Approved Patient Information Leaflet for Medicines for Human Use:

IVACID IV

SCHEDULING STATUS: S4

IVACID IV lyophilised powder for injection

Pantoprazole

Sugar free

Read all of this leaflet carefully before IVACID IV is administered to you.

- 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 IVACID IV is and what it is used for

IVACID IV contains the active substance pantoprazole. IVACID IV belongs to a group of medicines called "proton pump inhibitors". They work by reducing the amount of acid produced in your stomach.

It is used for treating the following acid-related diseases of the stomach and intestine in adults:

- Ulcers (sores that are slow to heal or keep returning) in the lining of the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Reflux oesophagitis also called gastroesophageal reflux disease (GERD), where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Zollinger-Ellison Syndrome, when excess stomach acid is produced due to a growth in the pancreas.
- Duodenal ulcers which are infected with bacteria called "*Helicobacter pylori*". If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

This preparation is injected into a vein and will only be given to you if your doctor thinks pantoprazole injections are more suitable for you at the moment than pantoprazole tablets. Tablets will replace your injections as soon as your doctor sees fit.

2. What you need to know before IVACID IV is administered to you

IVACID IV should not be administered to you

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of IVACID IV (listed in section 6).
- if you are pregnant or breastfeeding.
- if you have severely impaired liver function.
- if you are also taking medicines called atazanavir or nelfinavir (used in HIV-1 treatment)
- if you (or your child) are younger than 18 years as safety and efficacy in children have not been established.

Warnings and precautions

Tell your doctor or health care provider before being given IVACID IV injection:

IVACID IV may hide the symptoms of other diseases.

Therefore, if any of the following happen to you before you start taking IVACID IV, or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing
- You get stomach pain or indigestion
- You begin to vomit food or blood
- You pass black, tarry stools (blood-stained faeces).

Your doctor may decide that you need some tests to rule out malignant disease because IVACID IV also alleviates the symptoms of stomach cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

Tell your doctor if you:

- experience severe or persistent diarrhoea, as IVACID IV has been associated with an increased risk of infectious diarrhoea caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away
- have kidney problems as IVACID IV can cause a type of kidney problem (acute interstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including IVACID IV, may develop a kidney problem called acute nephritis that can happen at any time during treatment with IVACID IV. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine
- are taking a medicine called atazanavir or nelfinavir (see section 2, IVACID IV should not be administered to you), ask your doctor for specific advice

- have liver problems. Please tell your doctor if you ever had problems with your liver in the past, therefore your doctor may want to reduce your dose. He will check your liver enzymes more frequently. In the case of a rise of liver enzymes the treatment should be stopped
- suffer from a condition called osteoporosis (weak bones which are easily broken) or if you are taking medicines called corticosteroids (which can increase the risk of osteoporosis)
- suffer from symptoms of low magnesium levels such as tiredness, involuntary muscle contractions, metal confusion, convulsions (fits), dizziness, disturbances in the heart rate. Taking IVACID IV for more than three months may lower the levels of magnesium in your blood. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may want to measure your magnesium levels before starting treatment with IVACID IV or decide to perform regular blood tests during treatment to monitor your levels of magnesium, especially if you are taking a medicine called digoxin or other medicines that decrease your magnesium levels (e.g. diuretic medicines also called water pills)
- get a rash or skin reaction, especially after being exposed to the sun, after treatment with IVACID IV. Sometimes the rash or skin reaction can be accompanied by other ill-effects like pain in your joints. Tell your doctor as soon as you can, as you may need to stop your treatment with IVACID IV
- have a problem with vitamin B_{12} levels in your body, especially if you have been taking any acid-blocking medicines over a long period of time (i.e. longer than 3 years), because IVACID IV may interfere with the absorption of vitamin B_{12}
- start suffering from stomach infections and runny tummy (diarrhoea) that does not improve
- are due to have a specific blood test (Chromogranin A) used to diagnose tumours arising from neuroendocrine cells (nerve cells that receive messages (signals) from the nervous system and respond by making and releasing hormones). IVACID IV treatment should be stopped for at least 5 days before the blood test measurements are taken as it increases the Chromogranin A levels
- are taking methotrexate, a medicine used to treat cancer, rheumatoid arthritis and psoriasis.

Children and adolescents

IVACID IV is not recommended for use in children as it has not been proven to work in children below 18 years of age.

Other medicines and IVACID IV

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

IVACID IV may have effects on other medicine

IVACID IV may weaken the effect of the following medicines:

- Nelfinavir and atazanavir (used to treat HIV infection) – the blood levels may be decreased when taken together with IVACID IV and may cause the HIV to become resistant to this HIV medicine and cause it to stop working effectively. You must not take IVACID IV with nelfinavir and atazanavir.
- Clopidogrel (used to treat blood clots) – taking IVACID IV together with clopidogrel or 12 hours apart results in a lower concentration of clopidogrel in the blood, thereby weakening the blood thinning effect and increasing the risk of blood clotting. You should not use IVACID IV if you are taking medicine containing clopidogrel.
- Ketoconazole, itraconazole, posaconazole (used to treat infections caused by a fungus).
- Ampicillin medicines (antibiotics used to treat bacterial infections).
- Iron supplements (used to treat anaemia (a condition characterized by the lack of healthy red blood cells or haemoglobin). Iron plays a key role in making red blood cells that transport oxygen molecules throughout the body).
- Erlotinib (used to treat certain types of cancer).

IVACID IV may strengthen the effect of the following medicines:

- Warfarin or other vitamin K blockers (used to thin the blood) – this may lead to excessive bleeding. Your doctor may need to take regular blood tests to check how well your blood can clot.

- Cilostazol (used to improve the symptoms of a certain blood flow problem in the legs e.g. pain in the legs that worsens when walking and improves when resting that is caused by narrowing of the blood vessels that supply blood to the legs).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy). This can cause you to fall into a deep sleep or experience blurred or double vision.
- Phenytoin (used to treat epilepsy) - Your doctor may need to take blood tests to check your phenytoin blood levels.
- Tacrolimus (used to prevent rejection of transplanted organs). Your doctor may need to take blood tests to check the tacrolimus concentrations in your blood and to check your kidney function (creatinine clearance) and then may adjust your dosage of tacrolimus if needed.
- Methotrexate (used to treat certain types of cancer or to control severe psoriasis or rheumatoid arthritis). If you are taking a high dose of methotrexate, your doctor may temporarily stop your IVACID IV treatment because pantoprazole can increase levels of methotrexate in the blood.

Other medicine may have effects on IVACID IV

The following medicines may weaken the effect of IVACID IV:

- Rifampicin (used to treat tuberculosis)
- St John's wort (*Hypericum perforatum*) (a complementary medicine used to treat mild depression).

The following medicines may increase the blood levels of pantoprazole and strengthen the effect of IVACID IV or lead to more unwanted side effects:

- Voriconazole (used to treat infections caused by a fungus). When voriconazole and pantoprazole as in IVACID IV are given together, the blood levels of either voriconazole or pantoprazole can increase
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.

IVACID IV with food and drink

IVACID IV may be administered with food or on an empty stomach.

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 health care provider for advice before taking this medicine.

You must not be administered IVACID IV if you are pregnant or breastfeeding your baby (see section 2, IVACID IV should not be administered to you).

Driving and using machines

IVACID IV may cause dizziness or blurred vision. Make sure how treatment with IVACID IV affects you before driving or using machinery as loss of concentration could lead to accidents.

3. How IVACID IV should be administered to you

IVACID IV is given to patients who cannot take oral medication.

Your doctor will decide how much and for how long you must be administered IVACID IV. This will depend on your condition and how old you are.

IVACID IV will be given to you as an infusion (a drip for 2 – 15 minutes) into a large vein.

You will not be expected to give yourself IVACID IV. It will be prepared by and administered to you by a person who is qualified to do so.

As soon as oral therapy is possible, your doctor will change over from intravenous to oral medicine.

If you have the impression that the effect of IVACID IV is too strong or too weak, talk to your doctor, pharmacist or nurse.

If are administered more IVACID IV than you should

Since a health care provider will administer IVACID IV, these doses are carefully checked by your nurse or your doctor so an overdose is extremely unlikely. There are no known symptoms of overdose. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of IVACID IV

Your doctor or health care provider will have instructions about when to give IVACID IV. It is unlikely that you will not be given IVACID IV as it is prescribed and thus miss a dose. If you think that you may have missed a dose, then talk to your doctor or health care provider.

If you have any further questions about the use of IVACID IV, ask your doctor or other health care provider.

4. Possible side effects

IVACID IV can have side effects.

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

If any of the following happens, stop receiving IVACID IV and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe allergic reaction which causes sudden wheezing, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing or fainting

- severe skin rash, reddening of the skin with blisters or peeling, itching, or hives (elevated patches of red or pale skin that often itch) with flushing or ulcers and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (these are signs and symptoms of a very serious condition called Stevens-Johnson syndrome) or a severe rash with reddening and swelling that may lead to blistering and peeling of the skin and resembles burns (toxic epidermal necrolysis)
- liver inflammation (hepatitis), which may include jaundice which can cause yellow skin and eyes, dark urine and tiredness; liver failure
- symptoms such as severe (bloody or repeated watery) diarrhoea, with or without fever, abdominal pain or tenderness (you may have bowel inflammation caused by a bacterial infection).

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

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

- signs of infection, such as high temperature, chills, shivering, sore throat, mouth ulcers, headaches, sweating, flu-like symptoms or weakness, bleeding or bruising easily, pale skin and/or breathlessness. This may be the result of blood disorders (such as agranulocytosis (lack of white blood cells), leukopenia (lower-than-normal levels of white blood cells) and pancytopenia (low counts for all three types of blood cells: red blood cells, white blood cells, and platelets)
- increased fat levels in blood (hyperlipidaemias and increases in triglycerides and cholesterol); these will be identified through blood tests
- experiencing tiredness, a lack of energy and enthusiasm, intermittent muscular spasms or cramps, mental confusion, disorientation, sudden, violent, irregular, involuntary muscle contraction, dizziness and abnormal heart rhythms. These can be symptoms of low blood sodium and low blood magnesium (which may result in low blood calcium and/or blood potassium) and can happen if you are on IVACID

IV. for more than three months. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium

- feeling depressed, disorientated, confused, or seeing, feeling or hearing things that are not there (hallucinations)
- effects on your stomach or gut: Diarrhoea that does not improve (if the diarrhoea is severe, it may be necessary to stop treatment with IVACID IV), constipation, abdominal pain and discomfort, non-cancerous (benign) abnormal tissue growth (polyps) in the stomach
- changes in blood tests that check how the liver is working
- skin rash, itchy skin, lumpy rash (hives), skin sensitivity to light
- rapid and sudden swelling of the area beneath the skin (angioedema) affecting the deeper layers of the skin, especially in areas with loose areas of tissue, such as the face and throat, as well as the limbs and genitals. In serious cases, there may be a severe allergic reaction known as anaphylaxis
- itchy skin rash with blood spots, bruising or discolouring of the skin leading to red patches characterised by bull's-eye-shaped lesions (erythema multiforme)
- osteoporotic bone fractures of the hip, wrist or spine (osteoporosis is a condition where certain bones become brittle), joint pains (arthralgia), muscle pains (myalgia) or muscle spasms
- decrease in urine volumes or if you suspect that there is blood your urine or if you are experiencing weakness, nausea and loss of appetite as this may be due to severe kidney problems (acute interstitial nephritis). This can lead to chronic renal failure if it is not diagnosed quickly. Your doctor will likely discontinue your treatment with IVACID IV
- enlargement of breasts in men
- swelling of hands, ankles or feet (peripheral oedema).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected.

Less frequent side effects:

- weight changes
- trouble in sleeping
- headache
- dizziness
- taste disturbances
- blurred vision
- nausea
- vomiting
- bloating and flatulence (wind)
- dry mouth
- abnormal physical weakness or lack of energy
- tiredness and a feeling of overall discomfort, illness, or generally not feeling well
- 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 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 IVACID IV.

5. How to store IVACID IV

Unopened vial:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Keep the vial in the carton until required for use.
- Do not use IVACID IV after the expiry date stated on the label or carton. The expiry date refers to the last day of that month.

Reconstituted and/or diluted solution:

- After preparation of the solution in physiological sodium chloride 9 mg/mL (0,9 %) solution or 5 % glucose, it must be stored at or below 25 °C and used within 12 hours and any unused portion must be discarded after 12 hours.
- From a microbiological point of view, the product should be used immediately.
- The contents of the vial are for single use only. Any product that has remained in the container or the visual appearance of which has changed (e.g. if cloudiness or precipitation is observed) should be disposed of in accordance with local requirements.

Return all unused medicines to your pharmacist.

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

6. Contents of the pack and other information

What IVACID IV contains

- The active substance is pantoprazole. Each IVACID IV vial contains Pantoprazole sodium sesquihydrate equivalent to pantoprazole 40 mg.
- The other ingredients are

sodium citrate dihydrate

mannitol

sodium hydroxide (alkalising agent)

What IVACID IV looks like and contents of the pack

Unopened vial:

A white to off-white lyophilised powder for solution for injection.

IVACID IV is supplied in a 10 mL Type I amber glass vial with a grey chlorobutyl rubber stopper and yellow polypropylene flip-off cap with an aluminium seal containing 40 mg lyophilised powder for solution for injection.

Pack size: 1 x 10 mL or 5 x 10 mL vial packed into a cardboard carton together with a leaflet.

Reconstituted and/or diluted solution:

The reconstituted solution is clear and brownish-yellow coloured.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: https://austell.co.za/product-info/

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