1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

ULSANIC 1 g TABLETS

ULSANIC EFFERVESCENT TABLETS

ULSANIC SUSPENSION

COMPOSITION

ULSANIC 1 g TABLETS:

Each tablet contains 1 g of sucralfate.

Excipients:

Carmellose calcium, macrogol, magnesium stearate, microcrystalline cellulose

ULSANIC EFFERVESCENT TABLETS:

Each effervescent tablet contains 1 g of sucralfate.

Excipients:

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

ULSANIC SUSPENSION:

Each 5 ml contains 1 g of sucralfate.

Excipients:

Flavour orange, glycerol, purified water, saccharin sodium, sodium acid phosphate, sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, Xanthan gum

Preservatives:

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

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

Contains sweetener: Saccharin sodium 0,3 mg

CATEGORY AND CLASS

A 11.4.3 Medicines acting on the gastrointestinal tract: Other

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Sucralfate is therapeutically anti-ulcerogenic and capable of inhibiting the proteolytic action of pepsin.

Sucralfate forms a protective film over the mucosa in ulcerated or inflamed areas of the stomach and protects the gastric mucosa, and has the ability to absorb pepsin, trypsin and bile acids.

INDICATIONS

- Gastric ulcer, duodenal ulcer, chronic gastritis and reflux oesophagitis.
- ULSANIC produces relief of subjective symptoms of peptic ulceration e.g. epigastric pain, hyperchlorhydria, vomiting.
- Maintenance treatment after successful endoscopically proven, recently healed duodenal ulcer.

CONTRAINDICATIONS

Hypersensitivity to sucralfate or to any of the excipients found in ULSANIC (see COMPOSITION).

WARNINGS AND SPECIAL PRECAUTIONS

ULSANIC should be administered with caution in patients with renal impairment or on dialysis, due to the possibility of increased aluminium absorption. In patients with renal failure, absorption of aluminium may cause adverse effects. Aluminium accumulation and toxicity (aluminium osteodystrophy, osteomalacia, encephalopathy) have been described in patients with renal impairment. Blood levels of aluminium, phosphate, calcium, alkaline phosphatase, should be periodically measured in these patients.

Caution is advised when ULSANIC is administered in patients with phosphate deficiencies as aluminium binds to phosphate in the gastrointestinal tract, inhibiting its absorption.

Occasional cases of bezoar (an insoluble mass formed within the gastric lumen) have been reported in patients taking ULSANIC. Bezoars have been described in patients after administration of ULSANIC in severely ill patients in Intensive Care Units, and especially in premature infants in whom the use of ULSANIC is not recommended, and should be used with caution in patients with delayed gastric emptying or receiving concomitant enteral feeds.

Since the elderly often have reduced physiological function, the dosage should be adjusted with care.

The safety and efficacy of the maintenance treatment exceeding a period of 12 months have not been established.

Effects on ability to drive and use machines

ULSANIC may cause dizziness and drowsiness. Patients should be cautioned about operating hazardous machinery including motor vehicles until they are reasonably certain that ULSANIC therapy does not affect them adversely.

Excipients

ULSANIC EFFERVESCENT TABLETS contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take ULSANIC EFFERVESCENT TABLETS.

INTERACTIONS

Sucralfate may interfere with the absorption of other medicines and it has been suggested that there should be an interval of 2 hours between the administration of ULSANIC and other concurrent non-antacid medication. Some of the medicines reported to be affected by ULSANIC include cimetidine, ranitidine, digoxin, ketoconazole, phenytoin, fluoroquinolone antibacterials, tetracycline, levothyroxine, quinidine, theophylline and possibly warfarin.

The recommended interval between ULSANIC administration and other antacids is 30 minutes.

Cases of bezoar formation has been reported when ULSANIC has been administered concomitantly with enteral feeds. An interval of one hour should separate ULSANIC administration and enteral feeding (see SIDE EFFECTS).

HUMAN REPRODUCTION

Safety in pregnant and lactating women has not been established.

Lactation

It is not known whether ULSANIC is excreted in human breast milk.

DOSAGE AND DIRECTIONS FOR USE

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

The effervescent tablet should be dissolved in a glass of water.

A dosage regime of 2 g twice daily (i.e. 2 tablets, or 2 effervescent tablets or 10 ml suspension, mornings and evenings) has also been shown to be effective for the treatment of duodenal ulcer.

Reflux oesophagitis

One tablet mixed with water or one effervescent tablet dissolved in water or 5 ml (one medicine measure) of suspension four times a day between meals and at bedtime.

Maintenance treatment after successful healing of duodenal ulcer

One tablet or one effervescent tablet twice daily i.e. one tablet half an hour before breakfast and one tablet half an hour before supper on an empty stomach. Treatment should be continued for 12 months.

Relief is usually experienced by peptic ulcer patients following the administration of ULSANIC alone, although a short-term regime with additional analgesic and spasmolytic

medicines may be of greater benefit in some patients with incipient clinical manifestations, especially severe pain in the epigastrium.

SIDE EFFECTS

Nervous system disorders

Less frequent: Dizziness, drowsiness

Frequency unknown: Vertigo

Skin and subcutaneous tissue disorders

Less frequent: Skin rashes, pruritus

Gastrointestinal disorders

Frequent: Constipation

Less frequent: Diarrhoea, nausea, dry mouth, gastric discomfort. A few cases of bezoar have been reported in patients with the administration of ULSANIC SUSPENSION and enteral feeds by nasogastric tube (see INTERACTIONS)

General disorders and administrative site conditions

Frequency unknown: Back pain

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Treatment should be symptomatic and supportive.

IDENTIFICATION

ULSANIC 1 g TABLETS: White, oblong, biconvex tablets, plain on one side and embossed “ULSANIC” on the other side.

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.

ULSANIC SUSPENSION: Thick off-white suspension with an orange odour.

PRESENTATION

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, white foam insert and a leaflet.

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.

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.

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.

STORAGE INSTRUCTIONS

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

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

ULSANIC 1 g TABLETS:	Q/11.4.3/147
ULSANIC EFFERVESCENT TABLETS:	31/11.4.3/0119
ULSANIC SUSPENSION:	V/11.4.3/315

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Dates of registration:

ULSANIC 1 g TABLETS:	19 October 1982
ULSANIC EFFERVESCENT TABLETS:	17 June 1997
ULSANIC SUSPENSION:	16 November 1988

Date of the most recent amendment to the professional information as approved by the Authority: 26 October 2012

Namibia:	NS0
ULSANIC 1 g TABLETS:	90/11.4.3/001257
ULSANIC EFFERVESCENT TABLETS:	04/11.4.3/0162
ULSANIC SUSPENSION:	04/11.4.3/0161

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