1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TRUSFLUKS 20

Esomeprazole 20 mg Gastro Resistant tablet

TRUSFLUKS 40

Esomeprazole 40 mg Gastro Resistant tablet

Contains sugar

TRUSFLUKS 20: Lactose monohydrate 18,76 mg & sucrose 6,3 mg

TRUSFLUKS 40: Lactose monohydrate 73,52 mg & sucrose 12,6 mg

Read all this leaflet carefully before you start taking TRUSFLUKS.

- 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.
- **TRUSFLUKS** 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 **TRUSFLUKS** is and what it is used for

2. What you need to know before you take **TRUSFLUKS**
3. How to take **TRUSFLUKS**
4. Possible side effects
5. How to store **TRUSFLUKS**
6. Contents of the pack and other information

1. What TRUSFLUKS is and what it is used for

TRUSFLUKS 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.

TRUSFLUKS 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 TRUSFLUKS

Do not take TRUSFLUKS:

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

Warnings and precautions

Take special care with TRUSFLUKS:

- 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.
- **TRUSFLUKS** 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 **TRUSFLUKS**, 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 **TRUSFLUKS**. Remember to also mention any other ill-effects like pain in your joints.
- **TRUSFLUKS**, 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 **TRUSFLUKS** 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 **TRUSFLUKS** in children younger than 12 years.

Other medicines with TRUSFLUKS

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 **TRUSFLUKS**.
- 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 **TRUSFLUKS**
- 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 **TRUSFLUKS** 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 **TRUSFLUKS** 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 **TRUSFLUKS** to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicines you are taking.

TRUSFLUKS with food, drink and alcohol

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 health care provider for advice before taking **TRUSFLUKS**.

Driving and using machines

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

TRUSFLUKS 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 **TRUSFLUKS** 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 **TRUSFLUKS** affects you (see section 4).

TRUSFLUKS contains lactose monohydrate & sucrose:

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

3. How to take TRUSFLUKS

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

Always take **TRUSFLUKS** 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 **TRUSFLUKS** 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 **TRUSFLUKS** 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 **TRUSFLUKS** 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

TRUSFLUKS 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.

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

TRUSFLUKS can be used in the elderly.

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

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

If you take more TRUSFLUKS than you should

In the event of an overdosage, 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 **TRUSFLUKS**

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

If you have missed a dose of **TRUSFLUKS**, 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

TRUSFLUKS can have side effects.

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

If any of the following happens, stop taking **TRUSFLUKS** 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 **TRUSFLUKS**. 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),
- 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 **TRUSFLUKS**. 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 or 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. By reporting side effects, you can help provide more information on the safety of **TRUSFLUKS**.

5. How to store TRUSFLUKS

- Store at or below 30 °C.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the carton/blister.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains and sewerage system (e.g. toilets).

6. Contents of the pack and other information

What **TRUSFLUKS** contains:

The active substance in **TRUSFLUKS** is Esomeprazole.

TRUSFLUKS 20: Each Gastro resistant tablet contains 20 mg esomeprazole.

TRUSFLUKS 40: Each Gastro resistant tablet contains 40 mg esomeprazole.

The other ingredients are:

Acetone, croscarmellose sodium, crospovidone, ethanol, ethyl alcohol, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1), microcrystalline cellulose, opadry pink: (hypromellose, iron oxide red, &yellow, macrogol/PEG and titanium dioxide), polysorbate, povidone, purified water, silica colloidal anhydrous, sodium hydroxide, sodium stearyl fumarate, sugar sphere: (povidone, starch & sucrose), talc and triethyl citrate.

TRUSFLUKS contains sugar:

TRUSFLUKS 20: Lactose monohydrate 18,76 mg & sucrose 6,3 mg

TRUSFLUKS 40: Lactose monohydrate 37,52 mg & sucrose 12,6 mg

What TRUSFLUKS looks like and contents of the pack

TRUSFLUKS 20: Pink, oblong, biconvex (approx. 12.15 mm x 6.15 mm), film-coated tablet, engraved '20' on one side and plain on other.

TRUSFLUKS 40: Pink, oblong, biconvex (approx. 16.15 mm x 8.15 mm), film-coated tablet, engraved '40' on one side and plain on other.

TRUSFLUKS 20 mg

Forming film: Alu/Alu Base Foil (OPA(25µ) + Alu (45µ) + PVC (60µ)film)

Lidding foil: Plain Aluminum Foil (heat seal lacquer coating)

Pack sizes: 28's (4x7) packed in a pre-printed cartons with a packaging leaflet.

TRUSFLUKS 40 mg

Forming film: Alu/Alu Base Foil (OPA(25µ) + Alu (45µ) + PVC (60µ)film)

Lidding foil: Plain Aluminum Foil (heat seal lacquer coating)

Pack sizes: 28's (4x7) packed in a pre-printed cartons with a packaging leaflet.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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Not applicable.

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Access to the corresponding Professional information is contained in the

packaging or Follow the link for the corresponding Professional Information for

TRUSFLUKS: pi-pil-repository.innovata.co.za, alternatively, please scan the

QR code below:

PLACE HOLDER: The QR code to be included after approval