PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

FLUXTRIN OTC gastro-resistant tablets
Esomeprasoole magnesium
Contain sugar: sucrose 14,6 mg and lactose monohydrate 31,88 mg

Read all of this leaflet carefully because it contains important information for you
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What FLUXTRIN OTC is and what it is used for

Esomeprasoole belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

FLUXTRIN OTC is used for the short-term treatment of reflux symptoms such as heartburn and regurgitation in adults.

2. What you need to know before you take FLUXTRIN OTC

Do not take FLUXTRIN OTC:
- If you are allergic to esomeprasoole or any of the other ingredients of FLUXTRIN OTC.
- If you are allergic to other "proton pump inhibitors".
- If you are taking medication for HIV treatment (atazanavir or nelfinavir).

Warnings and precautions

Tell your doctor or healthcare provider before taking FLUXTRIN OTC:
- if you have been experiencing indigestion
- if you develop kidney problems such as blood in the urine (acute interstitial nephritis)
- 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 FLUXTRIN OTC when necessary and your symptoms change
- If you have vitamin B_{12} 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 sun light (subacute cutaneous lupus erythematosus)

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

Children

There is no relevant use of FLUXTRIN OTC in the paediatric population below 18 years of age for the indication of short-term treatment of heartburn and acid regurgitation.

Other medicines and FLUXTRIN OTC

Always tell your healthcare provider if you are any other medicine.
- 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 (cilostazol)
- Medicines used to speed up stomach emptying (cisapride)
- Digoxin used in the treatment of heart problems.
- Rifampicin used for the treatment of Tuberculosis.
- St. John's Wort - used to treat depression, or certain type of antimalignancy medicines (such as erlotinib or another antimalignancy medicine from the same class.
- FLUXTRIN OTC should not be taken at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as FLUXTRIN OTC may reduce the blood levels of your antiretroviral medicine.
- Tipranavir used to treat HIV.
- Clarithromycin, an antibiotic
- If you are taking a high dose of methotrexate (a chemotherapy medicine in which high dose is used to treat cancer), FLUXTRIN OTC may need to be temporarily withdrawn.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine. You should not take FLUXTRIN OTC if you are pregnant or breastfeeding your baby.

Driving and using machines

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

FLUXTRIN OTC contains sugar in the form of lactose

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

3. How to take FLUXTRIN OTC

Do not share medicines with any other person.

The recommended dose is 20 mg esomeprasoole (one tablet) per day. It might be necessary to take the tablet for 2 – 3 consecutive days to achieve improvement of symptoms. The duration of treatment is up to 2 weeks. Once complete relief of symptoms has occurred, treatment should be discontinued. If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should consult a doctor.

If you take more FLUXTRIN OTC you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact nearest hospital or poison centre.

If you forget to take FLUXTRIN OTC

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

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

If any of the following happens, stop taking FLUXTRIN OTC and contact a 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'.
- 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 FLUXTRIN OTC. 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
- 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 white blood cell count

Side effects of which is 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, pharmacist or nurse. 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 FLUXTRIN OTC.

5. How to store FLUXTRIN OTC
- Store at or below 30 °C.
- Store in original package to protect from light and moisture.
- Store all medicines out of reach of children.
- 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 FLUXTRIN OTC contains

The active substance is Esomeprasoole. FLUXTRIN OTC gastro-resistant tablets contain 20 mg of esomeprasoole.
The other ingredients are sugar spheres (sucrose and maize starch), ethylcellulose, magnesium stearate, povidone (K-90), light magnesium oxide, sodium lauryl sulfate, polysorbate 80, methacrylic acid – ethyl acrylate copolymer, diethyl phthalate, talc (purified), cellulose microcrystalline, silica colloidal anhydrous, lactose monohydrate, maize starch, copovidone (K-28), macrogol 8000, crospovidone (type A), silica colloidal anhydrous, hypromellose, titanium dioxide (E171), ferric oxide red (E172), opacode S-1-17823 black ink (contains shellac glaze, isopropyl alcohol, iron oxide black, n-butyl alcohol, propylene glycol and ammonium hydroxide).

What FLUXTRIN OTC looks like and contents of the pack
- FLUXTRIN OTC mg gastro-resistant tablets are brick red coloured, round shape, biconvex, film coated tablets, imprinted with "20" on one side with black ink and plain on other side.

