

1.5.5.2.1 Patient Information Leaflet

SCHEDULING STATUS

S4

TRUSTAN® 20 mg Gastric Resistant TabletEsomeprazole

Contains sugar: Sucrose 28 mg

TRUSTAN® 40 mg Gastric Resistant TabletEsomeprazole

Contains sugar: Sucrose 30 mg

Read all of this leaflet carefully before you start taking TRUSTAN.

- 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.
- TRUSTAN 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 TRUSTAN is and what it is used for
2. What you need to know before you take TRUSTAN
3. How to take TRUSTAN

4. Possible side effects
5. How to store TRUSTAN
6. Contents of the pack and other information

1. What TRUSTAN is and what it is used for

TRUSTAN contains a medicine called esomeprazole. This belongs to a group of medicine called proton pump inhibitors (medicines used to treat ulcers). It reduces the production of acid in your stomach.

TRUSTAN is used for treating the following conditions:

- Gastro-oesophageal reflux disease (GORD).
Treatment and prevention of Gastro-oesophageal Reflux Disease (GORD). This is where fluid (acid) from the stomach escapes into the food pipe causing pain, inflammation (swelling) and heartburn.
- Prevention of ulcers caused by a medicine used for pain and inflammation (Non-steroidal anti-inflammatory drug treatment).
- Infection with bacteria called *Helicobacter pylori* that cause ulcers in the stomach with appropriate antibiotics.
- Hypersecretory conditions including hormone producing tumours causing excess acid in the stomach (Zollinger-Ellison syndrome).

2. What you need to know before you take TRUSTAN

Do not take TRUSTAN:

- if you are hypersensitive (allergic) to esomeprazole, other “proton pump inhibitors” or any of the other ingredients of TRUSTAN (listed in section 6).
- if you are taking medication for HIV treatment (atazanavir or nelfinavir)

Warnings and precautions

Take special care with TRUSTAN:

- if you notice any of the following:
 - if you feel that you are losing weight without trying to lose it.
 - you begin to vomit blood or food
 - you pass black (blood-stained) stool. You should contact your doctor immediately.
 - You get stomach pain or indigestion.
- TRUSTAN 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.
- if you have severe liver problems. You should discuss this with your doctor, as he/she may wish to reduce the dose.
- if you have severe kidney problems. You should discuss this with your doctor.
- if you have severe, debilitating diarrhoea (known as *Clostridium Difficile*- associated diarrhoea), that does not improve. Symptoms may include watery stools, stomach pain

and fever.

- if you are due to have a specific blood test (Chromogranin A).
- Taking a proton pump inhibitor like TRUSTAN, especially over a period of more than one year, may slightly 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 get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with TRUSTAN. Remember to also mention any other ill-effects like pain in your joints.
- TRUSTAN, as all acid-blocking medicines, may reduce the absorption of vitamin B12 (cyanocobalamin) due to hypo- or achlorhydria. 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 TRUSTAN 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.

Children and adolescents

There is no experience with TRUSTAN in children younger than 12 years.

Other medicines and TRUSTAN

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

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

- medicines used to prevent fungal infections (itraconazole, ketoconazole, voriconazole),
- certain type of anti-cancer medicines (such as erlotinib or another medicine from the same class)
- medicines used to treat anxiety, relax muscles or in epilepsy (diazepam)
- medicines used for epilepsy (phenytoin and sodium valproate). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking TRUSTAN.
- medicines that are used to thin your blood and to prevent blood clots (warfarin and clopidogrel) Your doctor may need to monitor you when you start or stop taking TRUSTAN
- medicines used for intermittent claudication, a condition where leg pain is caused by poor circulation (cilostazol),
- medicines used for transplant rejection (tacrolimus),
- medicines used for indigestion, heartburn and to speed up stomach emptying (cisapride),
- taking TRUSTAN at the same time as some medicines for HIV, such as nelfinavir and atazanavir is not recommended,
- medicines used for heart problems (digoxin),

- medicines used for cancer or rheumatoid arthritis (e.g. methotrexate). If you are taking a high dose of methotrexate, your doctor may temporarily stop your TRUSTAN treatment.
- medicines used for treatment of tuberculosis (rifampicin),
- medicines to treat depression (citalopram, imipramine, clomipramine or St John's Wort).
- antibiotics, amoxicillin and clarithromycin as well as TRUSTAN to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

TRUSTAN with food or drink:

You can take your tablets with food or on an empty stomach.

