PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S2**

OMIFLYNT 20 mg (Gastro-resistant tablets)

Esomeprazole

Each OMIFLYNT tablet contains sugar spheres (sucrose + glucose 16,13 mg).

Read all of this leaflet carefully before you start taking OMIFLYNT

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- OMIFLYNT 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 OMIFLYNT is and what it is used for
2. What you need to know before you take OMIFLYNT
3. How to take OMIFLYNT
4. Possible side effects
5. How to store OMIFLYNT
6. Contents of the pack and other information

1. What OMIFLYNT is and what it is used for

OMIFLYNT contains the active substance esomeprazole. It belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

OMIFLYNT is indicated for the temporary, short-term relief of heartburn and hyperacidity. Heartburn is the painful sensation in the chest rising up to your throat.

2. What you need to know before you take OMIFLYNT

Do not take OMIFLYNT:

- If you are hypersensitive (allergic) to esomeprazole or any of the other ingredients of OMIFLYNT (listed in section 6), or other medicines in this group.
- If you are taking a medicine called atazanavir or nelfinavir (used to treat HIV).

Warnings and precautions

Take special care with OMIFLYNT if:

- You have had a stomach ulcer or stomach surgery in the past.
- You have been taking treatment continuously for reflux or heartburn for 4 or more weeks.
- You have jaundice (yellowing of skin or eyes) or severe liver problems.
- You have severe kidney problems. Proton pump inhibitor medicines, such as OMIFLYNT, may rarely cause interstitial nephritis which can lead to inflammation that affects the tubules of the kidneys and the tissues that surround them. This condition may progress to kidney failure and is not necessarily reversed when treatment is discontinued.
- You need to take a non-prescription indigestion or heartburn remedy treatment every day.
- You have ever had a skin reaction after treatment with a medicine similar to OMIFLYNT that reduces stomach acid.

Tell your doctor immediately before or after taking this medicine, if you notice any of the following symptoms as OMIFLYNT can hide the symptoms of other diseases:

- You lose a lot of weight for no reason.
- You have problems or pain when swallowing.

- You get stomach pain or signs of indigestion such as nausea, fullness, bloating especially after food intake.
- You begin to vomit food or blood, which may appear as dark coffee grounds in your vomit.
- You pass black stools (blood-stained faeces).
- You have severe and/or persistent diarrhoea. Esomeprazole has been associated with a small increased risk of infectious diarrhoea. This diarrhoea may be caused by an infection (*Clostridium difficile*) in your intestines. Call your doctor right away if you have watery stool, stomach pain, and fever that does not go away.
- If you are due to have a specific blood test (Chromogranin A).

Subacute chronic lesions on the skin and mucous membranes (SCLE):

Proton pump inhibitor medicines, such as OMIFLYNT are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by pain in the joints, the patient should seek medical help immediately and the healthcare professional should consider stopping OMIFLYNT. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.

OMIFLYNT is not indicated for mild ailments of the stomach and intestines such as indigestion, mild pain in the abdomen, abdominal fullness and feeling full earlier than expected when eating due to nervousness, tension or anxiety.

Children and adolescents

OMIFLYNT is not recommended for use in children, as its safety and efficacy has not been demonstrated.

Other medicines and OMIFLYNT

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

OMIFLYNT can reduce the effectiveness of:

- Ketoconazole and itraconazole (medicines used to treat fungal infections),
- Imipramine (used to treat depression),
- Several antipsychotic medicines (medicines used to treat certain psychiatric disorders),
- Tacrine (used to treat Alzheimer's disease),
- Theophylline (used in treatment of certain respiratory diseases),
- Atazanavir and nelfinavir (used to treat HIV),
- Erlotinib (used for certain types of cancer),
- Clopidogrel (used to prevent blood clots).

Do not take OMIFLYNT if you are taking these medicines.

OMIFLYNT may increase the blood concentrations of the following medicines:

- Diazepam (used to treat anxiety and epilepsy or relax muscles),
- Citalopram (used to treat depression),
- Imipramine or clomipramine (used to treat behaviour disorders, depression or panic)
- Warfarin (used to thin blood),
- Phenytoin (used in epilepsy),
- Saquinavir (a medicine used to treat HIV),
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer),
- Tacrolimus (organ transplantation),
- Digoxin (used for heart problems),
- Cilostazol (used to treat intermittent claudication – a pain in your legs when you walk which is caused by an insufficient blood supply),

- Cisapride (used for indigestion and heartburn).

Your doctor may decide to reduce your dose of these medicines.

With voriconazole (used to treat fungal infections), the effectiveness of both medicines may be increased. Your doctor may therefore decide to reduce your dose of OMIFLYNT.

Clarithromycin (an antibiotic used to treat infections) may increase the blood levels of OMIFLYNT.

Rifampicin (used for treatment of tuberculosis) and St. John's wort *(Hypericum perforatum)* (used to treat depression) may reduce the effectiveness of OMIFLYNT.

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 OMIFLYNT.

The safety of OMIFLYNT in pregnant and breastfeeding women has not yet been established. Do not take OMIFLYNT if you are pregnant or breast-feeding your baby.

Driving and using machines

OMIFLYNT may cause dizziness and may affect the ability to drive or use machines.

OMIFLYNT contains sucrose and glucose

OMIFLYNT tablets contain sucrose and glucose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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

3. How to take OMIFLYNT

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

Always take OMIFLYNT exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of OMIFLYNT is too strong or too weak, talk to your doctor or pharmacist.

