NEW ZEALAND DATA SHEET

CARAFATE

1. Product Name

Carafate, 1 g, tablet.

2. Qualitative and Quantitative Composition

Each tablet contains 1 g sucralfate

For the full list of excipients, see section 6.1.

3. Pharmaceutical Form

Carafate is a large white capsule shaped tablet with a score line

Dimensions: 20 mm x 9 mm x 7mm

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4. Clinical Particulars

4.1 Therapeutic indications

Treatment of acute, non-malignant gastric ulcer and duodenal ulcer.

Maintenance therapy to prevent the recurrence of duodenal ulcers.

4.2 Dose and method of administration

Acute ulcerous conditions

The recommended adult dose of Carafate for duodenal ulcer and gastric ulcer is 1 g tablet three times a day, one hour before meals and one 1 g tablet at bedtime or two 1 g tablets twice daily taken before breakfast and at bedtime (for up to 8 weeks).

For relief of pain, antacids may be added to the treatment. However, they should not be taken within half an hour before or after sucralfate intake.

In duodenal ulcer, while healing with sucralfate often occurs within two to four weeks, treatment should be continued for up to 8 weeks unless healing has been demonstrated by x-ray and/or endoscopic examination. In the case of gastric ulcers an alternative treatment should be considered if no objective improvement is observed following 6 weeks of sucralfate therapy. Large gastric ulcers that show a progressive healing tendency may require the full 8 weeks of therapy.

Maintenance treatment

To reduce the risk of recurrence of duodenal ulcers, the recommended dose is one 1 g tablet before breakfast and one at bedtime (for up to 12 months). When necessary for relief of pain, antacids may be added to the treatment. However, they should not be taken within half an hour before or after taking sucralfate.

4.3 Contraindications

Carafate is contraindicated in patients on dialysis as long term administration may cause symptoms such as aluminium encephalopathy, aluminium osteomalacia and anaemia.

If considering the use of the drug in pregnant patients or women of child bearing potential. (see section 4.4 and section 4.6). The drug is not recommended for use in children (see section 4.4), patients with actively bleeding peptic ulcer or those with severely impaired renal function.

4.4 Special warnings and precautions for use

Proper diagnosis is important since symptomatic response to Carafate therapy does not preclude the presence of a gastric malignancy. There is no clinical experience in the use of sucralfate in patients with actively haemorrhaging ulcers.

Recurrence may be observed in patients with gastric or duodenal ulcers. While the treatment with sucralfate can result in complete healing of the ulcer, a successful course of treatment should not be expected to alter the underlying cause of ulcer disease.

The risk of recurrence of duodenal ulcers may be reduced by maintaining the patient on a reduced dose for up to 12 months after ulcer healing is complete (see section 4.2). Carafate should be administered with care in patients with phosphate deficiencies as aluminium binds to phosphate in the gastrointestinal tract it inhibits its absorption.

Use in children

The paediatric dose has not been determined, as clinical experience in children is limited. Therefore, sucralfate therapy cannot be recommended for children under 18 years of age unless, in the judgement of the physician, anticipated benefits outweigh the potential risk.

Renal impairment

Care should be taken in patients with impaired renal function as each g of sucralfate contains 190 mg of aluminium.

4.5 Interaction with other medicines and other forms of interaction

Antacids should not be taken within half an hour before or after sucralfate intake because of the possibility of decreased binding of sucralfate with the gastro-duodenal mucosa as a consequence of a change of intragastric pH. The interaction of food with sucralfate is also related to the effect of food on gastric pH.

4.6 Fertility, pregnancy and lactation

Pregnancy

There have been no reports to date on the use of sucralfate in pregnant women. Therefore, sucralfate should be used in pregnant women or women of child bearing potential only if, in the judgement of the physician, the anticipated benefits outweigh the potential risk.

Breast-feeding

No data available.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

No data available

4.8 Undesirable effects

Constipation has been encountered in about 2 to 3% of patients in various trials. Other adverse effects reported include headache (2.4%), urticaria (1%), nausea, diarrhoea, gastric discomfort, indigestion, dry mouth, thirst, skin rash, pruritus, back pain, dizziness, sleepiness and vertigo.

No additional side effects have been associated with maintenance use of sucralfate for up to 12 months at the recommended dose.

Carafate should be administered with care as long term use may cause symptoms such as aluminium encephalopathy, aluminium osteomalasia, and anemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

In acute oral toxicity studies in animals, using doses up to 12 g/kg body weight, a lethal dose could not be found. Risks associated with overdosage should, therefore, be minimal but constipation and nausea might be expected.

For further advice on management of overdose please contact the National Poisons Information Centre (0800 POISON or 0800 764 766).

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for peptic ulcer and gastro-oesophageal reflux disease,
ATC code: A02BX02

Four grams (4 g) daily of sucralfate is effective in increasing the rate of healing of duodenal ulcer and gastric ulcer over a period of 4 to 8 weeks. Two grams (2 g) daily is effective for prophylactic use.

Sucralfate is minimally absorbed after oral administration and is believed to act primarily at the ulcer site.

Sucralfate produces an adherent and cytoprotective barrier at the ulcer site. This barrier protects the ulcer site from the potential ulcerogenic properties of acid, pepsin and bile. Furthermore, sucralfate complexes directly with pepsin and bile and also blocks acid diffusion across the sucralfate-protein barrier at the ulcer site.

The enzyme pepsin is now known to be the primary agent that damages the gastric mucosa directly and the role played by acid is merely supportive in that it maintains an optimal pH condition for the damaging action of enzymes on the mucosa.

Experiments have shown that sucralfate is not an antacid.

Inhibition of pepsin by sucralfate is bimodal: formation of pepsin resistant complexes with substrate proteins and direct absorption of the proteolytic enzyme.

5.2 Pharmacokinetic properties

The action of sucralfate is nonsystemic as the drug is only minimally absorbed (3.5%) from the gastrointestinal tract. The minimal amounts of the sulphated disaccharide, which are absorbed, are primarily excreted in the urine.

5.3 Preclinical safety data

No data available.

6. Pharmaceutical Particulars

6.1 List of excipients

Carafate tablets also contain

- Carmellose sodium
- Macrogol 1500
- Magnesium stearate
- Microcrystalline cellulose
- Water

Carafate tablets contain 190 mg aluminium per tablet.

Carafate tablets are gluten, lactose, and sugar free.

6.2 Incompatibilities

No data available

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 30°C.

6.5 Nature and contents of container

HDPE bottle containing 120 tablets.

6.6 Special precautions for disposal

No data available

7. Medicines Schedule

General Sale Medicine

8. Sponsor Details

Mylan New Zealand Ltd
PO Box 11183
Ellerslie
AUCKLAND
Freephone: 0800 168 169

9. Date of First Approval

26 May 2005

10. Date of Revision of the Text

25 Oct 2019

Summary table of changes

Section	Summary of new information
All	Revise to Mylan's SPC format
3	Added in score line details
5.1	Added in Pharmacotherapeutic group and ATC Code
6.1	Added in aluminium, gluten, sucrose and lactose content details
8	Sponsor change to Mylan