

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

Applicant/PHCR: Innovata Pharmaceuticals (Pty) Ltd

Product Proprietary Name: TRUSFLUKS 20 & 40

Dosage Form & Strength: Gastro-Resistant tablets, esomeprazole 20 mg & 40 mg

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:

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- 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

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Product Proprietary Name: *TRUSFLUKS 20 & 40*
Dosage Form & Strength: *Gastro-Resistant tablets, esomeprazole 20 mg & 40 mg*

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.

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- 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

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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 **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;



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- 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)

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- 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,

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- 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.

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- 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

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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(25 μ) + Alu (45 μ) + PVC (60 μ)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(25 μ) + Alu (45 μ) + PVC (60 μ)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

Innovata Pharmaceuticals (Pty) LTD

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This leaflet was last revised in:

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TRUSFLUKS 20: 59/11.4.3/0325

TRUSFLUKS 40: 59/11.4.3/0326

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:



1.3.2 PASIËNT INLIGTINGBILJET

SKEDULERINGSSTATUS: **S4**

TRUSFLUKS 20

Esomeprasool 20 mg Gastro-Bestande tablet

TRUSFLUKS 40

Esomeprasool 40 mg Gastro-Bestande tablet

Bevat suiker

TRUSFLUKS 20: Laktose monohidraat 18,76 mg & sukrose 6,3 mg

TRUSFLUKS 40: Laktose monohidraat 73,52 mg & sukrose 12,6 mg

Lees die volledige biljet noukeurig deur voordat u TRUSFLUKS begin neem.

- Hou hierdie biljet. U mag dit moontlik weer wil lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgvoorsiener.
- **TRUSFLUKS** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander persone deel nie. Dit kan hulle kwaad aandoen, selfs indien hulle simptome dieselfde is as diè wat u het.

Wat is in hierdie biljet:

1. Wat **TRUSFLUKS** is en waarvoor dit gebruik word

2. Wat u behoort te weet voordat u **TRUSFLUKS** neem
3. Hoe om **TRUSFLUKS** te neem
4. Moontlike newe-effekte
5. Hoe om **TRUSFLUKS** te bêre
6. Inhoud van die pakkie en ander inligting

1. Wat **TRUSFLUKS** is en waarvoor dit gebruik word

TRUSFLUKS bevat 'n medisyne wat genoem word esomeprasool. Dit behoort aan 'n groep van medisyne wat genoem word proton-pomp remmers (medisynes wat gebruik word om ulkuse te behandel). Dit verminder die produksie van suur in u maag.

TRUSFLUKS word gebruik vir behandeling van die volgende toestande:

- Gastro-esofageale refluks-siekte (GORD).
Behandeling en voorkoming van Gastro-oesofageale Refluks Siekte (GORD). Dit is waar vloeistof (suur) van die maag ontsnap in die voedselpyp wat pyn, inflammasie (swelsel) and sooi-brand veroorsaak.
- Voorkoming van ulkuse veroorsaak deur 'n medisyne wat gebruik word vir pyn en inflammasie (Nie-steroïed anti-inflammatoriese medisyne behandeling).
- Infeksie met bakterieë wat genoem word *Helicobacter pylori*, wat ulkuse veroorsaak in die maag met toepaslike antibiotika.
- Hiperafskieding-toestande, insluitend hormoon-produiserende tumore wat oormaat suur in die maag veroorsaak (Zollinger-Ellison sindroom).

2. Wat u behoort te weet voordat u **TRANSFLUKS** neem

Moenie TRUSFLUKS neem:

- indien u hipersensitief (allergies) is vir esomeprasool, ander "proton-pomp remmers" of enige van die ander bestanddele van **TRUSFLUKS** nie (aangedui in afdeling 6).