The recommended dose is one tablet a day.

Do not take more than this recommended dose of one tablet (20 mg) a day, even if you don't feel an improvement immediately.

The treatment length is up to 14 days.

When your reflux symptoms have completely gone, you should stop taking OMIFLYNT.

If your symptoms get worse or do not improve after taking this medicine for 14 days in a row, you should consult a doctor.

If no symptom relief is obtained within 2 weeks of continuous treatment, you should contact your doctor.

Method of administration:

OMIFLYNT should be swallowed whole with liquid and not chewed or crushed.

Impaired liver function:

If you have severe liver function impairment, your doctor may prescribe a dose of 20 mg OMIFLYNT once daily.

If you take more OMIFLYNT than you should

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

If you forget to take OMIFLYNT

If you missed a dose, take it as soon as you remember. If it is almost time for you next dose, skip the missed dose and continue to take the tablet at the usual time. Do not take a double or larger dose to make up for the forgotten individual doses.

4. Possible side effects

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

If you notice any of the following serious side effects, stop taking OMIFLYNT and contact a doctor immediately:

- Sudden wheezing, swelling of the lips, tongue and throat or body, rash, fainting or difficulties in swallowing. These can be signs of a severe allergic reaction,
- 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 and whites of the eyes, 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 OMIFLYNT. You may need urgent medical attention or hospitalisation.

Consult your doctor as soon as possible if any of the following side effects continue or are bothersome:

The following side effects have been reported frequently:

- Headache,
- Diarrhoea, stomach pain, constipation, flatulence (wind),
- Nausea, vomiting,
- Benign polyps (non-cancerous growths) in the stomach.

The following side effects have been reported less frequently:

- Severe diarrhoea characterised by watery stools, stomach pain, fever (*Clostridium difficile* associated diarrhoea),
- A reduction in the number of white blood cells, which may lead to more frequent infections,
- A reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal,
- Coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in blood tests),
- Swelling of the extremities (peripheral oedema),
- Decreased sodium level in blood,
- Sleep disorders (insomnia),
- Agitation,
- Confusion,
- Depression,
- Aggression,
- Hallucinations,
- Disturbances in vision such as blurred vision,
- Spinning feeling (vertigo),
- Skin rash, lumpy rash (hives), itchy skin,
- Hair loss,
- Skin sensitivity on exposure to sunshine,

- Joint pains, muscle pains, muscle weakness,
- Kidney problems such as painful urination and lower back pain with fever,
- Dizziness,
- Feeling of tingling, prickling, pins and needles, burning sensation or numbness,
- Feeling drowsy or sleepy,
- Distortion or complete lack of the sense of taste,
- Dry mouth,
- An inflammation of the inside of the mouth,
- An infection called “thrush” which can affect the gut and is caused by a fungus,
- An increase in liver enzymes,
- Severe liver problems leading to liver failure and inflammation of the brain,
- Nose infection, chest infection,
- Difficulty breathing,
- Breast enlargement in males,
- Feeling weak, exhausted or generally unwell,
- Increased sweating,
- Severe kidney problems (tubulointerstitial nephritis).

The frequency of the following side effects are unknown:

- Decreased magnesium, calcium or potassium levels in blood,
- Inflammation in the gut, leading to diarrhoea (microscopic colitis),
- Skin rash on areas exposed to sunlight (subacute cutaneous lupus erythematosus).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of OMIFLYNT. Suspected adverse reactions can also be reported directly to the Holder of the Certificate of Registration (HCR) via the link: https://pvi1j.solutions.iqvia.com or the e-mail address, adverse.event.sac@sandoz.com.

5. How to store OMIFLYNT

- Store at or below 25 °C.
- Do not remove the blister from the carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use the tablets after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OMIFLYNT contains:

Active ingredient:

Each OMIFLYNT gastro-resistant tablet contains esomeprazole magnesium dihydrate which is equivalent to 20 mg esomeprazole.

The other ingredients are:

Tablet core:

Sugar spheres (composed of sucrose, maize starch and liquid glucose)

Hydroxypropylcellulose

Povidone

Talc

Titanium dioxide (E171)

Methacrylic acid-ethyl acrylate copolymer (1:1) dispersion 30 %

Glycerol monostearate 40 to 55 *Type II*

Propylene glycol

Stearic acid *Type 50*

Polysorbate 80

Simeticone

Microcrystalline cellulose

Macrogol 6000

Crospovidone *Type A*

Silica colloidal anhydrous

Magnesium stearate

Tablet coating:

Hypromellose

Macrogol 6000

Titanium dioxide (E171)

Talc

Ferric oxide red (E172)

Ferric oxide yellow (E172).

What OMIFLYNT looks like and contents of the pack

OMIFLYNT: Light pink oval gastro-resistant tablet.

OMIFLYNT is available in Aluminium (soft)/Aluminium (hard) blister cards or bottles (polyethylene bottles) closed with polypropylene caps with desiccant inserts in packs of 14 tablets.

Holder of Certificate of Registration

Sandoz SA (Pty) Ltd[1]

Magwa Crescent West

Waterfall City

Jukskei View

Midrand

2090

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Registration number

OMIFLYNT: 44/11.4.3/0335

Access to the corresponding Professional Information

Not applicable.

[1]Company Reg. No.: 1990/001979/07