

COMPLEMENTARY MEDICINE
D: WESTERN HERBAL MEDICINE D500848-33.6
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS: S0
PROPRIETARY NAME & DOSAGE FORM



Iberogast®

Oral Liquid

Read all of this leaflet carefully because it contains important information for you.

- Iberogast® is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Iberogast® carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share Iberogast® with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

WHAT IBEROGAST® CONTAINS

Each 100 ml contains:

Matricaria recutita L. (Chamomile) [flower, 1:2 - 4 Ethanol 30% (v/v) extract equivalent to 6,67 g dried flower]	20,0 ml
Iberis amara L. (Bitter candytuft) [whole plant, 1:1,5 - 2,5 Ethanol 50% (v/v) extract equivalent to 3,3 g fresh whole plant]	15,0 ml
Angelica archangelica L. (Angelica root) [root, 1:2,5 - 3,5 Ethanol 30% (v/v) extract equivalent to 3,3 g dried rhizome and root]	10,0 ml
Melissa officinalis L. (Balm leaf) [leaf, 1:2,5 - 3,5 Ethanol 30% (v/v) extract equivalent to 3,3 g dried leaf]	10,0 ml
Carum carvi L. (Caraway) [fruit, 1:2,5 - 3,5 Ethanol 30% (v/v) extract equivalent to 3,3 g dried fruit]	10,0 ml
Chelidonium majus L. (Celandine herb) [aerial parts, 1:2,5 - 3,5 Ethanol 30% (v/v) extract equivalent to 3,3 g dried herb]	10,0 ml
Glycyrrhiza species (Liquorice) [root, 1:2,5 - 3,5] From Glycyrrhiza glabra L., Glycyrrhiza inflata Bat. and Glycyrrhiza uralensis Fisch	10,0 ml
Silybum marianum L. gaertner (Milk thistle) [fruit, 1:2,5 - 3,5 Ethanol 30% (v/v) extract equivalent to 3,3 g dried fruit]	10,0 ml
Mentha × piperita L. (Peppermint) [leaf, 1:2,5 - 3,5 Ethanol 30% (v/v) extract equivalent to 1,67 g dried leaf]	5,0 ml

Other ingredients: Ethanol and purified water.

Contains alcohol: ethanol 31 % (v/v)

WHAT IBEROGAST® IS USED FOR

Iberogast® oral liquid help to relieve multiple digestive symptoms such as:

- Abdominal cramps & pain,
- Feeling of fullness,
- Bloating & flatulence,
- Heartburn,
- Nausea, and
- Constipation.

BEFORE YOU TAKE IBEROGAST®

Do not take Iberogast®:

- If you are allergic to any of the ingredients of Iberogast®.
- If you are under three (3) years of age.

Always tell your healthcare professional if you are taking any other medicines.

Take special care with Iberogast®:

- If you develop symptoms suggestive of liver damage such as yellowing of the skin or eyes (jaundice), dark urine and light stools, stop using Iberogast® immediately and consult your doctor.
- If you suffer from alcoholism as Iberogast® contains 31 % alcohol.
- If you are a pregnant or breastfeeding woman, if you are a child or a patient with liver disease or epilepsy.
- If symptoms do not improve or the use of Iberogast® does not result in the expected success, after a week, seek medical advice.
- In children below six (6) years a doctor, pharmacist or other healthcare professional should always be consulted if there is abdominal pain.

Pregnancy and Breastfeeding:

- If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking Iberogast®.
- If you are pregnant, it is preferable to avoid the use of Iberogast®.

HOW TO TAKE IBEROGAST®

Always take Iberogast® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

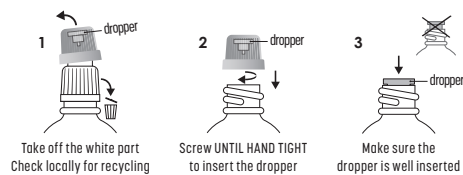
For Oral use:

Do not share medicines prescribed for you with any other person.

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

Adults and children

over 12 years: Take 20 drops (1,0 ml)
Children 6 to 12 years: Give 15 drops (0,75 ml)
Children 3 to 5 years: Give 10 drops (0,5 ml)



Shake the bottle before use. Remove the white part, screw until hand tight to insert the dropper and make sure the dropper is well inserted, 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

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

POSSIBLE SIDE EFFECTS

Iberogast® can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your health care provider for advice.

