# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0

**PROPRIETARY NAME & DOSAGE FORM**

Iberogast®

9 HERB TREATMENT

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 30 days.
- This medicine has not been evaluated by the Medicines Control Council and is not intended to diagnose, treat, cure or prevent any disease.

## WHAT IBEROGAST® CONTAINS

**Each 20 drops (1 ml) contain**

| | |
|---|---|
| *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** |

## WHAT IBEROGAST® IS USED FOR

Iberogast® oral liquid is specifically clinically proven to relieve

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

## BEFORE YOU TAKE IBEROGAST®

Do not take Iberogast®if you are hypersensitive (allergic) to any of the ingredients.

You should take Iberogast® under medical guidance if you are suffering from a serious chronic disease and/or undergoing medical treatment.

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

## HOW TO TAKE IBEROGAST®

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.

## POSSIBLE SIDE EFFECTS

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

## STORING AND DISPOSING OF IBEROGAST®

Store all medicines 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 built-in central dropper and a white plastic screw cap.

## REFERENCE NUMBER: 000258

## NAME OF APPLICANT

Flordis South Africa (Pty) Ltd. Marketed and Distributed by Bayer (Pty) Ltd. 27 Wrench Road, Isando, South Africa, Co. Reg. No. 1968/011192/07. Tel:(011)921 5000.

Iberogast® is manufactured in Germany.

Bayer

# PROFESSIONAL PACKAGE INSERT

**SCHEDULING STATUS:** S0

**PROPRIETARY NAME & DOSAGE FORM**

Iberogast®

9 HERB TREATMENT

Oral Liquid

## COMPOSITION

**Each 20 drops (1 ml) contain**

| | |
|---|---|
| *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** |
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| *Glycerrhiza glabra*, eq. to dry root | **33,3 mg** |

## PHARMACOLOGICAL CLASSIFICATION

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. This medicine has not been evaluated by the Medicines Control Council and is not intended to diagnose, treat, cure or prevent any disease.

## 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.

## PREGNANCY AND LACTATION

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.

## REFERENCE NUMBER: 000258

## NAME OF THE APPLICANT

Flordis South Africa (Pty) Ltd. Marketed and Distributed by Bayer (Pty) Ltd. 27 Wrench Road, Isando, South Africa, Co. Reg. No. 1968/011192/07. Tel:(011)921 5000.
Manufactured in Germany.

## DATE OF PUBLICATION OF THE PACKAGE INSERT

November 2015

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# PASIËNT-INLIGTINGSBLAADJIE

**SKEDULERINGSTATUS: S0**

**EIENDOMSNAAM & DOSEERVORM**

Iberogast®

9 KRUIE BEHANDELING

Mondelike vloeistof

**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 30 dae verbeter nie, moet jy 'n dokter raadpleeg.
- Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie en is nie bedoel om enige siektetoestand te diagnoseer, te behandel, te genees of te voorkom nie.

## WAT IBEROGAST® BEVAT

**Elke 20 druppels (1 ml) bevat**

| | |
|---|---|
| *Iberis amara*, gelyk aan vars heel plant | **75,0 mg** |
| *Angelica archangelica*, gelyk aan droë wortel | **33,0 mg** |
| *Matricaria recutita*, gelyk aan droë blomhoof | **66,7 mg** |
| *Carum carv*, gelyk aan droë vrug | **33,3 mg** |
| *Silybum marianum*, gelyk aan droë vrug | **33,3 mg** |
| *Melissa officinalis*, gelyk aan droë blaar | **33,3 mg** |
| *Mentha x piperita*, gelyk aan droë blaar | **16,7 mg** |
| *Chelidonium maju*, gelyk aan droë kruid | **33,3 mg** |
| *Glycerrhizaglabra*, gelyk aan droë wortel | **33,3 mg** |

## WAARVOOR IBEROGAST®GEBRUIK WORD

Iberogast® mondelike vloeistof is spesifiek klinies bewys om verligting te bring vir

- Buikpyne & -krampe
- Sooibrand & suurrefluks
- Opgeblaasdheid & winderigheid
- Chroniese hardlywigheid
- Naarheid & braking

## VOORDAT JY IBEROGAST® BEGIN GEBRUIK

Moenie Iberogast® gebruik as jy hipersensitief (allergies) is teenoor enige van die bestanddele nie. Jy moet Iberogast® onder mediese leiding gebruik indien jy aan 'n ernstige chroniese siekte ly en/of mediese behandeling ondergaan.

Lig jou gesondheidsorgkundige altyd daaroor in as jy enige ander medisynes gebruik.

## HOE OM IBEROGAST® TE GEBRUIK

Volwassenes en kinders ouer as 12 jaar:
Neem 20 druppels (1,0 ml) 3 keer per dag

Kinders 6 tot 12 jaar oud:
Gee 15 druppels (0,75 ml) 3 keer per dag

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

Skud die bottel voor gebruik. Verwyder die wit skroefdop, draai die bottel onderstebo, hou teen 'n hoek van 45° en gee 'n ligte skud. Tel die aantal druppels en meng met 'n klein bietjie warm water (30 – 60 ml) of enige ander vloeistof van keuse. Iberogast® moet voor of saam met maaltye geneem word, drie keer per dag.