- indien u hipersensitief (allergies) is vir esomeprasool, ander “proton-pomp remmers” of enige van die ander bestanddele van **TRUSFLUKS** nie (aangedui in afdeling 6).
- indien u ander medikasie neem vir MIV-behandeling nie (atasanavir of nelfinavir).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met TRUSFLUKS:

- indien u enige van die volgende opmerk:
 - indien u voel dat u gewig verloor sonder dat u probeer om te verloor.
 - u begin om bloed te braak of voedsel.
 - u swart (bloed-bevlekte) stoelgang het. U moet u dokter onmiddellik kontak.
 - u maagpyn of slegte spysvertering kry.
- **TRUSFLUKS** kan ‘n toename in die risiko van niersiekte veroorsaak wat tot gevolg het nierversaking.
Dit word genoem tubulo-interstisiële nefritis en u kan verhoogde uriene uitset ondervind, veranderinge in geestes-status, soos lomerigheid of verwarring, opswel van enige area van u liggaam.
- indien u ernstige lewerprobleme het. U moet dit met u dokter bespreek, omdat hy/sy kan verkies om die dosering te verminder.
- indien u ernstige nierprobleme het. U moet dit met u dokter bespreek.
- indien u ernstige, verswakkende diarree het (bekend as *Clostridium Difficile*-geassosieerde diarree), wat nie beter word nie. Simptome kan insluit waterige stoelgang, maagpyn en koors.
- indien u ‘n spesifieke bloedtoets benodig (Chromogranin A).
- die neem van ‘n proton-pomp remmer soos **TRUSFLUKS**, veral oor ‘n tydperk van meer as een jaar, kan u risiko van frakture van die heup, gewrig of rugwerwel effens verhoog. Vertel u dokter indien u osteoporose het of indien u kortikosteroïede neem (wat die risiko van osteoporose kan laat toeneem).

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- indien u 'n veluitslag kry, veral in areas wat aan die son blootgestel word, vertel u dokter so spoedig moontlik, omdat u moontlik u behandeling met **TRUSFLUKS** moet staak. Onthou ook om enige ander siek effekte te meld, soos pyn in u gewrigte.
- **TRUSFLUKS**, soos alle suur-blokker medisynes, kan die absorpsie van vitamien B12 verminder (sianokobalamien) weens hipo- of achloorhidrie. Dit moet oorweeg word by pasiënte met verminderde liggaamsberging of risiko faktore vir afname van vitamien B12 absorpsie met langtermyn-terapie.
- indien u **TRUSFLUKS** vir meer as drie maande neem is dit moontlik dat die vlakke van magnesium in u bloed kan afneem. Lae vlakke van magnesium kan gesien word as uitputting, onwillekeurige spiërsametrekkings, disoriëntasie, konvulsies, duiseligheid of verhoogde hart-tempo. Indien u enige van hierdie simptome kry, vertel asseblief dadelik vir u dokter. Lae vlakke van magnesium kan ook 'n afname in kalium- of kalsiumvlakke tot gevolg hê. U dokter kan besluit om gereëld bloedtoetse te monitor van u vlakke van magnesium.

Kinders en adolessente

Daar is geen ondervinding met **TRUSFLUKS** in kinders jonger as 12 jaar oud nie.

Ander medisynes met TRUSFLUKS

Vertel altyd u gesondheidsorgvoorsiener indien u enige ander medisyne neem (dit sluit in komplementêre of tradisionele medisynes).

Vertel u dokter indien u enige van die volgende neem:

- medisyne wat gebruik word vir voorkoming van fungusinfeksies (itrakonasool, ketokonasool, vorikonasool),
- sekere tipes van anti-kanker medisyne (soos erlotinib of 'n ander medisyne van dieselfde klas),
- medisyne wat gebruik word vir behandeling van angs, spierverslapping of in epilepsie (diasepam),
- medisyne wat gebruik word vir epilepsie (fenitoïen en natriumvalproaat). Indien u fenitoïen neem, moet u dokter u monitor wanneer u **TRUSFLUKS** begin neem of staak,
- medisyne wat gebruik word om u bloed te verdun en om bloedklonte te voorkom (warfarien en klopidogrel). U dokter sal u moontlik moet monitor wanneer u **TRUSFLUKS** begin neem of staak,
- medisyne wat gebruik word vir onderbroke kloudikasie, 'n toestand waar beenpyn veroorsaak word deur swak sirkulasie (silostazol),
- medisyne wat gebruik word vir oorplanting verwerping (takrolimus),
- medisyne wat gebruik word vir slegte spysvertering, sooibrand en om die maaglediging te versnel (sisapried),
- neem van **TRUSFLUKS** dieselfde tyd as sommige medisyne vir MIV, soos nelfinavir en atasanavir word nie aanbeveel nie,
- medisyne wat gebruik word vir hartprobleme (digoksien),

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- medisyne wat gebruik word vir kanker of rumatoïede artritis (bv. metotreksaat). Indien u 'n hoë dosis van metotreksaat neem, kan u dokter u **TRUSFLUKS**-behandeling tydelik staak.
- medisyne wat gebruik word vir behandeling van tuberkulose (rifampisien).
- medisyne om depressie te behandel (sitalopram, imipramien, klomipramien of St John's Wort).
- antibiotika, amoksisillien en klaritromisien, sowel as **TRUSFLUKS**, vir behandeling van ulkuse veroorsaak deur *Helicobacter pylori*-infeksie, is dit baie belangrik dat u u dokter inlig omtrent enige ander medisyne wat u neem.

TRUSFLUKS met voedsel, drankies en alkohol

U kan u tablette neem met voedsel of op 'n leë maag.

Swangerskap, borsvoeding en fertiliteit

Indien u swanger is of borsvoed, dink dat u swanger kan wees of 'n baba beplan, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgvoorsiener vir advies voordat u **TRUSFLUKS** neem.

Bestuur en gebruik van masjinerie

TRUSFLUKS het matige invloed op die vermoë om te bestuur of gebruik van masjinerie.

TRUSFLUKS kan duiseligheid en dowwe visie veroorsaak, wat dus die vermoë om te bestuur of masjinerie te gebruik kan beïnvloed (sien afdeling 4).

Dit is nie altyd moontlik om te voorspel tot watter mate **TRUSFLUKS** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. U moet seker maak dat u nie aan boonste aktiwiteite deelneem nie, totdat u seker is tot watter mate **TRUSFLUKS** u beïnvloed (sien afdeling 4).

TRUSFLUKS bevat laktose monohidraat & sukrose:

Indien u deur u dokter ingelig is dat u 'n intoleransie het tot sommige suikers, kontak u dokter voordat u hierdie medisyne neem.

3. Hoe om TRUSFLUKS te neem

Moenie medisynes wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem altyd **TRUSFLUKS** presies soos u dokter of apteker aanbeveel het.

Raadpleeg u dokter of apteker indien u nie seker is nie.

Volwassenes

Behandeling van gastroësofageale refluks-siekte (GORD):

- vir behandeling van erosiewe refluks esofagitis.
Die gewone dosering is 40 mg een keer per dag vir 4 weke.
‘n Addisionele 4 weke behandeling sal deur u dokter voorgeskryf word indien u nog nie gesond is nie, of wanneer u aanhoudende simptome het.
- langtermyn hanteer van pasiënte met geneesde esofagitis om terugval te voorkom. Die gewone dosering is 20 mg een keer per dag.
- simptomatiese behandeling van gastroësofageale refluks-siekte (GORD). Die gewone dosis is 20 mg een keer per dag in pasiënte sonder esofagitis. Indien simptome nie bereik word na 4 weke nie, behoort u dokter verdere ondersoek te doen. Sodra die toestand onder beheer is, sal u dokter u inlig wanneer om u medisyne te neem, tot ‘n maksimum van een **TRUSFLUKS** 20 mg tablet elke dag.

