

Patient information leaflet for JUBIGORD 20 and JUBIGORD 40

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

JUBIGORD (20 and 40 mg gastro-resistant tablets)

Esomeprazole

Contains sugar.

JUBIGORD 20: Each tablet contains 57,6 mg sucrose.

JUBIGORD 40: Each tablet contains 115,1 mg sucrose.

Read all of this leaflet carefully before you start taking JUBIGORD

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- JUBIGORD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What JUBIGORD is and what it is used for.
2. What you need to know before you take JUBIGORD.
3. How to take JUBIGORD.
4. Possible side effects.
5. How to store JUBIGORD.
6. Contents of the pack and other information.

1. What JUBIGORD is and what it is used for

Esomeprazole (contained in JUBIGORD) belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

JUBIGORD is used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the stomach or upper part of the gut (intestine) that 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.
- Stomach ulcers caused by medicines nonsteroidal anti-inflammatory drugs (NSAIDs). Esomeprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

2. What you need to know before you take JUBIGORD

Do not take JUBIGORD:

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of JUBIGORD (listed in section 6).
- If you are allergic to any other 'proton pump inhibitors'.
- If you are taking medicine for human immunodeficiency virus (HIV) treatment (atazanavir or nelfinavir).

Warnings and precautions

Tell your doctor or health care provider before taking JUBIGORD:

- if you have been experiencing indigestion;
- if you have been on continuous medication for longer than a year;
- if you have been taking a medication that contains clopidogrel (used in the treatment of blood clots);
- if you are due to have a specific blood test (Chromogranin A);
- if you have had previous intestinal conditions;
- if you develop severe diarrhoea that has watery stools, abdominal pain and fever;
- if you are taking JUBIGORD when necessary and your symptoms change;

- if you have a vitamin B₁₂ deficiency;
- if you develop tiredness, dizziness, tremor and muscle problems (hypomagnesaemia);
- if you have been diagnosed with osteoporosis (brittle bones) or are at risk of breaking your bones;
- if you develop 'butterfly rash' with sensitivity to sunlight (subacute cutaneous lupus erythematosus).
- if you have a kidney disorder. Taking JUBIGORD may lead to acute kidney injury and/or chronic kidney failure.

If any of these applies to you, tell your doctor or nurse before you are given JUBIGORD.

Children

JUBIGORD should not be used in children younger than 1 year.

Other medicines and JUBIGORD

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

It is particularly important that you mention the following:

- Itraconazole, ketoconazole voriconazole used in the treatment of fungal infections.
- Diazepam used in the treatment of anxiety.
- Medicines used to prevent fitting (phenytoin).
- Medicines used to prevent blood clotting (warfarin or clopidogrel).
- Medicine used to help the symptoms of intermittent claudication (aching pain in your legs when you walk or exercise that goes away when you rest) (cilostazol).
- Medicines used to speed up stomach emptying (cisapride).
- Digoxin used in the treatment of heart problems.
- Rifampicin used for the treatment of tuberculosis (TB).
- St. John's Wort – used to treat depression, or certain type of anti-malignancy medicines (such as erlotinib or another anti-malignancy medicine from the same class).
- JUBIGORD should not be taken at the same time as some medicines for HIV, such as atazanavir

and nelfinavir, as JUBIGORD may reduce the blood levels of your antiretroviral medicine.

- Tipranavir used to treat HIV.
- Clarithromycin, an antibiotic.
- Tacrolimus used to prevent organ transplant rejection.
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer). JUBIGORD may need to be temporarily withdrawn.

Taking JUBIGORD with food and drink

JUBIGORD may be taken with or without food.

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 JUBIGORD.

You should not take JUBIGORD if you are pregnant or breastfeeding your baby.

Driving and using machines

JUBIGORD may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery.

JUBIGORD contains sugar in the form of sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking JUBIGORD.