## MOONTLIKE NEWE-EFFEKTE

Daar is geen vermeldings van newe-effekte tydens kliniese proewe en roetinegebruik van Iberogast® vermeld nie.

## BERGING EN WEGDOENINGSINLIGTING VAN IBEROGAST®

Bêre alle medisyne buite die bereik en sig van kinders. Iberogast® moet teen temperature teen of benede 25 °C geberg 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 rioolstelsels weggooi nie.

## AANBIEDING VAN IBEROGAST®

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

## IDENTIFIKASIE VAN IBEROGAST®

Iberogast® is 'n bruin, helder tot effens troebel vloeistof wat in bruin glasbottels met 'n ingeboude sentrale drupper en 'n wit plastiekskroefdop verskaf word.

## VERWYSINGSNOMMER: 000258

## NAAM VAN DIE APPLIKANT

Flordis Suid Afrika (Edms) Bpk. Bemark and verprei deur Bayer (Edms) Bpk. Wrenchweg 27, Isando, Gauteng, Suid Afrika. Mpy. Reg. Nr. 1968/011192/07. Tel: +27 11 921 5000.

Iberogast® word in Duitsland vervaardig.

Bayer

# PROFESSIONELE VOUBILJET

**SKEDULERINGSTATUS: S0**

**EIENDOMSNAAM EN DOSEERVORM**

Iberogast®

9 KRUIE BEHANDELING

Mondelike vloeistof

## SAMESTELLING

**Elke ml bevat**

| | |
|---|---|
| *Iberis amara*, gelyk aan vars heel plant | **75,0 mg** |
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## FARMAKOLOGIESE KLASSIFIKASIE

Kategorie D.12.10 Ander. Westerse-kruie medisyne

## FARMAKOLOGIESE WERKING

Daar is in beheerde kliniese proewe aangetoon dat die kombinasie van 9 kruie-ekstrakte in Iberogast® gastriese en abdominale ongemak, verbind met funksionele en beweeglikheids-ingestelde gastro-intestinale versteurings soos funksionele dispepsie en prikkelbare dermsindroom, verlig. Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie en is nie bedoel om enige siektetoestand te diagnoseer, te behandel, te genees of te voorkom nie.

## INDIKASIES

- Buikpyne & -krampe
- Sooibrand & suurrefluks
- Opgeblaasdheid & winderigheid
- Chroniese hardlywigheid
- Naarheid & braking
- Prikkelbare dermsindroom

## KONTRA-INDIKASIES:

Hipersensitief teenoor enige van die bestanddele.

## WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Pasiënte met voorafbestaande lewersiekte moet hulle dokter raadpleeg alvorens hulle behandeling met Iberogast®begin.

## INTERAKSIES

Daar is geen interaksies met ander geneesmiddels bekend nie. Pasiënte wat aan ernstige chroniese siektes ly en/of mediese behandeling ondergaan moet Iberogast® slegs onder mediese toesig en leiding gebruik.

Iberogast® kan deur diabete gebruik word.

## SWANGERSKAP EN LAKTASIE

Die gebruik van Iberogast® tydens swangerskap en laktasie is nog nie volledig bestudeer nie en dit behoort slegs onder die leiding van 'n gesondheidsorgkundige gebruik te word in hierdie omstandighede.

## DOSIS EN GEBRUIKSAANWYSINGS

Volwassenes en kinders ouer as 12 jaar:
Neem 20 druppels (1,0 ml) 3 keer per dag

Kinders 6 tot 12 jaar oud:
Gee 15 druppels (0,75 ml) 3 keer per dag

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## NEWE-EFFEKTE

Daar is geen vermeldings van newe-effekte tydens kliniese proewe en roetinegebruik van Iberogast® vermeld nie.

## BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Daar is geen verslae oor oordosering met Iberogast®in die literatuur gevind nie. In gevalle van vermoedelike oordosering moet behandeling simptomaties en ondersteunend wees.

## IDENTIFICATION

Iberogast® is 'n bruin, helder tot effens troebel vloeistof wat in bruin glasbottels met 'n ingeboude sentrale drupper en 'n wit plastiekskroefdop verskaf word.

## AANBIEDING

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

## BERGINGSAANWYSINGS

Berg op 'n droë plek, teen of benede 25 °C, beskerm teen direkte sonlig. Hou buite bereik van kinders.

## VERWYSINGSNOMMER: 000258

## NAAM VAN DIE APPLIKANT

Flordis Suid Afrika (Edms) Bpk. Bemark and verprei deur Bayer (Edms) Bpk. Wrenchweg 27, Isando, Gauteng, Suid Afrika. Mpy. Reg. Nr. 1968/011192/07. Tel: +27 11 921 5000.
Vervaardig in Duitsland

## DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET

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