IBEROGAST®

Active Ingredients

The medicinal product IBEROGAST®, oral liquid, contains active ingredients Iberis amara whole plant extract liquid, Angelica archangelica root extract liquid, *Matricaria chamomilla* flower extract liquid, *Carum carvi* fruit extract liquid, *Silybum marianum* fruit extract liquid, *Melissa offIcianalis* leaf extract liquid, *Mentha x piperitae* leaf extract liquid, *Chelidonium majus* herb extract liquid and *Glycyrrhiza glabra* root extract liquid.

Description

IBEROGAST® oral liquid is a dark brown, clear to light cloudy liquid. IBEROGAST® contains the active ingredients listed above, as well as ethanol and water purified.

Pharmacology

Pharmacodynamic Properties

Pharmacotherapeutic group: IBEROGAST® is a herbal medicinal product for gastrointestinal disorders.

ATC Code: A03

IBEROGAST® is a fixed combination of 9 liquid extracts and exhibits is effects in the gastrointestinal tract via a multi-targeted action. *In-vitro* studies as well as investigations in animals show a dual method of action at different segments of stomach and intestine. On unstimulated and weakly stimulated stomach and intestine segments basic tone is increased, primarily by *Iberis amara*, leading to relief of symptoms such as a feeling of fullness and abdominal distension. The spasmolytic properties of the other drug extracts of IBEROGAST® trigger relaxation in strongly stimulated stomach and intestine segments. IBEROGAST® also decreases the afferent sensitivity to stimuli in the intestine which are caused by dilation and serotonin *in vivo*. Therefore IBEROGAST® shows effects which help to reduce visceral hypersensitivity due to binding of the different ingredients of IBEROGAST® to specific serotonin, muscarinic and opioid-receptors.

IBEROGAST® also increases the concentration of mucosa-protective prostaglandins and mucins, decreases the concentration of mucosa-damaging leukotrienes and inhibits the production of gastric acid in acid cells.

IBEROGAST® shows antiinflammatory properties, which can be ascribed to the inhibition of the 5-lipoxygenase, carminative, anti-oxidative and anti-bacterial actions.

It is therefore appararent that IBEROGAST® exhibits the aforementioned criteria and it exhibits ist effect via a multi-targeted mode of action.

Pharmacokinetic Properties

A fast gastro-intestinal resorption has been proven for many ingredients. From toxicological studies it can be concluded that even at repeated administration of up to six months that the active ingredients in IBEROGAST® do not accumulate.

Clinical Trials

In the areas of functional dyspepsia and irritable bowel syndrome 5 randomized, double-blind controlled clinical studies according to ICH-GCP guidelines were conducted.

Functional dyspepsia

Four studies were conducted in patients with functional dyspepsia, three of them were placebo-controlled and one vs. the prokinetic cisapride. The main outcome variable in these studies was the validated dyspepsia specific gastrointestinal symptom score (GIS). The GIS comprises 10 dyspepsia symptoms which are assessed as a sumscore. A change in the sumscore during treatment indicates a change of disease intensity and efficacy of therapy. In these studies 243, 60, 186 and 308 patients with functional dyspepsia according to Rome criteria were recruited and after a wash-out period of 7 or 14 days, treated for four weeks with IBEROGAST®, placebo or cisapride. One placebo controlled study (308 patients) was conducted over a treatment period of eight weeks. In the placebo-controlled studies, IBEROGAST® showed a significantly superior efficacy vs. placebo for the main outcome criterion. In the study vs. cisapride, an equivalent efficacy for IBEROGAST® was determined.

Irritable bowel syndrome

In a further randomised, double-blind controlled clinical study, 208 patients with irritable bowel syndrome according to Rome criteria were treated, after a 7 day wash-out period for four weeks with IBEROGAST® or placebo. The main outcome parameter was an abdominal symptom profile consisting of eight disease specific symptoms which were analysed as a sumscore. A change of the sumscore indicated an improvement or worsening of the disease. In this trial IBEROGAST®also showed a significantly superior efficacy vs. placebo for improving the symptoms of irritable bowel syndrome.

Indications

IBEROGAST® is indicated for the treatment of gastric and abdominal discomfort associated with functional and motility-conditioned gastrointestinal disturbances such as functional dyspepsia and irritable bowel syndrome.

Contraindications

IBEROGAST® must not be taken in case of known allergies to the active ingredients (listed under "Presentation").

Precautions

If symptoms persist a doctor should be consulted.

