

Package leaflet: information for the user

Imogas® 240 mg soft capsule

Simeticone

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

This medicine is available without prescription. However, you still need to use Imogas carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms are no better after 7 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- **What Imogas is and what it is used for** see section 1
- **Before you take Imogas** see section 2
- **How to take Imogas** see section 3
- **Possible side-effects** see section 4
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- **Further information** see section 6

1 WHAT IMOGAS IS, AND WHAT IT IS USED FOR

Imogas works by breaking up the wind that causes bloating. It is used for the symptomatic treatment of wind (flatulence) that makes your stomach feel bloated. Simeticone is an antifatulent which helps bring up wind or air trapped in the stomach. The pain associated with bloating may be caused by the build-up of small gas bubbles trapped in your stomach. The simeticone in Imogas helps the little trapped gas bubbles join into bigger bubbles which are easier to dispel.

2 BEFORE YOU TAKE IMOGAS

X Do not take Imogas if you are allergic to simeticone or any of the other ingredients in the capsule (see section 6).

Imogas is used as a treatment for wind and bloating, which is a sensation that the stomach is larger than normal leading to a feeling of discomfort. In contrast, stomach distension occurs when the stomach is actually larger than normal. Imogas is not a suitable treatment for this condition and patients suffering from stomach distension should seek medical advice.

⚠ TAKE SPECIAL CARE

Talk to your doctor if:-

- Your wind does not get better after 7 days of treatment
- You have constipation which will not get better
- If you have stomach distension (your stomach is physically larger than normal)
- If you have recurrent, severe or prolonged abdominal pain



- If you suffer from any of the following conditions:
 - constipation
 - gastro enteritis, giardiasis (infection of the bowel)
 - malabsorption
 - inflammatory bowel disease
 - subacute obstruction (partial obstruction of the bowel)
 - abdominal and pelvic malignancy (cancer in the abdomen or pelvis)
 - eating disorder or laxative abuse
 - anxiety, depression
 - endocrine conditions eg:
 - cushing's syndrome
 - hypothyroidism

⚠ PREGNANCY AND BREAST-FEEDING

- Ask your doctor or pharmacist for advice before taking any medicine.
- However, since simeticone is not absorbed from the gastrointestinal tract, Imogas can nevertheless be used in pregnant and lactating women.

⚠ Driving and using machines:

- Imogas has no known effects on the ability to drive or use machines.

3 HOW TO TAKE IMOGAS

The usual dose is:

- **If you are aged 15 years or over:** Take one capsule at the end of each main meal. Swallow the capsule with a large glass of water. Do not exceed 3 soft capsules per day. Do not take the capsules for more than 10 days.
- Do not give Imogas to children less than 15 years old.

⚠ If you take more Imogas that you should

- Consult your doctor.

⚠ If you forget to take Imogas:

- Take a capsule after the next main meal. Do not take a double dose to make up.

4 POSSIBLE SIDE-EFFECTS

- Like all medicines, Imogas can cause side effects, although not everybody gets them.
- You should stop taking Imogas and see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or pharynx, difficulty in swallowing, hives and difficulty breathing.
- The following adverse events have been reported with a frequency "not known":
 - abdominal pain, nausea, vomiting and constipation
 - allergic reactions, such as skin rash, itching, angioedema, swelling of the face, lips, throat and tongue or difficulty breathing.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.



5 HOW TO STORE THIS MEDICINE

This medical product does not require any special storage precautions. Keep out of the reach and sight of children.

Do not use Imogas after the expiry date (EXP) on the blister and carton. The expiry date refers to the last date of that month. Medicines should not be disposed of via the waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6 FURTHER INFORMATION

What Imogas contains:

The active substance is simeticone. Each capsule contains 240 mg simeticone. The other ingredients are gelatin and glycerol.

What Imogas looks like, and the contents of the pack:

Imogas is a transparent soft gelatin capsule. Each pack contains 10, 20 or 30 capsules. Not all pack sizes may be marketed.

Marketing authorisation holder and manufacturer:

Marketing authorisation holder: McNeil Healthcare (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland. Manufacturer: Catalent France Beinheim SA, 67930 Beinheim, France.

This medicinal product is authorised in other countries under the following names:

Denmark: IMOGAS
Finland: IMOGAS 240 mg pehmeä kapseli
France: IMONOGAS
Luxembourg: IMOGAS
Spain: IMONOGAS 240mg capsulas blandas
Sweden: IMOGAS 240 mg kapsel, mjuk
Norway: IMOGAS kapsel, 240 mg
Belgium: IMONOGAS
Iceland: IMOGAS 240 mg hylki, mjuk
Portugal: IMOGAS 240 mg capsulas moles

This leaflet was last revised in September 2014.

Health education advice

What should you do if you get digestive problems?

Indigestion:

You can get problems if you:

- Eat too much
- Eat food which is too rich
- Eat too quickly, without chewing
- Drink too much alcohol with your food

Try to avoid these triggers.

Wind (flatulence):

Some foods are more likely to cause wind because:

- They contain air themselves (for example fizzy drinks, fresh bread)
- They contain high levels of carbohydrates which cannot be absorbed (for example, dried vegetables, cabbage, raw vegetables, onions)

Try to avoid these foods. Ask your pharmacist or doctor if you need more advice.

McNeil
Healthcare (Ireland) Ltd.

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14-0184

Johnson & Johnson		COLOURS:	
Job Bag No.	14-0184	PMS 526	Black Profile
Version	4		
Product	Imogas 240 mg 10 Caps		
Description	PIL		
Country	IRE		
Date	03/09/2014		
Manufacturer	Catalent		
		SIZE: Main body text (PIL's only)	
		400 x 150 mm	8 pts

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