The gastro-resistant tablets are packed in
- Aluminium – Aluminium blister pack using Aluminium foil with heat seal lacquer and cold formable blister aluminium foil. The blister strips are packed in cartons.
- HDPE container (High Density Polyethylene container of neck finish with induction sealing wad and a silica gel canister as desiccant).

Pack sizes:
7 and 14 gastro-resistant tablets.
Not all packs and pack sizes may be marketed.

Holder of Certificate of Registration
TRINITY PHARMA (PTY) LTD
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Gauteng,
2031.

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Registration number
FLUXTRIN OTC: 47/11.4.3/0318

Access to the corresponding Professional Information
www.trinity.co.za

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

S2

FLUXTRIN OTC gastries-bestande tablette
Esomeprasoolmagnesium
Bevat suiker: sukrose 14,6 mg en laktosemonohidraat 31,88 mg

Lees die hele pamflet sorgvuldig deur, want dit bevat belangrike inligting vir u
- Hou hierdie pamflet. U mag dit dalk later weer moet lees.
- Indien u enige verdere vrae het, vra u dokter, apteker of verpleegster.
- Indien u enige newe-effekte ervaar, praat met u dokter of apteker. Dit sluit in enige moontlike newe-effekte wat nie in hierdie pamflet gelys is nie.

Wat in hierdie pamflet is

1. Wat FLUXTRIN OTC is en waarvoor dit gebruik word
2. Wat u moet weet voordat u FLUXTRIN OTC neem
3. Hoe om FLUXTRIN OTC te neem
4. Moontlike newe-effekte
5. Hoe om FLUXTRIN OTC te stoor
6. Inhoud van die houer en ander inligting

1. Wat FLUXTRIN OTC is en waarvoor dit gebruik word

Esomeprasool behoort tot 'n groep medisyne genaamd 'protonpompinhibeerders'. Hulle werk deur die hoeveelheid suur wat u maag produseer te verminder.

FLUXTRIN OTC word gebruik vir die korttermynbehandeling van refluksimptome soos sooibrand en regurgitasie in volwassenes.

2. Wat u moet weet voordat u FLUXTRIN OTC neem

Moet nie FLUXTRIN OTC neem:
- Indien u allergies is vir esomeprasool of enige van die ander bestanddele van FLUXTRIN OTC.
- Indien u allergies is vir ander "protonpompinhibeerders".
- Indien u enige medikasie vir MIV behandeling neem (atasanavir of nelfinavir).

Waarskuwings en voorsorgmaatreëls

Vertel u dokter of gesondheidsorgverskaffer voordat u FLUXTRIN OTC neem:
- as u slegte spysvertering ervaar,
- as u nierprobleme ontwikkel soos bloed in die urien (akute interstisiële nefritis),
- as u langer as 'n jaar op kontinuë medikasie is,
- as u medikasie neem wat klopidogrel bevat (gebruik in die behandeling van bloedklonte), as u 'n spesifieke bloedtoets moet ondergaan (Chromogranien A),
- as u voorheen intestinale toestande gehad het,
- as u erge diarree opdoen met waterige stoelgange, buikpyn en koors,
- as u FLUXTRIN OTC neem indien nodig en u simptome verander,
- as u 'n vitamien B_{12} tekort het,
- as u moegheid, duiseligheid, bewing en spierprobleme (hipomagnesemie) ontwikkel, as u gediagnoseer is met osteoporose (bros bene) of op risiko is om u bene te breek,
- as u 'vlinder-uitslag' ontwikkel met sensitiwiteit vir sonlig (sub-akute kutaneuse lupus eritematose).

Indien enigeen van dié op u van toepassing is, vertel u dokter of verpleegster voordat u FLUXTRIN OTC kry.

Kinders

Daar is geen relevante gebruik van FLUXTRIN OTC in die pediatriese populasie onder die ouderdom van 18 jaar, vir die aanduiding van korttermynbehandeling van sooibrand en suurregurgitasie nie.

