PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PHARMA-Q CIMETIDINE INJECTION 200 mg/2 ml solution for injection

Cimetidine hydrochloride

Sugar free

Read all of this leaflet carefully before you are administered PHARMA-Q CIMETIDINE INJECTION

- 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 PHARMA-Q CIMETIDINE INJECTION is and what it is used for
2. What you need to know before PHARMA-Q CIMETIDINE INJECTION is administered to you.
3. How PHARMA-Q CIMETIDINE INJECTION will be administered.
4. Possible side effects.
5. How to store PHARMA-Q CIMETIDINE INJECTION.
6. Contents of the pack and other information.

1. What PHARMA-Q CIMETIDINE INJECTION is and what it is used for

Cimetidine is known as a histamine H_2 receptor antagonist, and it inhibits the natural production of acid in the stomach. Excess acid in the stomach can cause ulcers, heartburn, and other medical complications. Cimetidine is therefore used

to treat and relieve the symptoms of excess production of stomach acid. It will also help in the healing of ulcers and reduce the inflammation due to these conditions. Your doctor has prescribed PHARMA-Q CIMETIDINE INJECTION for you because you may be suffering from one of the following conditions

- Gastric and duodenal ulcers (ulcers of the stomach or small intestine)
- Oesophageal reflux (acid being pushed back into the food pipe causing heartburn)
- Zollinger-Ellison syndrome (increased acid production due to tumours of the pancreas or small intestine)
- Medical conditions which require the reduction of acid production in the stomach.

You doctor may also prescribe PHARMA-Q CIMETIDINE INJECTION for you, to manage your medical condition

- If you are a patient who suffers from a high risk of bleeding of the upper gastro-intestinal tract due to liver failure
- If you are a patient who have had treatment with medicines which depress your immune system e.g., following a kidney transplant.

2. What you need to know before PHARMA-Q CIMETIDINE INJECTION is administered to you

PHARMA-Q CIMETIDINE INJECTION should not be administered to you

- If you are hypersensitive (allergic) to cimetidine or any of the other ingredients of PHARMA-Q CIMETIDINE INJECTION (listed in section 6).
- If the patient is an infant under one year of age If you are pregnant or breastfeeding as the safety in pregnancy and lactation has not been established.

You must not be administered PHARMA-Q CIMETIDINE INJECTION if any of the above applies to you. If you are not sure, talk to your doctor before PHARMA-Q CIMETIDINE INJECTION is administered to you.

Warnings and precautions

Take special care with PHARMA-Q CIMETIDINE INJECTION

- If you suffer from stomach ulcers, the possibility of cancer will first be excluded before you are given this injection, since it may hide your symptoms and allow temporary healing of stomach cancer, delaying your diagnoses
- Your doctor will reduce your dosage if you suffer from impaired kidney function
- If you are given this injection directly into a vein, it will be injected slowly, to avoid a drop in blood pressure or any heart problems
- This injection will first be diluted and then given by drip directly into your vein, if you suffer from any heart problems
- You may be at an increased risk of developing community acquired pneumonia (inflammation of the lungs) if you are old, suffer from long term lung disease, have increased blood sugar levels or you have a weak immune system.

Other medicines and PHARMA-Q CIMETIDINE INJECTION

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

PHARMA-Q CIMETIDINE INJECTION may inhibit the way medicines are cleared from the body, and this may prolong the elimination of certain medicines and may increase their blood concentrations. A reduction in the dosages of these medicines will have to be made in order to prevent toxicity.

Tell your doctor if you are taking any of the following medicines

Significant or potentially significant interactions may occur with

- Medicines used to control heart rhythms e.g., lignocaine and procainamide.
- Medicines used to prevent or control fits e.g., phenytoin and carbamazepine.
- Medicines used to control increased blood sugar levels e.g., glipizide, metformin.
- Medicines used to thin your blood e.g., warfarin.
- Medicines used to treat depression e.g., amitriptyline.
- Medicines used for the heart e.g., nifedipine.
- Medicines used to suppress the immune system e.g., ciclosporin, tacrolimus.
- Medicines used to treat bacterial infections e.g., chloramphenicol.
- Medicines used to treat mental disorders e.g., chlorpromazine.
- Medicines used to treat respiratory diseases e.g., theophylline.
- Medicines used to relax muscles in anaesthesia e.g., suxamethonium.
- Medicines which are strong painkillers e.g., pethidine, morphine.
- Medicines used to treat vasopressin.
- Medicines used to treat HIV/AIDS (e.g., atazanavir).
- Medicines used to treat fungal (yeast) infections (e.g., ketoconazole, itraconazole, posaconazole).
- Medicines used treat tumours or cancer (e.g., carmustine, fluorouracil, epirubicin), or if you are having radiation therapy.
- Vitamin $B_{12.}$

Close monitoring of blood concentrations will be carried out and your dosage will be adjusted accordingly.

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 PHARMA-Q CIMETIDINE INJECTION.

