

Boots

Package leaflet: Information for the user

One-a-day Acid Reflux Relief 20mg Gastro Resistant Capsules (Omeprazole)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

The name of your medicine is, 'Boots One-a-day Acid Reflux Relief 20mg Gastro Resistant Capsules, and it will be referred to as Acid Reflux Capsules throughout the rest of this leaflet.'

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet?

1. What Acid Reflux Capsules are and what they are used for
2. What you need to know before you take Acid Reflux Capsules
3. How to take Acid Reflux Capsules
4. Possible side effects
5. How to store Acid Reflux Capsules
6. Contents of the pack and other information

1. What Acid Reflux Capsules are and what they are used for

This medicine contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. It works by reducing the amount of acid that your stomach produces.

The capsules are used in adults for the short-term treatment of reflux symptoms (for example, heartburn, acid regurgitation).

Reflux is the backflow of acid from the stomach into the gullet ('foodpipe') which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

This medicine is not meant to bring immediate relief. It might be necessary to take the capsules for 2-3 consecutive days to achieve improvement of symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

2. What you need to know before you take Acid Reflux Capsules

Do not take Acid Reflux Capsules if you are:

- Allergic (hypersensitive) to omeprazole or any of the other ingredients of this medicine (listed in section 6)
- Allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- Taking a medicine containing nelfinavir (used for HIV infection).

Do not take Acid Reflux Capsules if any of the above applies to you; If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Acid Reflux Capsules if:

- You are due to have a specific blood test (Chromogranin A)
- You are due to have an endoscopy or a urea breath test
- Your body does not absorb vitamin B12 very well (cobalamin deficiency).

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with omeprazole. Stop using this medicine and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Do not take Acid Reflux Capsules for more than 14 days without consulting a doctor. If you do not experience relief, or if you experience a worsening of symptoms, consult your doctor.

Acid Reflux Capsules may hide the signs and symptoms of other conditions. Therefore, if you notice any of the following while you are taking this medicine, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing
- You get stomach pain or signs of indigestion (such as nausea, fullness, bloating especially after eating)
- You begin to vomit food or blood
- You pass black stools (blood-stained faeces)
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea
- You have ever had a skin reaction after treatment with a medicine similar to Acid Reflux Capsules that reduces stomach acid
- You have had previous gastric ulcer or gastrointestinal surgery
- You are on continuous symptomatic treatment of indigestion or heartburn for 4 or more weeks
- You continuously suffer from indigestion or heartburn for 4 or more weeks
- You have jaundice or severe liver disease
- You are aged over 55 years with new or recently changed symptoms.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to

3. How to take Acid Reflux Capsules

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 20mg capsule once a day for up to 14 days. Contact your doctor if you are not free from

stop your treatment with Acid Reflux Capsules. Remember to also mention any other ill-effects like pain in your joints.

Seek urgent medical attention if you experience chest pain with lightheadedness, sweating, dizziness or shoulder pain with shortness of breath. This could be a sign of a serious condition with your heart.

When taking omeprazole, inflammation in your kidneys may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to your doctor.

This medicine may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B12:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

Do not take this medicine if you do not have symptoms of reflux (e.g. heartburn or acid regurgitation).

Children and adolescents

This medicine should not be used by children and adolescents under 18 years of age.

Other medicines and Acid Reflux Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription. This is because this medicine can affect the way some medicines work, and some medicines can have an effect on these capsules.

Do not take Acid Reflux Capsules if you are taking any of the following medicines:

- Nelfinavir (used to treat HIV infection)
- Medicines that reduce stomach acid such as other proton pump inhibitors (e.g. pantoprazole, rabeprazole or esomeprazole) or an H2 antagonist (e.g. ranitidine or famotidine).

You should specifically tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots (thrombi)).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Clarithromycin (used to treat infections)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy)
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Acid Reflux Capsules
- Rifampicin (used to treat tuberculosis)
- Atazanavir, saquinavir (used to treat HIV infection)
- Tacrolimus (used in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Erlotinib (used to treat cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer)—if you are taking a high dose of methotrexate, your doctor may temporarily stop your Acid Reflux Capsules treatment.