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 healthcare provider for advice before taking this medicine.

Driving and using machines

TRUSTAN has moderate influence on the ability to drive and use machines.

TRUSTAN may cause dizziness and blurred vision, thereby affecting the ability to drive or use machinery (see section 4).

It is not always possible to predict to what extent TRUSTAN may interfere with the daily activities of a patient. You should ensure that you do not engage in the above activities until

you are aware of the measure to which TRUSTAN affects you (see section 4).

TRUSTAN contains sucrose

TRUSTAN tablets contain sucrose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking TRUSTAN.

3. How to take TRUSTAN

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

Always take TRUSTAN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Adults

To treat gastroesophageal reflux disease (GORD):

- for treatment of erosive reflux oesophagitis.

The usual dose is 40 mg once daily for 4 weeks.

An additional 4 weeks treatment will be prescribed by your doctor when you have not healed, or who have persistent symptoms.

- long-term management of patients with healed oesophagitis to prevent relapse.

The usual dose is 20 mg once daily.

- symptomatic treatment of gastro-oesophageal reflux disease (GORD).

The usual dose is 20 mg once daily in patients without oesophagitis.

If symptom control has not been achieved after 4 weeks, your doctor will need to do investigate further. Once the condition has been controlled, your doctor may tell you

to take your medicine as and when you need it, up to a maximum of one TRUSTA 20 mg tablet each day.

Patients requiring continued NSAID therapy:

- prevention of gastric and duodenal ulcers associated with NSAID therapy in patients at risk.

The usual dose is 20 mg or 40 mg once daily.

In combination with appropriate antibacterial therapeutic regimens for the eradication of *Helicobacter pylori* and

- healing of *Helicobacter pylori* associated duodenal ulcer.
- prevention of relapse of peptic ulcers in patients with *Helicobacter pylori* associated ulcer disease.

The usual dose is 20 mg TRUSTAN 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 usual initial dosage is TRUSTAN 40 mg twice daily. The dosage should then be individually adjusted, and treatment continued as long as clinically indicated. Doses up to 120 mg twice daily have been administered.

Adolescents 12-18 years:

Gastro-oesophageal Reflux Disease (GORD):

- treatment of erosive reflux oesophagitis,
the usual dose is 40 mg once daily for 4 weeks.

An additional 4 weeks treatment is recommended for patients in whom oesophagitis has

not healed, or who have persistent symptoms.

- long-term management of patients with healed oesophagitis to prevent relapse,
the usual dose is 20 mg once daily.
- symptomatic treatment of gastro-oesophageal reflux disease (GORD),
the usual dose is 20 mg once daily in patients without oesophagitis. If symptom control
has not been achieved after 4 weeks, your doctor will need to do investigate further.
Once symptoms have resolved, subsequent symptom control can be achieved using 20
mg once daily under medical supervision.

Children

TRUSTAN is not recommended for children less than 12 years old.

Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.

If you have trouble swallowing the tablets:

- Disperse the tablets in half a glass of non-carbonated water. Do not use any other
liquids.
- Stir until the tablet/s disintegrate and be sure to swallow all the tiny pellets that come out
of the tablet without chewing them.
- Do not let the pellets sit in the water for more than 30 minutes before drinking.
- After drinking, rinse the glass with water and drink this as well.

Try to take your medicine at the same time each day.

TRUSTAN should not be used in children younger than 12 years.

TRUSTAN can be used in the elderly.

Your doctor will tell you how long your treatment with TRUSTAN will last. If you have the impression that the effect of TRUSTAN is too strong or too weak, tell your doctor or pharmacist.

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

If you take more TRUSTAN than you should

In the event of an overdose, immediately consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take TRUSTAN

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

If you have missed a dose of TRUSTAN, take the dose that you have missed as soon as you remember.

However, if it is nearly time for the next dose, skip the missed dose.

If you have forgotten to take several doses, contact your doctor without delay

4. Possible side effects

TRUSTAN can have side effects.

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

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

- Sudden wheezing, swelling of the hands, feet, ankles, face, lips and mouth or throat , which may cause difficulty in swallowing or breathing.
- rash or itching,
- fainting
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS).