Ander medisyne en FLUXTRIN OTC

Noem altyd aan u gesondheidswerker indien u enige ander medisyne neem.
- Itrakonasool, ketokonasool, vorikonasool gebruik in die behandeling van swaminfeksies.
- Diasepam gebruik in die behandeling van angstigheid.
- Medisyne wat gebruik word om stuiptrekkings te voorkom (fenitoïen).
- Medisyne wat gebruik word om bloedstolling te voorkom (warfarien of klopidogrel).
- Medisyne wat gebruik word om te help met die simptome van intermitterende kloudikasie (silostasool).
- Medisyne wat gebruik word om maagleiding te versnel (sisapried).
- Digoksien wat gebruik word in die behandeling van hartprobleme.
- Rifampisien wat gebruik word in die behandeling van tuberkulose.
- St. Janskruid – gebruik vir depressie, of sekere tipes anti-maligne medisyne (soos erlotinib of ander anti-maligne medisyne van dieselfde klas).
- FLUXTRIN OTC moet nie terselfdertyd geneem word as sommige medisyne vir MIV, soos atasanavir en nelfinavir nie, aangesien FLUXTRIN OTC die bloedvlakke van u antiretrovirale medisyne kan verlaag.
- Tipranavir wat gebruik word om MIV te behandel.
- Klaritromisien, 'n antibiotika.
- Indien u 'n hoë dosis metotreksaat neem ('n chemoterapeutiese middel wat in 'n hoë dosis gebruik word om kanker te behandel), moet FLUXTRIN OTC moontlik tydelik gestaak word.

Swangerskap en borsvoeding

Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg deskundige vir advies voordat u hierdie medisyne neem. U moet nie FLUXTRIN OTC neem indien u swanger is of u baba borsvoed nie.

Bestuur en gebruik van masjiene

FLUXTRIN OTC kan duiseligheid en dowwe visie veroorsaak en sodoende die vermoë om te bestuur of masjinerie te hanteer beïnvloed.

FLUXTRIN OTC bevat suiker in die vorm van laktose

Indien u dokter aan u genoem het dat u 'n onverdraagsaamheid vir sekere suikers het, kontak u dokter voordat u hierdie medisyne gebruik.

3. Hoe om FLUXTRIN OTC te neem

Moenie medisyne met enige ander persoon deel nie.

Die aanbevole dosis is 20 mg esomeprasool (een tablet) per dag. Dit mag nodig wees om die tablet vir 2 – 3 opeenvolgende dae te neem om verbetering van simptome te verkry. Die duur van die behandeling is tot 2 weke. Behandeling moet gestaak word sodra volledige verligting van simptome ervaar word. Indien geen simptoomverligting binne 2 weke van deurlopende behandeling verkry word nie, moet die pasiënt 'n dokter raadpleeg.

Indien u meer FLUXTRIN OTC neem as wat u moet

In geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien u vergeet om FLUXTRIN OTC te neem

Moet nie 'n dubbele dosering neem om op te maak vir die vergete individuele dosis nie.
Indien dit amper tyd is vir u volgende dosis, moet nie die dosis wat u gemis het neem nie, en neem net die volgende dosis op tyd.

4. Moontlike newe-effekte

FLUXTRIN OTC mag newe-effekte hê.
Nie alle newe-effekte wat vir FLUXTRIN OTC aangemeld is, is in hierdie pamflet ingesluit nie. As u algemene gesondheid versleg of as enige onaangename gevolge ervaar tydens die gebruik van FLUXTRIN OTC, raadpleeg asseblief gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, staak FLUXTRIN OTC en kontak onmiddellik 'n dokter of gaan na die ongevalle-afdeling in u naaste hospitaal:
- Skielike aamborstigheid, swelling van u lippe, tong en keel of liggaam, uitslag, floute of probleme met sluk (erge allergiese reaksie).
- Uitslag of jeuk in die vorm van roolheid van die vel met blase of afskilfer. Daar kan ook erge blase en bloeding in die lippe, oë, mond, neus en geslagsdele wees. Dit kan 'Stevens-Johnson-sindroom' of 'giftige epidermale nekrolise' wees.
- Geel vel, donker urine en moegheid, wat simptome van lewerprobleme kan wees. Dit is alles baie ernstige newe-effekte. As u dit het, het u moontlik 'n ernstige reaksie op FLUXTRIN OTC gehad. U mag dalk dringend mediese hulp of hospitalisasie benodig.

