

LEBERSAL

COMPOSITION

(Per 100 g)

Bicarbonate of soda 12.5g

Anhydrous disodium phosphate 8.4g

Anhydrous sodium sulphate 3.15g

Desiccated magnesium sulphate 1.05g

Excipients: tartaric acid, bicarbonate of soda, sodium carbonate, lemon and saccharine essence.

One spoonful (2.5 g) neutralizes 3.72 meq of acid and contains 470 mg of sodium.

PHARMACEUTICAL FORM AND CONTENTS OF PACKET

100g bottle containing granulated effervescent.

ACTIVITY

LEBERSAL has an antacid and laxative double action, which neutralizes excess gastric acidity.

REGISTERED MANUFACTURERS

Laboratorios ERN S.A.C / Pedro IV nº 499 - 08020 Barcelona.

INDICATIONS

Symptomatic, temporary relief from constipation and digestive problems related to stomach acidity.

COUNTERINDICATIONS

Hypersensitivity or allergy to any of its constituents. Alkalosis. Ileostomy.

Gastrointestinal or rectal haemorrhage. Appendicitis or its symptoms (abdominal pain, cramps, nausea, swollen stomach, intestinal obstruction or inflammation). Abdominal pain of unknown origin.

Do not use LEBERSAL if you suffer from hypertension, serious cardiac or renal insufficiency, if you are pregnant, if you have a tendency to water retention (edemas), or in general if you are being treated with diuretics or are following a low salt (low in sodium) diet. It is also not to be used by those suffering diarrhoea.

PRECAUTIONS

If the symptoms persist, or get worse, for more than week, you should consult a doctor.

Do not exceed the stated dose.

Do not use when your stomach is excessively full of food and drink.

INTERACTIONS

It should not be used at the same time as astringents or anti-diarrhea medication, milk, milk derivatives or calcium.

LEBERSAL can affect the absorption of other medication: Iron, lithium, tetracycline, ketoconazol, cimetadine, ranitidine, famotidine, mecamlamine, metenamine. Separate taking these drugs and taking LEBERSAL by at least two hours.

With diagnostic tests.

LEBERSAL alters the results of gastric secretion tests and so should not be taken on the morning of a test.

WARNING

Do not use when pregnant or breast feeding without first consulting the doctor.

IMPORTANT NOTICE FOR WOMEN

If you are pregnant, or believe you may be, consult your doctor before taking this medicine. The consumption of medication during pregnancy can be dangerous for the embryo or foetus, and should be closely controlled by your doctor

USE IN CHILDREN: Consult your doctor before giving to children under 12 years.

Effects on ability to drive: None have been described.

Warning about excipients:

As this medicine contains 470 mg of sodium per spoonful, it may be harmful to those on low sodium diets.

DOSAGE

To be taken orally. The usual dose is 1 or 2 teaspoonfuls on an empty stomach, or before main meals. It is not recommendable to take more than 4 spoonfuls 4 times a day.

INSTRUCTIONS FOR CORRECT ADMINISTRATION

Put the granules into half a glass of water, with the aid of a teaspoon. It can be drunk before or after effervescence.

OVERDOSE

If a very large of LEBERSAL quantity is ingested, metabolic alkalosis may occur. Its symptoms are diarrhoea, headaches, nausea, vomiting, abdominal cramps, weakness and loss of appetite.

In the case of overdose or accidental ingestion, consult the Servicio de Información Toxicológica. Tel 91 5620420, giving the name of the product and the quantity ingested.

ADVERSE REACTIONS

Vomiting, diarrhoea and swollen feet may occur at high doses. At very high doses in prolonged treatments, alkalosis may occur.

STORAGE

Close the lid tightly, and store in a cool, dry place.

EXPIRY

This medicine must not be used after the date indicated on the packet.

KEEP ALL MEDICATION OUT OF THE REACH, AND SIGHT, OF CHILDREN

TEXT REVISED: May 1998

TITULAR AUTHORIZED FOR COMMERCIALIZATION

Laboratorios ERN, S.A. Pedro IV, 499-08020 Barcelona, España

RESPONSIBLE FOR MANUFACTURING

Laboratorios ERN, S.A. Polígono Industrial Can Salvatella, c/ Gorcs i Lladó, 188
Barberá de Vallés. Barcelona. España

Laboratorios ERN, S.A. c/ Perú, 228 - 08020 Barcelona. España