PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

OMIFLUX 20 (capsules)

Read all of this leaflet carefully because it contains important information for you.

OMIFLUX 20 is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use OMIFLUX 20 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share OMIFLUX 20 with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

1. WHAT OMIFLUX 20 CONTAINS:

Active ingredient: each capsule contains 20 mg omeprazole in a formulation that is not affected by stomach acid.

The other ingredients are gelatine, hypromellose, magnesium oxide heavy, methacrylic acid – ethyl achrylate copolymer 1:1 dispersion, povidone K25, sodium lauryl sulphate, talc and triethyl citrate.

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Contains sugar (sucrose 43,350 mg).

2. WHAT OMIFLUX 20 IS USED FOR:

OMIFLUX 20 is used for the temporary, short-term relief of heartburn and high stomach acid levels in adults.

3. BEFORE YOU TAKE OMIFLUX 20:

Do not take OMIFLUX 20:

- If you are hypersensitive (allergic) to omeprazole or any of the other ingredients of OMIFLUX 20.
- If you are pregnant or breastfeeding a baby.
- If you are using the medicine atazanavir and nelfinavir (antiretroviral medicine).

Take special care with OMIFLUX 20:

Tell your doctor:

- If your kidney or liver function is impaired.
- If you have to drive, climb dangerous heights or operate dangerous machinery. (Your ability to concentrate might be impaired and this can lead to accidents.)
- If you are using the medicine clopidogrel (used to prevent the forming of blood clots), as concomitant use of clopidogrel and OMIFLUX 20 may lead to a decrease in the effects of the clopidogrel which may lead to an increase in cardiovascular events.
- If you develop severe diarrhoea while using OMIFLUX 20. Please consult your doctor immediately if you experience watery stools, abdominal pain and fever while taking OMIFLUX 20.
- If you experience unintentional weight loss, vomiting, vomiting blood, difficulty swallowing and black tar like stools.

Taking OMIFLUX 20 with food and drink:

The capsule should be swallowed whole with a glass of water. Do not open the capsule. Do not crush, break or chew the capsule contents. The capsule can be taken with food or on an empty stomach in the morning.

Pregnancy and breastfeeding:

You should not take OMIFLUX 20 when you are pregnant or breastfeeding your baby.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking OMIFLUX 20.

Driving and using machinery:

OMIFLUX 20 may cause drowsiness, dizziness and may impair concentration. Do not drive or operate any machinery before you know how OMIFLUX 20 affects you.

Important information about some of the ingredients of OMIFLUX 20:

OMIFLUX 20 contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltse insufficiency should not take OMIFLUX 20.
Sucrose may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with OMIFLUX 20:

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

Please consult your doctor, pharmacist or other healthcare professional for advice if you are taking any of the following medicines:

- Diazepam (medicine to treat anxiety and tension).

- Warfarin (medicine that keeps your blood thin).
- Phenytoin (medicine used to treat epilepsy).
- Digoxin (medicine to treat heart conditions).
- Clarithromycin (antibiotic medicine used to treat bacterial infection).
- Atazanavir, ritonavir, nelfinavir, saquinavir (antiretroviral medicines used to treat HIV infection).
- Tacrolimus (an immunosuppressive medicine that is mainly used after an organ transplant in order to lower the risk of organ rejection).
- Methotrexate (used in treatment of cancer, autoimmune diseases and ectopic pregnancy).
- Vitamin B_{12} (vitamin supplement).
- Rifampicin (medicine used to treat tuberculosis (TB)).
- St John's wort (herbal medicine used to treat depression).
- Clopidogrel (medicine used to prevent the forming of blood clots) (see "Take special care with OMIFLUX 20").
- Itraconazole, voriconazole, posaconazole and ketoconazole (medicines used to treat fungal infections).
- Erlotinib (medicine used to treat several types of cancer).
- Cilostazol (medicine used in the treatment of peripheral arterial disease).

Not all the medicines that would interact with OMIFLUX 20 are listed above. Please tell your doctor, pharmacist or healthcare professional about all the medicines you are taking before you start taking OMIFLUX 20.

4. HOW TO TAKE OMIFLUX 20:

Always take OMIFLUX 20 exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of OMIFLUX 20 is too strong or too weak, talk to your doctor or pharmacist.

The recommended dose is one OMIFLUX 20 capsule daily for up to 14 days.

The capsule should be swallowed whole with a glass of water in the morning.

Do not crush, break, open or chew the capsule or its contents.

Do not use continuously for more than 14 days without consulting a doctor.

If you take more OMIFLUX 20 than you should:

In the event of an overdosage you may experience blurred vision, confusion, flushing, headache and nausea. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take OMIFLUX 20:

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

5. POSSIBLE SIDE EFFECTS:

OMIFLUX 20 can have side effects.

Not all side effects reported for OMIFLUX 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OMIFLUX 20, please consult your health care provider for advice.

Contact your doctor immediately and stop taking OMIFLUX 20 if any of the following side effects occur: hypersensitivity reactions and fever, difficulty in breathing, swelling of the face, lips or

throat or severe allergic reactions, hives, tightness in chest (anaphylactic reactions). These are all very serious side effects. If you have them you may have had a serious allergic reaction to OMIFLUX 20. You may need urgent medical attention or hospitalisation.

Check with your doctor as soon as possible if any of the following side effects occur.

The following side effects have occurred frequently:

- Severe headache, dizziness, sleeping disturbances.
- Diarrhoea, constipation, nausea, vomiting, flatulence, stomach pain, colic.

The following side effects have occurred less frequently:

- Blood disorders, bloody or cloudy urine.
- Low sodium, magnesium or calcium levels in the blood.
- Tingling, prickling or numbness of the skin, mental confusion, aggression, hallucinations, restlessness, depression.
- Blurred vision.
- Swelling of tissues in the lower limbs.
- Taste disturbances, dry mouth, persistent heartburn.
- Skin sensitivity, skin rash, itching, hair loss.
- Abnormal loss of strength.
- Pain in the joints or muscle.
- Enlargement of male breasts.
- Burning or painful urination or frequent urge to urinate.
- Unusual tiredness or weakness, increased sweating.
- Jaundice (yellowing of the skin).

Not all side effects reported for OMIFLUX 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OMIFLUX 20, please consult your doctor, pharmacist or other healthcare professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF OMIFLUX 20:

Do not store above 25 °C. Store in the original packaging in order to protect from light and moisture.

Do not store your medicine in the bathroom.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the capsules after the expiry date printed on the container or label.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF OMIFLUX 20:

OMIFLUX 20 is packaged in HDPE plastic bottles with polypropylene screw caps with induction heat seal liner or CRC polypropylene screw caps with induction heat seal liner and 1 g silica gel capsules or in aluminium blisters.

8. IDENTIFICATION OF OMIFLUX 20:

OMIFLUX 20 is a white capsule filled with almost white to light brown pellets.

9. REGISTRATION NUMBER:

43/11.4.3/0457

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

Waterfall 5-lr

Magwa Crescent West

Waterfall City

Jukskei View

2090

11. DATE OF PUBLICATION:

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