Stel u dokter onmiddellik in kennis of gaan na die ongevalle-afdeling in u naaste hospitaal indien u enige van die volgende opmerk:
- Aamborstigheid gepaardgaande met erge hoes (brongospasma).
- Verlies of verminderde visie.
- Abdominale swelling (mag 'n indikasie wees van lewerversaking).
- Oormatige sweet.
- Bloed in die urien (nefritis).
- Beduidende vermindering in die hoeveelheid urien met kortasem (dit kan 'n teken van niersversaking wees).

Hierdie is als ernstige newe-effekte. U mag dalk dringende mediese hulp benodig.

Stel u dokter in kennis indien u enige van die volgende opmerk:
Gereelde newe-effekte:
- Maagpyn
- Diarree
- Naarheid/Braking
- Konstipasie
- Hoofpyn

Minder Gereelde newe-effekte:
- Spierswakheid/pyn
- Koors
- Ontwikkeling van borste in mans
- Gewrigspyn
- Haarverlies
- Droë mond
- Inflammasie van die mond en lippe
- Duiseligheid
- Dowwe visie
- Tinteling sensasie
- Verlies van balans
- Smaakversteurings
- Slaperigheid
- Onvermoë om te slaap
- Verwarring
- Depressie
- Agitasie
- Hallusinasie
- Lae witbloedseltelling

Newe-effekte met onbekende frekwensie:
- Verlaagde vlakke van kalsium
- Verlaagde vlakke van magnesium
- "Vlinder-uitslag " wat ure-dae aanhou

Indien u enige newe-effekte opmerk wat nie genoem is in hierdie pamflet nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Praat met u dokter, apteker of verpleegster as u newe-effekte ervaar. U kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting in te win oor die veiligheid van FLUXTRIN OTC.

5. Hoe om FLUXTRIN OTC te stoor
- Stoor teen of benede 30 °C.
- Stoor in die oorspronklike verpakking om te beskerm teen lig en vog.
- Stoor alle medisyne buite bereik van kinders.
- Moet nie in die badkamer stoor nie.
- Moet nie gebruik na die vervaldatum op die verpakking.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels wegdoen nie (bv. toilette).

6. Inhoud van die pak en ander inligting

Wat FLUXTRIN OTC bevat

Die aktiewe bestanddeel is Esomeprasool. FLUXTRIN OTC gastries-bestande tablette bevat 20 mg esomeprasool.
Die ander bestanddele is suikersfere (sukrose en mieliestysel), etielsellulose, magnesiumstearaat, povidoon (K-90), ligte magnesiumoksied, natriumlaurielsulfaat, polisorbaat 80, metakrielsuur-etielakrilaat-kopolimeer, dietielftalaat, talk (gesuiwer), sellulose mikrokristallyn, silika kolloïdaal anhidriese, laktosemonohidraat, mieliestysel, kopovidoon (K-28), makrogol 8000, krospovidoon (tipe A), hipromellose, titaandioksied (E171), ferrioksied rooi (E172), opacode S-1-17823 swart ink (bevat sjellak glasuur, isopropielalkohol, ysteroksied swart, n-butielalkohol, propileenglikol en ammoniumhidroksied).

Hoe FLUXTRIN OTC lyk en die inhoud van die pak
- FLUXTRIN OTC mg gastries-bestande tablette is baksteen-rooi gekleurde, ronde vorm, bikonvekse, film-bedekte tablette, ingeprent met '20' aan die een kant met swart ink en plein aan die ander kant.

Die gastries-bestande tablette is verpak in
- Aluminium – Aluminium stolpverpakking met aluminiumfoelie, hitteverseëling lakvernis en koud-vormbare stolpverpakking aluminiumfoelie. Die stolpverpakking stroke word in kartonne verpak.
- HDPE-houer (Hoëdigtheid Polietileenhouer van nek-afwerking met induksieseël-voering en 'n silikagelhouer as droogmiddel)

Pakgroottes:
7 of 14 gastries-bestande tablette.
Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat
TRINITY PHARMA (PTY) LTD
Gwen Laan 3,
4de Vloer,
Sandton,
Gauteng,
2031.

Hierdie pamflet is laas hersien in
28 October 2021

Registrasienommer
FLUXTRIN OTC: 47/11.4.3/0318

Toegang tot die ooreenstemmende professionele inligting
www.trinitypharma.co.za

150 x 600 mm