Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about IBEROGAST®.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet

You may need to read it again.

What IBEROGAST® is used for

IBEROGAST® is a herbal medicine for the relief and treatment of discomfort associated with medically diagnosed Irritable Bowel syndrome (IBS) and Functional Dyspepsia (FD) symptoms such as:

- · stomach pain,
- abdominal cramps
- · Bloating,
- · Gas,
- · Heartburn,
- Nausea and indigestion

Advice before using IBEROGAST®

When you must not take it

Do not take/use IBEROGAST® after the expiry date printed on the pack has passed. If you take this medicine after the expiry date it may have no effect at all, or an unexpected effect.

Do not take IBEROGAST® if the packaging shows signs of having been tampered with.

Do not use in children under 3 years.

There is insufficient experience with the use of IBEROGAST® in children under 3 years

Before you take IBEROGAST®

Tell your healthcare professional if you are allergic to any of the active ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; rash, itching (pruritus) or hives on the skin.

If you have a pre-existing liver disease consult your doctor prior to using IBEROGAST®.

Greater celandine may harm the liver in some people. Use only under the supervision of a healthcare professional.

Talk to your doctor or pharmacist if you are pregnant or intend to become pregnant before using IBEROGAST.

Talk to your doctor or pharmacist if you are breast-feeding or plan to breast-feed before using IBEROGAST.

For children under 6 years, consult a doctor if there is abdominal pain.

Taking other medicines

There are no known interactions of IBEROGAST® with any other types of medication.

How to use IBEROGAST® properly

IBEROGAST® contains a built-in central dropper in the mouth of the bottle. To dispense the accurate number of drops required remove the white screw cap, turn the bottle upside down, hold it at a 45° angle and give a slight shake. You

will notice that the drops will begin to be dispensed

Directions for Use

Shake well before use.

IBEROGAST® is taken in some liquid (e.g. warm water) before or with meals, 3 times daily as follows:

How much to take

Adults and adolescents from 13 years Take 20 drops (1.0mL) 3 times a day

Children 6 to 12 years

Give 15 drops (0.75mL) 3 times a day

Children 3 to 6 years

Give 10 drops (0.5mL) 3 times a day

If you forget to take it

Skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If symptoms persist consult your doctor or pharmacist.

Unwanted effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using IBEROGAST®.

Allergic reaction can occur in predisposed patients.

Cases of liver injury have been reported. Stop use and consult your healthcare professional if there are signs or symptoms of liver injury (eg. jaundice, dark urine or uncoloured stool).

If you experience side effects that are not mentioned in this package insert then you should report them to a healthcare professional.

Tell your doctor or pharmacist immediately if you experience any of the formerly described allergic side effects, particularly if they worry you.

Other side effects not listed above may occur in some patients. Tell your healthcare professional if you notice anything that is making you feel unwell when you are taking, or soon after you have finished taking, IBEROGAST®.

Do not be alarmed by the above mentioned side effects. You may not experience any of them.

In case of overdose

If you take too much (overdose)

If you have taken more than you are meant to consult your healthcare professional.

Storage conditions

Keep IBEROGAST® in a cool place where the temperature stays below 25°C.

Do not use if the bottle seal is missing or broken, or if the packaging shows signs of tampering.

Do not use after the expiry date printed on the bottle label and outer packaging. IBEROGAST® should not be used more than eight weeks after initial opening of the bottle.

Keep IBEROGAST® where young children cannot reach it.

Product description

What it looks like

IBEROGAST® is a dark brown, clear to lightly cloudy liquid supplied in brown glass bottles with a built-in central dropper, and a white screw cap.

Ingredients

1ml (20 drops) IBEROGAST Oral Liquid contains:

Iberis amara (Bitter candytuft)	
whole plant ext. liquid 150 microlitre	
equiv. fresh whole plant	75.0 mg
Angelica archangelica (Angelica)	_
root dry 100 microlitre	
equiv. root dry	33.3 mg
Matricaria chamomilla (Chamomile)	
flower ext. dry 200 microlitre	
equiv flower dry	66.7 mg
Carum carvi (Caraway)	
fruit ext. liquid 100 microlitre	
equiv. fruit dry	33.3 mg
Silybum marianum (St. Mary's thistle	
fruit ext. dry 100 microlitre	
equiv. fruit dry	33.3 mg
Melissa officinalis (Lemon balm)	
leaf ext. liquid 100 microlitre	
equiv. leaf dry	33.3 mg
Mentha x piperita (Peppermint)	
leaf dry 50 microlitre	
equiv. leaf dry	16.7 mg
Chelidonium majus (Greater celandine)	
herb dry 100 microlitre	
equiv. herb dry	33.3 mg
Glycyrrhiza glabra (Liquorice)	
root ext. dry 100 microlitre	
equiv. root dry	33.3 mg

 $IBEROGAST \ @\$ also contains alcohol as ethanol 31%v/v and purified water.

IBEROGAST® is available in the following pack sizes:

20mL, 50 mL and 100mL bottle - AUST R 168967

Sponsor / Distributor

Bayer Australia Ltd. 875 Pacific Highway Pymble NSW 2073 Ph: 1800 008 757

Date of Preparation

This leaflet was prepared in February 2020