Patients with pre-existing liver disease should consult their doctor prior to commencing treatment with IBEROGAST®.

Pregnancy and lactation

From a toxicological perspective no evidence of concern regarding the administration of IBEROGAST® during pregnancy and lactation can be determined from the available data on reproduction toxicity (embryotoxicity, teratogenicity, peri- and postnatal toxicity).

Extensive investigations with IBEROGAST® in two animal species were performed assessing acute, subchronic and chronic toxicity (3 and 6 months), in the areas of reproductive toxicity, fertility, embry-onic, pre-and post-natal development and muta-genicity. There is no evidence for any acute or chronictoxicity, reproductive- or embryo-toxic potentials, even when doses of up to 1200 times the recommended daily dose were tested.

Effects on ability to drive and use machines

None.

Interactions with other medicinal products and other forms of interaction

No interactions were known at time of printing.

Adverse Reactions

Very rare (in less than one of 10,000 cases) hypersensitivity reaction such as exanthema, pruritus, dyspnea can occur.

Dosage and Administration

Unless otherwise prescribed, IBEROGAST® is taken before or with meals in some liquid as following:

Adults and children over 12 years
Take 20 drops 3 times a day (1.0 mL)
Children 6 to 12 years
Give 15 drops 3 times a day (0.75 mL)
Children 3 to 6 years
Give 10 drops 3 times a day (0.5 mL)
Children 3 months to 3 years
Give 8 drops 3 times a day (0.4 mL)
Children under 3 months
Give 6 drops 3 times a day (0.3 mL)

Duration of use depends on the kind, severity and course of the disease.

Shake bottle before use.

Overdosage

In acute oral toxicity testing of IBEROGAST® in various animal species and long-term therapeutic experience, no toxic signs of overdose were observed.

Presentation

IBEROGAST® oral liquid contains:

Active ingredients:

Iberis amara (bitter candytuft) whole plant ext. liq. (1:1.5-2.5 in 50% E:W) 150 microlitre/mL
EQUIV. Iberis Amara whole plant fresh 75.00 mg/mL

Angelica archangelica root ext. liq. (1:2.5-3.5 in 30% E:W) 100 microlitre/mL
EQUIV. Angelica archangelica root dry 33.33 mg/mL

Matricaria chamomilla (chamomile) flower ext. liq. (1:2-4 in 30% E:W) 200 microlitre/mL
EQUIV. Matricaria chamomilla flower dry 66.67 mg/mL

Carum carvi fruit (caraway) ext. liq. (1:2.5-3.5 in 30% E:W) 100 microlitre/mL
EQUIV Carum carvi fruit dry 33.33 mg/mL

Silybum marianum (milk thistle) fruit ext. liq. (1:2.5-3.5 in 30% E:W) 100 microlitre/mL
EQUIV. Silybum marianum fruit dry 33.33 mg/mL

Melissa officinalis (balm leaf) leaf ext. liq. (1:2.5-3.5 in 30% E:W) 100 microlitre/mL
EQUIV. Melissa officinalis leaf dry 33.33 mg/mL

Mentha x piperitae (peppermint) leaf ext. liq. (1:2.5-3.5 in 30% E:W) 50 microlitre/mL
EQUIV. Mentha x piperitae leaf dry 16.67 mg/mL

Chelidonium majus (celandine) herb ext. liq. (1:2.5-3.5 in 30% E:W) 100 microlitre/mL
EQUIV. Chelidonium majus herb dry 33.33 mg/mL

Glycyrrhiza glabra (liquorice) root ext. liq. (1:2.5-3.5 in 30% E:W) 100 microlitre/mL
EQUIV. Glycyrrhiza glabra root dry 33.33 mg/mL

Shelf life

The shelf-life of IBEROGAST® is 24 months.

Should IBEROGAST® show any turbidity or cloudiness , this will have no effect on the efficacy of the preparation.

Do not use IBEROGAST® after the expiry date printed on the container and outer packaging.

IBEROGAST® should not be used more than eight weeks after initial opening of the bottle.

Special precautions for storage

Store below +25 °C

Nature and contents of container

IBEROGAST®, oral liquid, is supplied in an amber glass bottle with a built in dropper and screw cap closure in volumes of 20 ml, 50 ml and 100 ml.

Special precautions for disposal

None.

Name and Address of the Sponsor

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Poison Schedule of the Drug

Unscheduled

Date of recent amendment

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