

PROFESSIONAL INFORMATION

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

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PROPRIETARY NAME AND DOSAGE FORM

Iberogast[®]

Oral Liquid

COMPOSITION

Each ml contains:

Active ingredients:

Iberis amara, eq. to fresh whole plant	75,0 mg
Angelica archangelica, eq. to dry root	33,0 mg
Matricaria recutita, eq. to dry flower head	66,7 mg
Carum carvi, eq. to dry fruit	33,3 mg
Silybum marianum, eq. to dry fruit	33,3 mg
Melissa officinalis, eq. to dry leaf	33,3 mg
Mentha x piperita, eq. to dry leaf	16,7 mg
Chelidonium majus, eq. to dry herb	33,3 mg
Glycerrhiza glabra, eq. to dry root	33,3 mg

Inactive ingredients:

Ethanol 96 % (v/v) and purified water.

Contains 31 % alcohol.

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CATEGORY AND CLASS

Category D.12.10 Others

Western herbal medicine

PHARMACOLOGICAL ACTION

The combination of 9 herbal extracts in Iberogast® has been shown in controlled clinical trials to relieve gastric and abdominal discomfort associated with functional and motility-conditioned gastrointestinal disturbances such as functional dyspepsia and irritable bowel syndrome.

INDICATIONS

- Abdominal pain & cramps
- Heartburn & acid reflux
- Bloating & flatulence
- Chronic constipation
- Nausea & vomiting
- Irritable bowel syndrome

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of Iberogast®.

WARNINGS AND SPECIAL PRECAUTIONS

Patients with pre-existing liver disease should consult with their doctor before starting treatment on Iberogast®.

INTERACTIONS

There are no known interactions with other medicines.

Patients affected with serious chronic diseases and/or undergoing medical treatment should take Iberogast® under medical guidance.

Iberogast® may be taken by diabetics.

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HUMAN REPRODUCTION

The use of Iberogast® during pregnancy and lactation has not been fully studied and it should only be used in these circumstances under the guidance of a healthcare professional.

DOSAGE AND DIRECTIONS FOR USE

Adults and children over 12 years: Take 20 drops (1,0 ml) 3 times a day

Children 6 to 12 years: Give 15 drops (0,75 ml) 3 times a day

Children 3 to 5 years: Give 10 drops (0,5 ml) 3 times a day

Shake the bottle before use. Remove the white screw cap, turn the bottle upside down, hold at an angle of 45° and give a slight shake. Count the number of drops and mix with a small quantity of warm water (30 – 60 ml) or any drink of choice.

Iberogast® should be taken before or with meals, three times a day.

SIDE EFFECTS

During clinical trials and routine use of Iberogast® no specific side effects have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

No reports of overdosage have been found in the literature on Iberogast®. In cases of suspected overdosage treatment should be symptomatic and supportive.

IDENTIFICATION

Iberogast® is a brown, clear to slightly cloudy liquid supplied in brown glass bottles with a built-in central dropper and a white plastic screw cap.

PRESENTATION

Iberogast® is available in packs of 20 ml and 50 ml.

STORAGE INSTRUCTIONS

Store in a dry place, at or below 25 °C, protected from direct sunlight. Keep out of reach of children.

PROFESSIONAL INFORMATION

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

Flordis South Africa (Pty) Ltd.

Marketed and distributed by Bayer (Pty) Ltd., 27 Wrench Road, Isando, 1600, South Africa

Co. Reg. No. 1968/011192/07

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Manufactured and packed by Steigerwald Arzneimittelwerk GmbH, Germany for Bayer (Pty) Ltd.