System Organ	Class Frequency	Adverse Drug Reaction
Immune system disorders	Very rare	Allergic reactions (itching, shortness of breath or skin reactions) can occur in predisposed patients
Hepato-biliary disorders	Not known	Cases of liver injury have been reported

In these cases, treatment with Iberogast® should be discontinued.

STORING AND DISPOSING OF IBEROGAST®

KEEP OUT OF REACH OF CHILDREN. Iberogast® should be kept at temperatures at or below 25 °C, protected from direct sunlight.

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems.

PRESENTATION OF IBEROGAST®

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

IDENTIFICATION OF IBEROGAST®

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

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE APPLICANT

Bayer (Pty) Ltd. 27 Wrench Road, Isando, 1600, South Africa Co. Reg. No. 1968/011192/07 Tel: +27 11 921 5000

Manufactured by Steigerwald Arzneimittelwerk GmbH, Havelstrabe 5, 34295 Darmstadt, Germany.

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

November 2015

The professional Information is available online at www.bayer.co.za

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	typopharma no: # 148660



PASIËNT-INLIGTINGSBLAADJIE
SKEDULERINGSSTATUS: S0
EIENDOMSNAAM & DOSEERVORM



Iberogast®

oral liquid

Lees asseblief hierdie inligtingsblaadjie in sy geheel sorgvuldig deur, aangesien dit belangrike inligting vir jou bevat.

Iberogast® is sonder 'n doktersvoorskrif beskikbaar vir jou om 'n ligte aandoening te behandel. Jy moet nogtans, ten einde die beste resultate daaruit te verkry, Iberogast® versigtig gebruik.

- Hou hierdie blaadjie. Jy sal dit dalk weer wil deurlees.
- Moenie Iberogast® met enige ander persoon deel nie.
- Vra jou apteker indien jy verdere inligting of raad nodig het.
- Indien jou simptome vererger of nie binne 7 dae verbeter nie, moet jy 'n dokter raadpleeg.

WAT IBEROGAST® BEVAT

Elke 100 ml bevat

Matricaria recutita L. (Chamomile) [blomhof, 1:2 - 4 Etanol 30% (v/v) uittreksel gelykstaande aan 6,67 g droë blom]	20,0 ml
Iberis amara L. (Bitter candytuft) [vars hele plant, 1:1.5 - 2.5 Etanol 50% (v/v) gelykstaande aan 7,5 g vars heel plant]	15,0 ml
Angelica archangelica L. (Angelica root) [wortel, 1: 2,5 - 3,5 Etanol 30% (v/v) uittreksel gelykstaande aan 3,3 g droë risoom en wortel]	10,0 ml
Melissa officinalis L. (Balm leaf) [blaar, 1:2,5 - 3,5 Etanol 30% (v/v) uittreksel gelykstaande aan 3,3 mg droëblaar]	10,0 ml
Carum carvi L. (Caraway) [vrugte, 1:2,5 - 3,5 Etanol 30% (v/v) uittreksel gelykstaande aan 3,3 g droëvrugte]	10,0 ml
Chelidonium majus L. (Celandine herb) [lugdele, 1: 2,5 - 3,5 Etanol 30% (v/v) uittreksel gelykstaande aan 3,3 g droëkruid]	10,0 ml
Glycyrrhiza species (Liquorice) [wortel, 1:2.5 - 3.5] Van Glycyrrhiza glabra L., Glycyrrhiza inflata Bat. and Glycyrrhiza uralensis Fisch	10,0 ml
Silybum marianum L. GAERTNER (Milk thistle) [vrugte, 1:2,5 - 3,5 Etanol 30% (v/v) uittreksel gelykstaande aan 3,3 g droëvrugte]	10,0 ml
Mentha x piperita L. (Peppermint) [blaar, 1:2,5 - 3,5 Etanol 30% (v/v) uittreksel gelykstaande aan 1,67 g droëblaar]	5,0 ml

Ander bestanddele: Etanol en gesuiwerde water.

Bevat alkohol: 31 %

WAARVOOR WORD IBEROGAST® GEBRUIK?

Iberogast® mondelinge vloeistof word aangedui vir die behandeling van:

- Buikkrampe en pyn
- Gevoel van volheid
- Opgeblasenheid
- Winderigheid
- Sooibrand
- Naarheid
- Hardlywigheid

VOORDAT JY IBEROGAST® BEGIN GEBRUIK

Moenie Iberogast® neem nie:

- As u allergies is vir enige van die bestanddele van Iberogast®.
- As jy onder drie (3) jaar oud is.