Pasiënte wat voortgesette NSAID-terapie benodig:

- voorkoming van gastriese en duodenale ulkuse geassosieer met NSAID-terapie by pasiënte wat ‘n risiko het. Die gewone dosis is 20 mg of 40 mg een keer per dag.

In kombinasie met toepaslike antibakteriële terapeutiese regimens vir die eradikasie van *Helicobacter pylori* en

- genesing van *Helicobacter pylori*-geassosieerde duodenale ulkus.

- voorkoming van terugval van peptiese ulkuse in pasiënte met *Helicobacter pylori*-geassosieerde ulkus siekte.

Die gewone dosis is 20 mg **TRUSFLUKS** met 1 g amoksisillien en 500 mg klaritromisien, alles twee keer per dag vir 7 dae.

Vir behandeling van te veel suur in die maag, veroorsaak deur 'n groeisel in die pankreas (Zollinger-Ellison sindroom).

Die gewone aanvanklike dosering is **TRUSFLUKS** 40 mg twee keer per dag. Die dosering moet dan individueel aangepas word en behandeling moet volgehou word vir so lank as wat dit klinies aangedui word.

Dosering van tot 120 mg twee keer per dag was toegedien.

Adolescente 12-18 jaar:

Gastroësofageale Refluks-Siekte (GORD):

- behandeling van erosiewe refluks esofagitis, is die gewone dosering 40 mg een keer per dag vir 4 weke. 'n Addisionele 4 weke behandeling word aanbeveel vir pasiënte by wie esofagitis nie genees het nie, of nog voortdurend simptome het.
- langtermyn behandeling van pasiënte met geneesde esofagitis om terugval te voorkom, is die gewone dosering 20 mg een keer per dag.
- simptome behandeling van gastroësofageale refluks-siekte (GORD), is die dosering 20 mg een keer per dag by pasiënte sonder esofagitis. Indien beheer van simptome nie bereik word na 4 weke nie, behoort u dokter verdere ondersoek te doen. Sodra simptome opgeklaar het kan daaropvolgende simptome kontrole bereik word deur die gebruik van 20 mg een keer per dag onder mediese toesig.

Kinders

TRUSFLUKS word nie aanbeveel vir kinders van jonger as 12 jaar oud nie. Sluk u tablette heel in met 'n drankie of water. Moenie die tablette kou of fyn druk nie.

Indien u probleme het met die insluk van tablette:

- Los die tablette op in 'n halwe glas van nie-gekarboneerde water. Moenie gebruik met enige ander vloeistowwe nie.
- Roer totdat die tablet/te oplos en maak seker om al die klein korreltjies te sluk wat uit die tablet gekom het, sonder om dit te kou.
- Moenie die korreltjies vir meer as 30 minute in die water laat voordat u dit drink nie.
- Nadat u dit gebruik het, spoel die glas uit met water en drink dit ook.

Probeer om u medisyne op dieselfde tyd elke dag te neem.

TRUSFLUKS moet nie gebruik word in kinders van jonger as 12 jaar oud nie.

TRUSFLUKS kan in bejaardes gebruik word.

U dokter sal u vertel hoe lank u behandeling met **TRUSFLUKS** sal aanhou. Indien u die indruk het dat die effek van **TRUSFLUKS** te sterk of te swak is, vertel u dokter of apteker.

Indien u die indruk het dat die effek van **TRUSFLUKS** te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer TRUSFLUKS geneem het as wat u moes

Ingeval van 'n oordosering, raadpleeg u dokter of apteker onmiddellik.

Indien albei nie beskikbaar is nie, kry hulp by die naaste hospitaal of vergiftingsentrum.



Indien u vergeet het om u **TRUSFLUKS** te neem

Moenie 'n dubbele dosis neem om op te maak vir individuele doserings wat u vergeet het nie.

Indien u 'n dosis van **TRUSFLUKS** gemis het, neem die dosis wat u gemis het so gou as wat u onthou.