3. How to take JUBIGORD

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

Always take JUBIGORD exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended doses are given below:

Adults & adolescents (12 – 18 years):

- *Gastro-oesophageal reflux disease (GORD):*
 - To treat an inflamed food pipe caused by gastro-oesophageal reflux disease (GORD): 40 mg once daily for 4 weeks.
 - Long-term management of patients with healed inflammation: 20 mg once daily.
- *Patients requiring continued nonsteroidal anti-inflammatory drugs (NSAIDs) therapy:*
 - To prevent stomach ulcers if you are taking NSAIDs: 20 mg or 40 mg once daily.
- *Eradication of Helicobacter pylori and healing of Helicobacter pylori associated ulcers:*
 - 20 mg JUBIGORD with 1 g amoxicillin and 500 mg clarithromycin, all twice daily for 7 days.
- *To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):*
 - The recommended initial dosage is 40 mg twice daily. The dosage should then be individually adjusted, and treatment continued as long as clinically indicated.

The tablets should be swallowed whole with liquid. The tablets should not be chewed or crushed.

Your doctor will tell you how long your treatment with JUBIGORD will last. Do not stop treatment early because you feel better.

If you have the impression that the effect of JUBIGORD is too strong or too weak, tell your doctor or pharmacist.

If you take more JUBIGORD than you should

In the event of overdose, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take JUBIGORD

Do not take a double dose to make up for forgotten individual doses.

If it is almost time for your next dose, do not take the missed dose, and just take the next dose on time.

4. Possible side effects

JUBIGORD can have side effects.

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Rash or itching in the form of reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis' (TEN).
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

These are all very serious side effects. If you have them, you may have had a serious reaction to JUBIGORD. 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:

- Tightening of chest accompanied with severe coughing (bronchospasm).
- Loss or decreased vision.
- Abdominal swelling (may be an indication of liver failure).
- Excessive sweating.
- Blood in the urine (nephritis).
- Significant reduction in the amount of urine with shortness of breath. (This could be a sign of

kidney failure.)

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:

- Stomach pain.
- Diarrhoea.
- Nausea/vomiting.
- Constipation.
- Headache.

Less frequent side effects:

- Muscle weakness/pain, fracture of the hips, wrist or spine.
- Fever.
- Development of breast tissue in males.
- Joint pain.
- Hair loss.
- Dry mouth.
- Inflammation of the mouth and lips.
- Dizziness.
- Blurred vision.
- Tingling sensation.
- Loss of balance.
- Taste disturbance.
- Sleepiness.
- Inability to sleep.
- Confusion.
- Depression.
- Agitation.

- Hallucination.
- Low blood cell count.
- Acute kidney injury or chronic kidney failure.

Side effects of which the frequency is unknown:

- Decreased levels of calcium.
- Decreased levels of magnesium.
- “Butterfly rash” that lasts hours – days.

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 or pharmacist. 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 JUBIGORD.

5. How to store JUBIGORD

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry stated on the carton / blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What JUBIGORD contains

The active substance is esomeprazole magnesium.

JUBIGORD 20: Each tablet contains esomeprazole magnesium equivalent to 20 mg esomeprazole.

JUBIGORD 40: Each tablet contains esomeprazole magnesium equivalent to 40 mg esomeprazole.

The other ingredients are colloidal silica (hydrated), crospovidone, glycerol monostearate, hydroxypropyl cellulose, hypromellose phthalate, iron oxide red (E172), magnesium oxide (light) (E530), methacrylic acid ethyl acrylate polymer, microcrystalline cellulose (E460(i)), Opadry pink (containing hypromellose (E464), iron oxide red (E172), polyethylene glycol 400 and titanium dioxide (E171)), polyethylene glycol 400, polyethylene glycol 6000, polysorbate 80, povidone, powdered sugar (maize starch and sucrose), pregelatinised starch, sugar spheres (maize starch and sucrose) and talc (E553b).

What JUBIGORD looks like and contents of the pack

JUBIGORD 20: Light pink coloured, oblong, biconvex, coated tablets debossed with '20' on one side and 'CE' on the other.

JUBIGORD 40: Pink coloured, oblong, biconvex, coated tablets debossed with '40' on one side and 'CE' on the other side.

OPA/Aluminium/PVC/Aluminium blister strips placed in an outer carton.

JUBIGORD 20: 14 or 28 or 30 tablets. Not all pack sizes may be marketed

JUBIGORD 40: 28 or 30 tablets. Not all pack sizes may be marketed.

Holder of certificate of registration

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This leaflet was last revised in:

Date of Registration: 4 August 2022.

Registration numbers

JUBIGORD 20: 47/11.4.3/0449

JUBIGORD 40: 47/11.4.3/0450