Lig jou gesondheidsorgkundige altyd daarvoor in as jy enige ander medisyne gebruik.

Wees veral versigtig met Iberogast®:

- As u simptome ontwikkel wat dui op lewerskade soos vergeling van die vel of oë (geelsug), donker urine en ligte stoelgang, stop die gebruik van Iberogast® dadelik en raadpleeg u dokter.
- As jy aan alkoholisme ly, aangesien Iberogast® 31% alkohol bevat.
- As jy 'n swanger of borsvoedende vrou is, as jy 'n kind of pasiënt met lewersiekte of epilepsie is.
- As simptome nie verbeter of die gebruik van Iberogast® nie na verwagting suksesvol is nie, moet u na 'n week mediese advies aanvra.
- By kinders onder ses (6) jaar moet 'n dokter, apteker of ander gesondheidswerker altyd geraadpleeg word indien daar buikpyn is.

Swangerskap en borsvoeding:

- As u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of ander gesondheidswerker voordat u Iberogast® neem.
- As u swanger is, is dit verkieslik om die gebruik van Iberogast® te vermy.

HOE OM IBEROGAST® TE GEBRUIK

Neem altyd Iberogast® presies soos u dokter u opdrag gegee het. U moet seker maak met u dokter of apteker as u onseker is.

Vir mondelinge gebruik:

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.

Iberogast® moet drie keer per dag voor of met etes geneem word.

Volwassenes en kinders ouer as 12 jaar:

Neem 20 druppels (1,0 ml)

Kinders 6 tot 12 jaar oud: Gee 15 druppels (0,75 ml)

Kinders 3 tot 5 jaar oud: Gee 10 druppels (0,5 ml)



Skud die bottel voor gebruik. Verwyder die wit gedeelte, skroef met die hand vas om die druppelaar in te sit en maak seker die druppelaar is goed ingesit, draai die bottel onderstebo, hou teen 'n hoek van 45° en gee 'n effense skud. Tel die aantal druppels en meng met 'n klein bietjie warm water (30 - 60 ml) of enige ander vloeistof van keuse.

In geval van oormatige dosering, raadpleeg u dokter of apteker. As beide onbeskikbaar is, kontak die naaste hospitaal of gifbeheer sentrum.

MOONTLIKE NEWE-EFFEKTE

Iberogast® kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir hierdie medisyne gerapporteer word, word in hierdie bylae ingesluit nie. Indien u algemene gesondheid vererger of indien u enige onnodige effekte ondervind wanneer u hierdie medisyne gebruik, raadpleeg u gesondheidsorgverskaffer vir advies.

Stelselorgane	Frekwensie klas	Nadelige geneesmiddelreaksie
Immuunstelselversteurings	Baie skaars	Allergiese reaksies (Jeuk, kortasem of velreaksies) kan voorkom in vatbare pasiënte.
Hepatobiliêre versteurings	Onbekend	Gevalle van lewerskade is aangemeld.

In hierdie gevalle moet behandeling met Iberogast® gestaak word.

BERGING EN WEGDOENING VAN IBEROGAST®

HOU BUIE BEREIK VAN KINDERS. Iberogast® moet teen temperature by of benede 25 °C geborg word en moet teen direkte sonlig beskerm word.

Besorg alle medisyne wat jy nie gebruik nie, terug aan jou apteker.

Moenie ongebruikte medisyne in afvoerpype of rioelstelsels weggooi nie.

AANBIEDING VAN IBEROGAST®

Iberogast® is beskikbaar in verpakings van 20 ml en 50 ml.

IDENTIFIKASIE VAN IBEROGAST®

Iberogast® is 'n bruin, helder tot effens troebel vloeistof wat in bruin glasbottels met 'n druppelaar en 'n wit plastiekskroef dop verskaf word.

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN APPLIKANT

Bayer (Edms) Bpk. Wrenchweg 27, Isando, Suid Afrika, Maatskappy. Reg. Nr 1968/011192/07
Tel: +27 11 921 5000

vervaardig deur Steigerwald Arzneimittelwerk GmbH, Havelstrasse 5, 34295 Darmstadt, Duitsland.

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Steigerwald Arzneimittelwerk GmbH	typo pharma	Typopharma GmbH Mühlstr. 57 D-79539 Lörrach produktion@typopharma.com www.typopharma.com typopharma no: # 148660											

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