1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

ULSANIC SUSPENSION

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ULSANIC SUSPENSION 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 SUSPENSION CONTAINS

The active substance is sucralfate. Each 5 ml contains 1 g of sucralfate.

The other ingredients are flavour orange, glycerol, purified water, saccharin sodium, sodium acid phosphate, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate and Xanthan gum.

Preservatives:

Sodium methyl hydroxybenzoate 0,09 % *m/v*

Sodium propyl hydroxybenzoate 0,048 % *m/v*

Contains sweetener: Saccharin sodium 0,3 mg

WHAT ULSANIC SUSPENSION IS USED FOR

ULSANIC SUSPENSION 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 SUSPENSION

Do not take ULSANIC SUSPENSION:

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

Take special care with ULSANIC SUSPENSION

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

Taking ULSANIC SUSPENSION with food and drink

ULSANIC SUSPENSION 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 SUSPENSION.

Driving and using machinery

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

Taking other medicines with ULSANIC SUSPENSION

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

Some of the medicines that may be affected by ULSANIC SUSPENSION 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 SUSPENSION

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

Always take ULSANIC SUSPENSION 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 SUSPENSION will continue.

The usual dose is 5 ml (one medicine measure) of suspension three or four times a day between meals and at bedtime.

Sometimes a dose of 10 ml suspension taken in the morning and evening is recommended.

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

Shake the suspension well before use.

If you take more ULSANIC SUSPENSION 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 SUSPENSION

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

POSSIBLE SIDE EFFECTS

ULSANIC SUSPENSION can have side effects.

If any of the following happens, stop taking ULSANIC SUSPENSION 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 SUSPENSION. 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. A few cases of bezoar (an insoluble mass formed within the gastric lumen) have been reported in patients with the administration of ULSANIC SUSPENSION and enteral feeds by nasogastric tube.

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

- Back pain.
- Feeling dizzy.

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

STORING AND DISPOSING OF ULSANIC SUSPENSION

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 SUSPENSION

100 ml are packed into a round, natural, high-density polyethylene bottle and sealed with a white low-density polyethylene snap-on cap. The bottle is packed in an outer cardboard carton together with a leaflet.

250 ml are packed into a round, white high-density polyethylene bottle and sealed with a white screw cap with an expanded polyethylene liner. The bottle is packed in an outer cardboard carton together with a blue polystyrene 5 ml medicine measure and a leaflet.

600 ml are packed into a round, white high-density polyethylene container and sealed with a white polypropylene screw cap with a white expanded polyethylene liner.

Not all packs and pack sizes are necessarily marketed.

IDENTIFICATION OF ULSANIC SUSPENSION

Thick, off-white suspension with an orange odour.

REGISTRATION NUMBER

V/11.4.3/315

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

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