



Ulcars® 1 g Oral suspension in sachets

sucralfate

sanofi aventis

IDENTIFICATION OF THE MEDICINE

COMPOSITION

Sucralfate 1 g
Excipients : sodium saccharine, caramel flavouring, aniseed flavouring, sodium propylhydroxybenzoate, sodium methylhydroxybenzoate, dihydrate monosodium phosphate, xanthan gum, 85% glycerol, purified water q.s.f. one sachet.

PHARMACEUTICAL FORM AND PRESENTATION

Oral suspension (box of 30 sachets).

PHARMACOTHERAPEUTIC CLASS

ANTIULCEROSUS

(A: alimentary tract and metabolism)

NAME AND ADDRESS OF THE MARKETING COMPANY

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MANUFACTURER'S NAME AND ADDRESS

Pharmatis
Zone d'Activités Est n° 1
60190 Estrées-Saint-Denis - FRANCE

WHEN SHOULD YOU USE THIS MEDICINE

This medicine is indicated for the treatment of gastric or duodenal ulcers and to prevent the recurrence of a duodenal ulcer.

ATTENTION !

WHEN SHOULD YOU NOT USE THIS MEDICINE

This medicine **MUST NOT BE USED** in the following cases :
- In premature or non-mature neonates,
- In the event of allergy to one of the ingredients.
IF ANY DOUBT, YOU MUST ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

SPECIAL WARNINGS

A few cases of bezoar (obstruction of the digestive tract) have been reported in patients hospitalized in an intensive care unit ; these were mainly seen in those receiving tube feeding or in neonates, particularly premature or non-mature infants.

PRECAUTIONS FOR USE

This medicine should be used *WITH CARE* in the event of :

- chronic renal failure (impaired kidney function),
 - reduced levels of phosphorous in the blood.
- IF ANY DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.**

Regular medical supervision is essential to ensure the correct use of this medicine; monitoring should include examinations of the stomach : fibroscopy.

DRUG INTERACTIONS AND OTHER INTERACTIONS

Sucralfate may decrease the effect of certain medicines if they are administered simultaneously. A two-hour delay should be allowed between dosing with this medicine and with other medicines.

IN ORDER TO PREVENT POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICINES, YOU MUST SYSTEMATICALLY INFORM YOUR DOCTOR OR PHARMACIST IF YOU ARE RECEIVING ANY OTHER TREATMENT.

PREGNANCY - BREAST-FEEDING

This medicine should preferably not be used during pregnancy.

If you discover that you are pregnant during treatment, you should ask your doctor for advice since only he/she can judge whether or not treatment should be continued. The use of sucralfate during breast-feeding is not recommended.

AS A GENERAL RULE, YOU SHOULD ALWAYS ASK THE ADVICE OF YOUR DOCTOR OR PHARMACIST BEFORE TAKING ANY MEDICINE DURING PREGNANCY OR BREAST-FEEDING.

LIST OF EXCIPIENTS THAT MUST BE KNOWN FOR A SAFE USE IN SOME PATIENTS

Sodium methylhydroxybenzoate and sodium propylhydroxybenzoate.

HOW TO USE THIS MEDICINE

DOSAGE

Healing of gastric ulcer :

- One sachet, four times a day, i.e. :
 - one sachet, half an hour to an hour before each of the three main meals,
 - one sachet at bed time, about two hours after the evening meal.

Healing of duodenal ulcer :

Two treatment schedules are possible :

- One sachet, four times a day, i.e. :
 - one sachet, half an hour to an hour before each of the three main meals,
 - one sachet at bed time, about two hours after the evening meal.

- Two sachets, morning and evening, i.e. :

- two sachets on waking in the morning, 30 minutes to an hour before breakfast,
- two sachets in the evening, about two hours after the evening meal.

Prevention of the recurrence of duodenal ulcer :

Two treatment schedules are possible :

- One sachet, twice a day, i.e. :
 - one sachet on waking in the morning, 30 minutes to an hour before breakfast,
 - one sachet in the evening, taken either 30 minutes to an hour before the meal or at bed time, about two hours after the evening meal.

- Two sachets in the evening, either 30 minutes to an hour before the meal or at bed time, about two hours after the evening meal.

MODE AND ROUTE OF ADMINISTRATION

Oral route.

To drink the content of the sachet, open it along the dotted line and then squeeze it while holding the open side between the lips.

DURATION OF TREATMENT

Healing of gastric or duodenal ulcers : 4 to 6 weeks.

UNWANTED AND UNPLEASANT EFFECTS

AS ANY ACTIVE PRODUCT, THIS MEDICINE MAY, IN CERTAIN PEOPLE, GIVE RISE TO MORE OR LESS UNPLEASANT EFFECTS :

- constipation,
- rarely : dry mouth, nausea, vomiting, skin rash, dizziness,
- if high doses are administered for a long period, there is a theoretical risk of reduced phosphorous levels in the blood,
- a few cases of bezoar (obstruction of the digestive tract) have been reported in certain patients (cf. Warnings).

REPORT TO YOUR DOCTOR OR PHARMACIST ANY UNDESIRABLE OR UNPLEASANT EFFECT NOT MENTIONED IN THIS LEAFLET.

STORAGE

DO NOT EXCEED THE EXPIRY DATE CLEARLY INDICATED ON THE PACKAGING.

DATE OF LEAFLET REVISION

November 2005.