Nogtans, indien dit amper tyd is vir die volgende dosis, slaan die dosis oor wat u gemis het.

Indien u vergeet het om etlike doserings te neem, kontak u dokter onmiddellik.

4. Moontlike newe-effekte

TRUSFLUKS kan newe-effekte hê.

Nie alle newe-effekte gerapporteer vir **TRUSFLUKS** is ingesluit in hierdie biljet nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ondervind terwyl u **TRUSFLUKS** neem, raadpleeg u gesondheidsorgvoorsiener vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **TRUSFLUKS** en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal:

- Skielike asemfluit, opswel van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk of asemhaling;
- uitslag of jeuk;
- floute;
- afskilfering van die vel, mond, oë en geslagsorgane omdat dit kan wees weens 'n baie ernstige allergiese reaksie wat bekend staan as Stevens-Johnson Sindroom (SJS).

Hierdie is almal baie ernstige newe-effekte. Indien u dit het, het u 'n ernstige reaksie gehad met **TRUSFLUKS**. U kan dringende mediese sorg of hospitalisering benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- engheid van die bors,
- skielike gevoel van heesheid of asemtekort (brongospasma),
- fraktuur van die heupe, gewrigte of rugstring,
- bloedafwykings (afname in die hoeveelheid selle in die bloed, d.i. leukopenie en trombositopenie),
- veranderinge in bloedtelling, insluitend agranulose (gebrek aan wit bloedselle) (agranulose en pansitopenie),
- lewerprobleme, insluitend inflammasie van die lewer (met of sonder geelsug wat 'n geel vel, donker uriene en moegheid kan veroorsaak).

Hierdie is almal baie ernstige newe-effekte. U kan moontlik dringende mediese sorg benodig.

Vertek u dokter indien u enige van die volgende opmerk:

Dikwelse newe-effekte:

- hoofpyn,
- maagpyn, diarree, wind (winderigheid),
- gevoel van siek wees (naarheid) / siek wees (braking),
- hardlywigheid.

Minder dikwelse newe-effekte:

- duiseligheid,
- sensasie van brand/prikkeling/gevoelloosheid,
- gevoel van slaperigheid,
- droë mond,
- velreaksies (uitslag, dermatitis, jeuk, huiduitslag),

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- perifêre swelsel,
- probleme om te slaap (insomnie),
- dronk gevoel (vertigo)
- smaakveranderinge,
- dowwe visie,
- inflammasie in die mond,
- gastroïntestinale fungus-infeksie,
- gastroïntestinale infeksie,
- haarverlies (alopesie),
- veluitslag weens sensitiwiteit tot sonlig,
- depressie, senuagtigheid, verwarring,
- lae bloednatrium,
- muskulêre pyn (mialgie), seer gewrigte (artralgie),
- siek gevoel en verhoogde sweet kan voorkom,
- aggressie,
- sien, gevoel van hoor van dinge wat nie daar is nie (hallusinasie),
- afname in bewussyn,
- muskulêre swakheid,
- inflammasie van die niere,
- ontwikkeling van borste in mans is gerapporteer,
- lae bloedmagnesium (wat tot gevolg kan hê in lae bloedkalsium en/of bloedkalium),
- inflammasie van die derms (met gevolglike diarree).

Die volgende newe-effekte kan ook voorkom met **TRUSFLUKS**. Dit kan slegs gesien word wanneer 'n bloedtoets gedoen word; toename in die hoeveelheid van lewerensieme.

Indien u enige newe-effekte opmerk wat nie gemeld word in hierdie biljet nie, vertel asseblief u dokter,

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apteker of ander gesondheidsorgpersoon.

Rapporteur van newe-effekte

Indien u newe-effekte kry, raadpleeg u dokter of apteker of verpleegkundige. U kan ook newe-effekte rapporteer aan SAHPRA via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat gevind word op SAHPRA se webtuiste. Deur newe-effekte te rapporteer, kan u help om meer inligting te voorsien omtrent die veiligheid van **TRUSFLUKS**.