Acid Reflux Capsules with food, drink and alcohol

You can take your capsules with food or on an empty stomach. Omeprazole is not recommended to be taken with alcohol.

Pregnancy, breast-feeding and fertility

Before taking this medicine, tell your doctor or pharmacist if you are pregnant or trying to get pregnant. Your doctor will decide whether you can take these capsules during this time.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take this medicine if you are breast-feeding.

There is no evidence that this medicine has any effect on fertility.

Driving and using machines

This medicine is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Information on sucrose and sodium content

This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially "sodium free".

symptoms after this period. It might be necessary to take the capsules for 2-3 consecutive days to achieve improvement of symptoms. Do not take more than the recommended dose (one 20mg capsule a day) even if you don't feel an improvement immediately.

When your reflux symptoms have gone completely you should stop taking this medicine.

Do not take this medicine if you do not have symptoms of reflux (e.g. heartburn or acid regurgitation).

Taking this medicine

- It is recommended that you take your capsules in the morning
- You can take your capsules with food or on an empty stomach
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the capsules

If you have trouble swallowing the capsules:

- Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce
- Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes
- To make sure that you have taken all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

If you take more Acid Reflux Capsules than you should

If you take more capsules than recommended, talk to your doctor or pharmacist straight away. You may experience symptoms such as diarrhoea, stomach ache, feeling or being sick, dizziness, headache, depression, confusion and apathy (lack of motivation).

If you forget to take Acid Reflux Capsules

If you forget to take a dose, take it as soon as you remember it on the same day. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. How to store Acid Reflux Capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Like all medicines, this medicine can cause side effects, although not everybody gets them.

What Acid Reflux Capsules contain

The active substance is omeprazole. Acid Reflux Capsules contain 20mg of omeprazole.

The other ingredients are maize starch, sucrose, magnesium hydroxide, disodium phosphate, hypromellose, sodium laurylsulfate,mannitol, sodium starch glycolate, talc, titanium dioxide (E171), macrogol, polysorbate, methacrylic acid-ethyl acrylate copolymer, FD&C Blue 2 (E132) (Indigoite), gelatin.

What Acid Reflux Capsules look like and contents of the pack

Acid Reflux Capsules are hard gelatin capsules with a blue cap and white body, containing white to off-white or cream spherical pellets.

The pack contains 7 or 14 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Maxwellia Ltd, Alderley Park, Alderley Edge, Cheshire, SK10 4TG, UK.

Manufacturer: Laboratorios Licensa, S.A., Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo, 19200 Azúqueca de Henares (Guadalajara), Spain.

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Further Helpful Information

What are the symptoms of heartburn?

The normal symptoms of reflux are a painful sensation in the chest rising up to your throat (heartburn) and a sour taste in the mouth (acid regurgitation).

Why do you get these symptoms?

Heartburn can be a result of eating too much, eating high fat food, eating too quickly and drinking lots of alcohol. You may notice that when you lie down your heartburn gets worse. If you are overweight or smoke, you increase the chance of suffering from heartburn.

What can I do to help relieve my symptoms?

- Try to avoid spicy and fatty foods and large meals late before bedtime
- Avoid fizzy drinks, coffee, chocolate and alcohol
- Eat slowly and eat smaller portions
- Try to lose weight
- Stop smoking.

When should I seek advice or help?

- You should seek urgent medical advice if you experience chest pain with light-headedness, sweating, dizziness or shoulder pain with shortness of breath
- If you experience any of the symptoms detailed in Section 2 of this leaflet and it advises you to talk to your doctor or pharmacist
- If you are suffering from any of the side effects detailed in Section 4 which require medical attention.

Reference number: PL 42807/0005.

If you would like any further information about this medicine, please contact The Boots Company PLC Nottingham NG2 3AA.