

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ASPEPRAZ 40 mg INJECTION

lyophilized powder for solution for injection/infusion

Esomeprazole

Sugar free

Read all of this leaflet carefully before ASPEPRAZ 40 mg INJECTION is administered to you

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

What is in this leaflet

1. What ASPEPRAZ 40 mg INJECTION is and what it is used for
2. What you need to know before ASPEPRAZ 40 mg INJECTION is administered to you
3. How ASPEPRAZ 40 mg INJECTION will be administered to you
4. Possible side effects
5. How to store ASPEPRAZ 40 mg INJECTION
6. Contents of the pack and other information

1. What ASPEPRAZ 40 MG INJECTION is and what is it used for

ASPEPRAZ 40 mg INJECTION is used for a condition known as Gastro-oesophageal Reflux Disease (GORD).

Gastro-oesophageal reflux disease:

- Treatment of inflammation of the oesophagus which is caused by acid reflux.
- Long-term management of patients who have healed from inflammation of the

oesophagus and to prevent relapse in such patients.

- Treatment of severe symptoms of acid reflux disease.

ASPEPRAZ 40 mg INJECTION is also used for the prevention of rebleeding in patients who have undergone therapeutic endoscopy (a procedure used to look inside the stomach using an endoscope). Your doctor will prescribe ASPEPRAZ 40 mg INJECTION for the shortest possible time.

2. What you need to know before ASPEPRAZ 40 mg INJECTION is administered to you

ASPEPRAZ 40 mg INJECTION should not be administered to you:

- If you are hypersensitive (allergic) to esomeprazole or to any of the other ingredients of ASPEPRAZ 40 mg INJECTION (see section 6).
- If you are allergic to substituted benzimidazoles.
- If you are pregnant or breastfeeding.
- If you take nelfinavir or atazanavir, used to treat HIV infection.
- If you take clopidogrel, used to prevent blood clots.

ASPEPRAZ 40 mg INJECTION is contraindicated in children.

Warnings and precautions

Take special care with ASPEPRAZ 40 mg INJECTION:

- Seek immediate care if you experience unintentional loss of weight, repeated vomiting, difficulty swallowing, vomiting of blood, if you look pale or and feel weak (anaemia) or if you notice blood in your stool or your stool appears black. Your doctor may decide that you need some tests to rule out malignant disease because ASPEPRAZ 40 mg INJECTION also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be

considered.

- Using ASPEPRAZ 40 mg INJECTION may increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you develop lesions (deterioration of tissue due to injury or disease) especially in sun-exposed areas of the skin, and if accompanied by severe joint pains consult your healthcare provider as this could be signs of a diseases called subacute cutaneous lupus erythematosus.

The following should be considered:

- ASPEPRAZ 40 mg INJECTION, as with all acid-blocking medicines, may reduce the absorption of vitamin B₁₂ (cyanocobalamin). This should be considered in patients with reduced body stores or risk factors for reduced vitamin B₁₂ absorption on long-term therapy.
- If you are on ASPEPRAZ 40 mg INJECTION for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- You should seek immediate help from a healthcare professional if you experience watery stools, abdominal pain and fever whilst ASPEPRAZ 40 mg INJECTION is being administered to you.
- Proton pump inhibitors, such as ASPEPRAZ 40 mg INJECTION, especially if used in high doses and over long durations (> 1 year), may increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. If you are at risk of osteoporosis, you should speak to your doctor.

ASPEPRAZ 40 mg INJECTION can cause an increased risk of kidney disease leading to kidney failure. This is called tubulointerstitial nephritis and you may have increased urine output, blood in your urine or dark urine, changes in mental status, such as drowsiness or confusion, swelling of any area of your body.

Other medicines with ASPEPRAZ 40 mg INJECTION

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

Also see section: Do not take ASPEPRAZ 40 mg INJECTION.

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

- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Citalopram, imipramine or clomipramine (used to treat depression).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop having ASPEPRAZ 40 mg INJECTION.
- When clopidogrel (used to prevent blood clots) is given together with ASPEPRAZ 40 mg INJECTION, the amount of clopidogrel in the blood is decreased. This will influence the way clopidogrel works.
- Medicines that are used to thin your blood, such as warfarin. Your doctor may need to monitor you when you start or stop having ASPEPRAZ 40 mg INJECTION.
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply).
- Digoxin (used for heart problems).
- Methotrexate (used for the treatment of e.g. certain cancers, psoriasis, arthritis) - if you

are taking a high dose of methotrexate, your doctor may temporarily stop your ASPEPRAZ 40 mg INJECTION treatment.

- Tacrolimus (used to prevent tissue rejection in organ transplantation).
- Rifampicin (used for treatment of tuberculosis).
- St. John's wort (*Hypericum perforatum*) (used to treat depression).

Pregnancy and breastfeeding

The safe use of ASPEPRAZ 40 mg INJECTION if you are pregnant or breastfeeding has not been established (see Do not take ASPEPRAZ 40 mg INJECTION).

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 receiving ASPEPRAZ 40 mg INJECTION.

Driving and using machinery

ASPEPRAZ 40 mg INJECTION will be administered in a hospital setting. Since adverse reactions such as blurred vision and dizziness have been reported in patients receiving ASPEPRAZ 40 mg INJECTION, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that ASPEPRAZ 40 mg INJECTION does not adversely affect your ability to do so (see Possible side effects).

3. How ASPEPRAZ 40 mg INJECTION will be administered to you

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

ASPEPRAZ 40 mg INJECTION will be administered to you in a hospital setting and your healthcare professional will prescribe a specific dose according to your condition.

The usual dose is 20 mg to 40 mg of ASPEPRAZ 40 mg injection.

Your healthcare professional will tell you how long your treatment with ASPEPRAZ 40 mg

INJECTION will last.

If you have the impression that the effect of ASPEPRAZ 40 mg INJECTION is too strong or too weak, tell your doctor or pharmacist.

If you receive more ASPEPRAZ 40 mg INJECTION than you should

If your healthcare professional gives you more ASPEPRAZ 40 mg INJECTION than they should:

- You may experience drowsiness, headaches and an increase in the rate of your heart beat.

Since a healthcare professional will administer ASPEPRAZ 40 mg INJECTION, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

Since a healthcare provider will administer ASPEPRAZ 40 mg INJECTION, it is unlikely that the dose will be missed.

4. Possible side effects

ASPEPRAZ 40 mg INJECTION can have side effects.

Not all side effects reported for ASPEPRAZ 40 mg INJECTION are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while ASPEPRAZ 40 mg INJECTION is being administered to you, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving ASPEPRAZ 40 mg 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,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) and Subacute cutaneous lupus erythematosus (SCLE).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASPEPRAZ 40 mg INJECTION. You may need urgent medical attention or hospitalisation.

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

- Severe pain in the chest (usually pain arising from the heart), faster heart beat; increased rate of heart beat or abnormally slow pulse rate; slower heartbeat.
- If you lose a lot of weight for no reason and have problems swallowing.
- If you get stomach pain or indigestion.
- If you begin to vomit food or blood.
- If you pass black stools (blood-stained faeces).
- Fracture of the hip, wrists or spine.
- Fatigue, confusion, convulsions, dizziness and abnormal heart rhythm.
- Yellowing of the skin and eyes, dark urine and tiredness as these may be symptoms of liver problems.
- Painful urination and low back pain as these may be symptoms of kidney problems.
- Inflammation of the pancreas which causes severe pain in the abdomen and back.
- Changes in blood count including agranulocytosis (lack of white blood cells),
- low levels of sodium, calcium and potassium in the blood,

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:

- Headache,
- excessive stomach or intestinal gas,
- constipation.

Less frequent side effects:

- Swelling of the hands and feet due to water retention,
- difficulty to sleep, agitation, depression, aggression and hallucination (senses created by the mind but that are not real),
- tingling feelings such as pins and needles,
- feeling sleepy,
- taste disturbance,
- suddenly feeling wheezy or shortness of breath,
- inflammation of the inside of the mouth,
- blurred vision, eye disorders,
- ringing in the ears,
- joint and muscle pains,
- muscle weakness,
- increased sweating,
- enlarged breasts in men,
- generally feeling unwell and lacking energy,
- rash, hair loss, skin rash on exposure to sunshine,
- changes in blood tests that check how the liver is working,
- loss of male sexual ability,

- tiredness,
- injection site reaction.

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 SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of ASPEPRAZ 40 mg INJECTION.

5. How to store ASPEPRAZ 40 mg INJECTION

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light and moisture.

For reconstituted and diluted solution:

Physical and chemical stability for the reconstituted solution has been proven for 12 hours at 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 use are the responsibility of

the user and would normally not be longer than 24 hours at 2 °C to 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

For single use only. Discard any unused portion.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 ASPEPRAZ 40 mg INJECTION contains

The active substance is 40 mg of esomeprazole.

The other ingredient is disodium edetate.

Sugar free

What ASPEPRAZ 40 mg INJECTION looks like and contents of the pack

ASPEPRAZ 40 mg INJECTION powder: White or almost white, uniform, porous cake

ASPEPRAZ 40 mg INJECTION reconstituted solution: clear solution free from particulate matter.

ASPEPRAZ 40 mg INJECTION is packaged in a Ph.Eur type 1 15 ml clear glass vial, with an opaque gray Ph.Eur type 1 20 mm chlorobutyl stopper and an aluminium flip-off cap with a dark blue plastic cover. 10 vials are packed in a printed carton together with a leaflet.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 118 088

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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