5. Hoe om TRUSFLUKS te berg

- Berg by of benede 30 °C.
- Hou in die oorspronklike houer totdat dit benodig word vir gebruik.
- Berg alle medisyne buite die bereik van kinders.
- Moenie gebruik na die vervaldatum wat gedruk is op die karton/stolpstrokie nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne weggooi in afvoerpype en rioolsisteme (bv. toilette) nie.

6. Inhoud van die pakkie en ander inligting

Wat **TRUSFLUKS** bevat:

Die aktiewe substans in **TRUSFLUKS** is esomeprasool.

TRUSFLUKS 20: Elke gastro-bestande tablet bevat 20 mg esomeprasool.

TRUSFLUKS 40: Elke gastro-bestande tablet bevat 40 mg esomeprasool.

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Die ander bestanddele is:

Asetoon, kroskarmellose natrium, krosprovidoon, etanol, etiel alkohol, gliseriel monostearaat, hidroksipropiel sellulose, hipromellose, laktose monohidraat, magnesiumstearaat, metakriliese suur-etiel akrilaat kopolymer (1:1), mikrokristallyn sellulose, opadry ligrooi: (hipromellose, ysteroksied rooi & geel, makrogol/PEG en titaniumdioksied), polisorbaat, povidoon, gesuiwerde water, silika kolloïdaal anhidries, natriumhidroksied, natriumsteariel-fumaraat, suiker sfere: (povidoon, stysel & sukrose), talk en triëtiel-sitraat.

TRUSFLUKS bevat suiker:

TRUSFLUKS 20: Laktose monohidraat 18,76 mg & sukrose 6,3 mg

TRUSFLUKS 40: Laktose monohidraat 37,52 mg & sukrose 12,6 mg

Hoe TRUSFLUKS lyk en inhoud van die pakkie

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TRUSFLUKS 20: Ligrooi, langwerpige, bikonvekse (ongeveer 12.15 mm x 6.15 mm),
filmbedekte tablet, gegraveer '20' op een kant en glad op die ander kant.

TRUSFLUKS 40: Ligrooi, langwerpige, bikonvekse (ongeveer 16.15 mm x 8.15 mm),
filmbedekte tablet, gegraveer '40' op een kant en glad op die ander kant.

TRUSFLUKS 20 mg

Vorming-foelie: Alu/Alu Basis-foelie (OPA(25 μ) + Alu (45 μ) + PVC (60 μ)film).

Bedekking-foelie: Gladde Aluminum-foelie (hitte verseelde verniste bedekking).

Pakgroottes: 28's (4x7) verpak in voorafgedrukte kartonne met 'n voubiljet.

TRUSFLUKS 40 mg

Vorming-foelie: Alu/Alu Basis-foelie (OPA(25 μ) + Alu (45 μ) + PVC (60 μ)film).

Bedekking-foelie: Gladde Aluminum-foelie (hitte verseelde verniste bedekking).

Pakgroottes: 28's (4x7) verpak in voorafgedrukte kartonne met 'n voubiljet.

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

Innovata Pharmaceuticals (Pty) Ltd

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100 Northern Parkway

Ormonde

Johannesburg

2091

Suid-Afrika

Hierdie biljet was laas hernu in:

TBI



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Product Proprietary Name: *TRUSFLUKS 20 & 40*
Dosage Form & Strength: *Gastro-Resistant tablets, esomeprazole 20 mg & 40 mg*

Registrasiennommers:

TRUSFLUKS 20: 59/11.4.3/0325

TRUSFLUKS 40: 59/11.4.3/0326

Toegang tot die ooreenstemmende Professionele Inligting is ingesluit in die verpakking, of Volg die skakel vir die ooreenstemmende Professionele Inligting vir TRUSFLUKS: pi-pil-repository.innovata.co.za, alternatief skandeer asseblief die QR kode hieronder:

