1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

ULSANIC 1 g TABLETS

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

ULSANIC 1 g TABLETS are available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use ULSANIC 1 g TABLETS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ULSANIC 1 g TABLETS with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within a few days.

WHAT ULSANIC 1 g TABLETS CONTAINS

The active substance is sucralfate. Each tablet contains 1 g of sucralfate.

The other ingredients are carmellose calcium, macrogol, magnesium stearate and microcrystalline cellulose.

WHAT ULSANIC 1 g TABLETS ARE USED FOR

ULSANIC 1 g TABLETS belongs to a group of medicines used to heal ulcers. It works by forming a protective barrier over the ulcer area.

BEFORE YOU TAKE ULSANIC 1 g TABLETS

Do not take ULSANIC 1 g TABLETS:

- If you are hypersensitive (allergic) to sucralfate or any of the other ingredients of ULSANIC 1 g TABLETS.

Take special care with ULSANIC 1 g TABLETS

- If you have kidney problems.
- If you have a phosphate deficiency.

Taking ULSANIC 1 g TABLETS with food and drink

ULSANIC 1 g TABLETS should be taken between meals.

Pregnancy and breastfeeding

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking ULSANIC 1 g TABLETS.

Driving and using machinery

In some patients ULSANIC 1 g TABLETS causes dizziness or drowsiness. If you feel dizzy or drowsy, do not drive or operate machinery.

Taking other medicines with ULSANIC 1 g TABLETS

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicine).

If you are taking any other medicine, be sure to leave a gap of about 2 hours between taking

ULSANIC 1 g TABLETS and the other medicine. If you are taking antacids, leave a gap of at least half an hour between taking the antacid and ULSANIC 1 g TABLETS.

Some of the medicines that may be affected by ULSANIC 1 g TABLETS are cimetidine or ranitidine (for stomach ulcers), digoxin (for heart conditions), phenytoin (for epilepsy), warfarin (for thinning blood), theophylline, ketoconazole, and some antibiotics.

HOW TO TAKE ULSANIC 1 g TABLETS

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

Always take ULSANIC 1 g TABLETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with ULSANIC 1 g TABLETS will continue.

The usual dose is one tablet three or four times a day between meals and at bedtime.

Sometimes a dose of two tablets taken in the morning and evening is recommended.

A dose of one tablet taken in the mornings and evenings may be recommended for maintenance treatment and may be continued for up to a year.

If you have the impression that the effect of ULSANIC 1 g TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more ULSANIC 1 g TABLETS than you should

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/missed a dose of ULSANIC 1 g TABLETS

Take your missed dose as soon as you remember and then continue to take your medicine as usual.

POSSIBLE SIDE EFFECTS

ULSANIC 1 g TABLETS can have side effects.

If any of the following happens, stop taking ULSANIC 1 g TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

Rash or swelling on the face or neck and shortness of breath.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ULSANIC 1 g TABLETS. You may need urgent medical attention or hospitalisation.

The following side effects have been reported frequently:

- Constipation.

The following side effects have been reported less frequently:

Dizziness, drowsiness, skin rashes, itchiness of the skin, diarrhoea, nausea, dry mouth, gastric discomfort may occur.

The following side effects have been reported, but the frequency is unknown:

- Back pain.
- Feeling dizzy.

Not all side effects reported for ULSANIC 1 g TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ULSANIC 1 g TABLETS, please consult your healthcare provider for advice.

STORING AND DISPOSING OF ULSANIC 1 g TABLETS

Store in a dry place at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

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).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ULSANIC 1 g TABLETS

20 or 120 tablets are packed in a white polypropylene container and sealed with a white low-density polyethylene cap, together with a silica gel sachet and white foam insert or a polypropylene desiccant disc and rayon insert, and a leaflet.

20 or 120 tablets are packed in white high-density polyethylene container and sealed with a white opaque polypropylene screw cap with induction wad, together with a silica gel sachet and white foam insert.

20 or 120 tablets are packed in metallised polyester laminated with opaque white linear low-density polyethylene lay-flat bag and sealed with a clear low-density polyethylene lay-flat zip. The packed patient-ready bank bags are grouped, packed and sealed into a polyethylene

bag, together with a leaflet.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ULSANIC 1 g TABLETS

White, oblong, biconvex tablets, plain on one side and embossed “ULSANIC” on the other side.

REGISTRATION NUMBER

Q/11.4.3/147

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912 (South Africa)

Tel: +27 11 239 6200 (Other)

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