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

- tightness of chest,
- suddenly feeling wheezy or short of breath (bronchospasm),
- fracture of the hip, wrists or spine,
- blood disorders (reduced number of cells in the blood i.e. leukopenia and thrombocytopenia),
- changes in blood count including agranulocytosis (lack of white blood cells) (agranulocytosis and pancytopenia),
- liver problems, including inflammation of the liver (with or without jaundice which can cause yellow skin, dark urine, and tiredness),

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,
- stomach pain, diarrhoea, wind (flatulence),
- feeling sick (nausea) / being sick (vomiting)
- constipation

Less frequent side effects

- dizziness,
- sensation of burning/prickling/numbness,
- feeling sleepy,
- dry mouth,
- skin reactions (rash, dermatitis, itching, hives),
- peripheral swelling,
- difficulty sleeping (insomnia),
- spinning feeling (vertigo)
- Taste changes,
- blurred vision,
- inflammation in the mouth,
- gastrointestinal fungal infection,
- gastrointestinal infection,
- hair loss (alopecia),

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- skin rash due to sensitivity to sunlight,
- depression, nervousness, confusion,
- low blood sodium,
- muscular pain (myalgia), sore joints (arthralgia),
- feeling ill and increased sweating may occur,
- aggression,
- seeing, feeling or hearing things that are not there (hallucination),
- decreased consciousness,
- muscular weakness,
- inflammation of the kidney,
- development of breasts in males have been reported.
- low blood magnesium (which may result in low blood calcium and/or low blood potassium),
- inflammation of the gut (leading to diarrhoea).

The following side effect may also occur with TRUSTAN. This would only be seen when a blood test is taken; increase in the amount of liver enzymes.

If you notice any side-effects not mentioned in this leaflet, please inform your doctor, pharmacist or other health care professional.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: <https://www.sahpra.org.za/health-products-vigilance/>

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E-mail: drugsafety_ZA@acino.swiss

Tel: 060 998 7896

By reporting side effects, you can help provide more information on the safety of TRUSTAN.

5. How to store TRUSTAN

Store all medicines out of reach of children.

Do not store in a bathroom.

Keep your medicine stored at or below 30 °C in a dry place.

Keep your tablets in the container they came in and keep the container tightly closed.

Keep the blisters in the carton until required for use.

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 TRUSTAN contains

TRUSTAN 20 mg

The active substance is 20 mg of esomeprazole (as magnesium trihydrate).

TRUSTAN 40 mg

The active substance is 40 mg of esomeprazole (as magnesium trihydrate).

The other ingredients are crospovidone, glycerol monostearate, hypromellose, hydroxypropylcellulose, iron oxide, magnesium stearate, methacrylic acid-ethyl acrylate

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Trustan 20 mg & 40 mg (Tablet)

copolymer, microcrystalline cellulose, macrogol, polysorbate 80, synthetic paraffin, sugar spheres (sucrose and maize starch), sodium stearyl fumarate, talc, triethyl citrate, titanium dioxide.

TRUSTAN 20 mg

Contains sugar: Sucrose 28 mg

TRUSTAN 40 mg

Contains sugar: Sucrose 30 mg

What TRUSTAN looks like and contents of the pack

TRUSTAN 20 mg is light pink, oval coated tablet marked with “20 mg” on one side and ^A_{EH} on the other side.

TRUSTAN 40 mg is a pink, oval coated tablet marked with “40 mg” on one side and ^A_{EH} on the other side.

TRUSTAN gastric resistant tablets are stored in cartons containing blister strips. These cartons may contain 3, 7, 14, 15, 28, 30, 50, 56, 60, 98 or 100 tablets.

TRUSTAN gastric resistant tablets are also stored in white plastic bottles, with screw type caps, with or without child resistance and a tamper proof ring, that contain 2, 5, 7, 14, 15, 28, 30, 56, 60 or 100 tablets. The bottles are packed in a cardboard carton.

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Trustan 20 mg & 40 mg (Tablet)

Holder of Certificate of Registration

Acino Pharma (Pty) Ltd

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1686

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REGISTRATION NUMBERS:

TRUSTAN 20 mg: 45/11.4.3/0777

TRUSTAN 40 mg: 45/11.4.3/0778

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

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