1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

ULSANIC EFFERVESCENT TABLETS

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS CONTAIN

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

The other ingredients are flavour orange natural, lactose monohydrate, macrogol, povidone, Quinoline Yellow WS (C.I. 47005), saccharin sodium, sodium cyclamate, sodium starch glycollate, Sunset Yellow FCF Lake (C.I. 15985).

Contains sugar: Lactose monohydrate 476 mg

Contains sweeteners: Sodium cyclamate 23,4 mg, saccharin sodium 3 mg

WHAT ULSANIC EFFERVESCENT TABLETS ARE USED FOR

ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS

Do not take ULSANIC EFFERVESCENT TABLETS:

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

Take special care with ULSANIC EFFERVESCENT TABLETS

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

Taking ULSANIC EFFERVESCENT TABLETS with food and drink

ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS.

Driving and using machinery

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

Important information about some of the ingredients of ULSANIC EFFERVESCENT TABLETS

ULSANIC EFFERVESCENT TABLETS contain lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ULSANIC EFFERVESCENT TABLETS.

Taking other medicines with ULSANIC EFFERVESCENT 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 EFFERVESCENT 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 EFFERVESCENT TABLETS.

Some of the medicines that may be affected by ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS

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

Always take ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS

will continue.

The usual dose is one effervescent tablet three or four times a day between meals and at bedtime. The effervescent tablet should be dissolved in a glass of water.

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

A dose of one effervescent 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 EFFERVESCENT TABLETS is too strong or too weak, tell your doctor or pharmacist.

If you take more ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS

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

POSSIBLE SIDE EFFECTS

ULSANIC EFFERVESCENT TABLETS can have side effects.

If any of the following happens, stop taking ULSANIC EFFERVESCENT 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 EFFERVESCENT 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 EFFERVESCENT TABLETS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ULSANIC EFFERVESCENT TABLETS, please consult your healthcare provider for advice.

STORING AND DISPOSING OF ULSANIC EFFERVESCENT 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 EFFERVESCENT TABLETS

10 or 20 effervescent tablets are wrapped in an aluminium foil, polyethylene square film, packed in a polypropylene tube and sealed with a white low-density polyethylene clip-on cap with a built-in drier. The tube is packed into an outer cardboard carton together with a leaflet.

Not all pack sizes are necessarily marketed.

IDENTIFICATION OF ULSANIC EFFERVESCENT TABLETS

Flat, round, faintly peach-coloured tablets with orange speckles and bevelled edges, producing an orange coloured opaque dispersion with an orange odour and bitter after taste.

REGISTRATION NUMBER

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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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