer from glaucoma (increased pressure in the eye)
- If you have a dysfunction of the nerves that regulate non-voluntary body functions, such as heart rate, blood pressure and sweating
- If you have any liver or kidney problems

Children and adolescents

PHENYLCORD is not recommended for use in children.

Other medicines and PHENYLCORD

- Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- Please talk to your doctor or pharmacist if you are taking any of the following medicines as they may cause changes in your heart rhythm or a severe increase in blood pressure when given with PHENYLCORD. They may also cause increased side effects when given with PHENYLCORD:
    - Bromocriptine, lisuride, cabergoline, pergolide, selegiline – used in the treatment of Parkinson's disease
    - dihydroergotamine, ergotamine, methylergometrine, methysergide – used for treatment of migraines
    - Linezolid, an antibiotic
    - Desipramine, imipramine, nortriptyline, venlafaxine – used to treat depression and anxiety
    - Moclobemide and toloxatone – these are another class of antidepressants
    - Guanethidine, which is used for treatment of high blood pressure
    - Digoxin and quinidine – used for certain heart conditions and to correct heart rhythm
    - Any other medicines used to treat high blood pressure, including water tablets (diuretics)
    - Eye drops to treat glaucoma
    - Medicines such as reserpine, used to treat high blood pressure
    - Oxytocic medicines – used during and after childbirth

- Medicines known as alpha blockers (used to treat Reynaud's syndrome or tumour of the adrenal gland e.g. doxazosin, labetalol, prazosin, haloperidol, phenothiazines) or beta blockers (used to treat heart conditions or reduce blood pressure).
- Atomoxetine – used to treat attention deficit/hyperactivity disorder (ADHD)
- Lithium carbonate – used for certain mental disorders.

Pregnancy, breastfeeding and fertility

PHENYLCORD should not be used during pregnancy and breastfeeding.

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 healthcare provider for advice before being given this medicine.

Driving and using machines

PHENYLCORD can cause dizziness, fainting, difficulty breathing and muscle weakness, which may affect your ability to drive or use machines.

It is not always possible to predict to what extent PHENYLCORD 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 PHENYLCORD affects you.

PHENYLCORD contains sodium metabisulphite

Sodium metabisulphite may cause allergic reactions and difficulty breathing.

3. How PHENYLCORD will be given to you

- PHENYLCORD will be given to you by a person who is qualified to do so.
- It will be given to you as an injection into your vein.
- Your doctor will work out the dose you need according to your weight and how you respond
- If you have the impression that the effect of PHENYLCORD is too strong or too weak, tell your doctor.

If you receive more PHENYLCORD than you should

Since a doctor will administer PHENYLCORD, he/she will control the dosage. However, in the event of an overdosage your doctor will manage the overdosage.

4. Possible side effects

- PHENYLCORD can have side effects.
- Not all side effects reported for PHENYLCORD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PHENYLCORD, please consult your doctor, pharmacist or other healthcare professional for advice.

If you experience any of the following tell your doctor immediately or go to the casualty department at your nearest hospital:

- Difficulty breathing
- Severe skin rash or itching
- Swollen tongue, lips or airways

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

Tell your doctor immediately if you experience any of the following:

- headache, dizziness, altered mental status, shortness of breath, chest pain, decreased urine output, vomiting, or changes in vision – these may be signs of a severe rise in your blood pressure.

These are serious side effects. They may indicate a severe increase in your blood pressure and you may need urgent medical attention.

- Tell your doctor if you notice any of the following:
  - <u>Frequent side effects</u>
    - Headache
  - <u>Less frequent side effects</u>

- Feeling anxious, excitable, agitated or confused
- Feelings of nervousness, restlessness
- Tingling and cooling feeling on the skin, tremor
- Difficulty sleeping
- Blurry vision due to dilation of pupils
- Heart beats faster or slower, pounding heart
- Increase or decrease in blood pressure
- Dizziness, fainting, flushing
- Difficulty breathing
- Nausea, vomiting
- Increased saliva production
- Sweating, pale skin
- reddening, swelling, pain, a burning sensation, ulceration of skin (at injection site)
- muscle weakness
- difficulty passing urine

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of PHENYLCORD.

5. How PHENYLCORD will be stored

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the vial in the outer carton to protect from light.

After dilution, chemical and physical in-use stability has been demonstrated for 4 hours at room temperature (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 the use are the responsibility of the user and would not normally be longer than 24 hours at 2° to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6. Contents of the pack and other information

What PHENYLCORD contains

- The active substance is phenylephrine hydrochloride.
- Each 1 ml vial contains 10 mg phenylephrine hydrochloride.
- The other ingredients are: sodium chloride, sodium citrate, citric acid monohydrate, sodium metabisulphite, hydrochloric acid, sodium hydroxide and water for injection.

What PHENYLCORD looks like and contents of the pack

PHENYLCORD 10 mg/ml solution for injection is a clear, colourless solution filled in a clear glass vial. When examined under suitable conditions of visibility it should be practically free from foreign particles.

Contents of the pack:

PHENYLCORD 10 mg/ml solution for injection is packed in a 2 ml siliconised glass vial (type I), with a 13 mm bromobutyl RTS rubber stopper and 13 mm aluminium royal blue flip off seal.

Pack size: 2 ml vial in pack size of 1 vial, 10 vials, or 25 vials per pack. Not all pack sizes may be marketed

HOLDER OF CERTIFICATE OF REGISTRATION

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