You will not be given PHARMA-Q CIMETIDINE INJECTION if you are pregnant or breast-feeding as the safety in pregnancy and breastfeeding has not been established.

This medicine may cross the placental barrier and may be excreted into your breast milk.

Driving and using machines

You should avoid potentially hazardous tasks such as driving and operating machinery until you know how PHARMA-Q CIMETIDINE INJECTION affects you.

3. How PHARMA-Q CIMETIDINE INJECTION will be administered

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

You will receive PHARMA-Q CIMETIDINE INJECTION through an injection directly into your vein or injected into your muscle. You will not be expected to give yourself PHARMA-Q CIMETIDINE INJECTION. PHARMA-Q CIMETIDINE INJECTION will be given to you by a person who is qualified to do so in a hospital setting. Your doctor will choose the dose that is right for you. Your total daily dose by any route will not normally exceed 2,4 g.

Adults

The usual dose is

- 200 mg to 400 mg every four to six hours
- The usual dose by intravenous injection (injected directly into the vein) will be 200 mg
- It will be given ***slowly*** over at least 2 minutes
- It may be repeated every 4 to 6 hours
- If a larger dose is required, or if you suffer from any heart problems, it will be given by administration of a drip connected directly into a vein

- If your dose is administered by intramuscular injection (directly into the muscle), the usual dose will be 200 mg, which may be repeated at intervals of 4 to 6 hours.

Special populations

- **Patients with impaired renal function**

If you suffer from impaired kidney function, your doctor will reduce your dosage according to your level of impairment

- **Elderly**

If you are old, the normal dosages will be used, unless you suffer from kidney problems which markedly impair your kidney function. Dosages will be reduced in such circumstances.

- **Children**

This injection will not be recommended to children. It will also not be administered to infants under the age of one year.

If you have the impression that the effect of PHARMA-Q CIMETIDINE INJECTION is too strong or too weak, talk to your doctor or pharmacist.

If you receive more PHARMA-Q CIMETIDINE INJECTION than you should

Since a health care provider will administer PHARMA-Q CIMETIDINE INJECTION, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

PHARMA-Q CIMETIDINE INJECTION overdose

- Your treatment will be aimed at treating your symptoms and giving you medical support
- If you suffer from renal failure, dialysis (artificial filtration and purification of the blood) may be necessary.

If you forget to receive PHARMA-Q CIMETIDINE INJECTION

Since a health care provider will administer PHARMA-Q CIMETIDINE INJECTION, it is unlikely that the dose will be missed.

4. Possible side effects

PHARMA-Q CIMETIDINE INJECTION can have side effects.

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

If any of the following serious side effects occur, stop receiving PHARMA-Q CIMETIDINE INJECTION and tell your doctor immediately or go to the casualty department at your nearest hospital

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing, rash or itching,
- fainting.

These serious side effects and you may have had an allergic reaction to PHARMA-Q CIMETIDINE INJECTION**.** You may need urgent medical care or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following

- Increased heart rate, decreased heart rhythm that originates from the sinus node of the heart and heart block
- Decreased red and white blood cells and platelets
- Liver toxicity, inflammation of the liver and increases in blood transaminase levels (liver enzymes) which could indicate liver damage.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following

Frequent

- Headache and dizziness.
- Diarrhoea.
- Skin rashes.
- Muscle aches and pain (Myalgia).
- Tiredness

Less frequent

- Low number of granulocytes (a type of white blood cell) in the blood.
- Deficiency of platelets in the blood.
- A reduction in the number of white cells in the blood.
- A condition that occurs when your body stops producing enough new blood cells.
- Anaphylaxis.
- Depression, hallucinations and reversible confusional states.
- An abnormally rapid heart rate, or slow heartbeat.
- Inflammation of the pancreas (pancreatitis) or liver (hepatitis).
- Hair loss.

- Joint pain.
- Enlargement of a man's breasts and reversible impotence.
- White discharge from the nipple.
- Fever.

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 Reactions 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 PHARMA-Q CIMETIDINE INJECTION.

5. How to store PHARMA-Q CIMETIDINE INJECTION

Store all medicines out of reach of children.

Keep ampoule in container until required for administration.

Store at or below 25 °C.

Protect from light

Do not use after the expiry date stated on the 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 PHARMA-Q CIMETIDINE INJECTION contains

- The active substance is cimetidine as hydrochloride.

Each 2 ml contains 200 mg cimetidine as hydrochloride.

- The other ingredients are hydrochloric acid (37% *m/m*) and water for injections

What PHARMA-Q CIMETIDINE INJECTION looks like and contents of the pack

A clear, colourless solution in 2 ml clear colourless ampoules.

2 ml clear, type 1, colourless ampoules in containers of 10 or 100.

Holder of Certificate of Registration

PHARMA-Q HOLDINGS (Pty) Ltd

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Johannesburg

This leaflet was last revised in

29 August 2022

Registration number

32/11.4.3/0196

Access to the corresponding Professional Information

Can be obtained on SAHPRA’s website