

Omeprazole 20mg Capsules
(Omeprazole)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again
• If you have any further questions, ask your doctor or pharmacist
• This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
• 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

- What is in this leaflet:
1. What Omeprazole Capsule is and what it is used for
 2. What you need to know before you take Omeprazole Capsules
 3. How to take Omeprazole Capsule
 4. Possible side effects
 5. How to store Omeprazole Capsule
 6. Contents of the pack and other information

1. What Omeprazole Capsule is and what it is used for

The active ingredient, omeprazole, belongs to a group of medicines called "proton pump inhibitors". It works by reducing the production of acid in your stomach.

Omeprazole is used to treat the following conditions:

In adults:

- Reflux oesophagitis and Oesophageal reflux disease, where acid from the stomach escapes into the food pipe causing pain, inflammation and heartburn
- Acid indigestion (dyspepsia) which can cause stomach pain and/or discomfort
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer). For patients who have had previous trouble with an ulcer and need to continue therapy with a non-steroidal anti-inflammatory drug (NSAID), omeprazole can heal ulcers or prevent an ulcer developing. In such patients, omeprazole protects the stomach or duodenum whilst they are taking NSAIDs
- Ulcers which are infected with bacteria called Helicobacter pylori. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal
- Prevention of damage to the lungs caused by breathing in stomach fluids (acid aspiration), e.g. before an operation
- Zollinger-Ellison syndrome, when excess stomach acids are produced due to a growth in the pancreas
- Treatment of reflux oesophagitis and oesophageal reflux disease in the children over 1 year old and weigh ≥10kg

In children:

Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn. In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

2. What you need to know before you take Omeprazole

Do not take Omeprazole Capsules:

If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling in the face lips throat or tongue

- If you are allergic to medicines containing other proton pump inhibitors (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- If you are taking a medicine containing atazanavir, nelfinavir (used for HIV infection)

Do not take Omeprazole Capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Omeprazole Capsules

Warnings and precautions

Talk to your doctor or pharmacist before taking Omeprazole Capsules:

- If you have liver problems
This is because your doctor may reduce the dose
- If you lose a lot of weight for no reason and have problems swallowing
- If you get stomach pain or indigestion
- If you begin to vomit food or blood
- If you pass black stools (blood-stained faeces)
- If you experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea
- If you are going to have an operation and anaesthetic (including at the dentist)
- If your doctor has told you that you have problems with an inherited sugar intolerance disease
- Taking a proton pump inhibitor like Omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis)

- If you have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid
- If you are due to have a specific blood test (Chromogranin A)

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

Other medicines and Omeprazole Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Please tell your doctor if you are taking any of the following medicines:

- Diazepam (for anxiety)
- Phenytoin (for epilepsy)
- Warfarin or other vitamin K blockers (for thinning of blood)
- Digoxin (for the heart)
- Ketoconazole, Itraconazole, Posaconazole or Voriconazole (for fungal infections)
- Clarithromycin (for bacterial infections)
- Tacrolimus (for immune suppression)
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- St John's wort (Hypericum perforatum) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- 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 Omeprazole treatment

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicines you are taking.

Omeprazole with food and drink

You can take your capsules with food or on an empty stomach.

Pregnancy and Breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Omeprazole Capsules if you are pregnant or breast feeding without discussion with your doctor.

Driving and using machines:

These capsules on rare occasions may make you hallucinate, confused and feel light-headed. Other possible side effects are sleepiness and visual impairment. Make sure you are not affected before you drive or operate machinery.

Omeprazole capsules contains sucrose

Omeprazole capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Omeprazole Capsules

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

The capsules should not be chewed or crushed. They should be swallowed whole with a drink of water. If you have trouble swallowing the capsules, open the capsule and mix the granules with some fruit juice or yoghurt and then take immediately.

The length of your course of treatment will depend on what condition you are suffering from:-

Treatment for heartburn (Reflux oesophagitis and oesophageal reflux disease)

The recommended dose for adults is 20 mg omeprazole taken once a day for 4 weeks. Your doctor may ask you to continue taking the capsules or increase the dose depending on how you respond to treatment. To stop your symptoms returning your doctor may tell you to continue to take 20 mg omeprazole or reduce the dose to 10mg.

For children (1 year and older): the usual dose is based on age and weight. The recommended dose is 10mg or 20mg. The dose will be taken once a day. The treatment for heartburn and acid reflux disease is 2-4 weeks but your doctor may treat for up to 8 weeks.

Relief of Acid Indigestion (Dyspepsia)

The recommended dose is 10mg or 20mg once a day for a period of 2 - 4 weeks. Your doctor will tell you how long to take your capsules for. If you do not experience any improvement in your symptoms you should return to your doctor.

Treatment of ulcers in the upper part of the intestine (duodenal ulcer) and stomach (gastric ulcer)

The recommended dose is 20 mg omeprazole once a day for a period of 4 - 8 weeks depending on your symptoms. Your doctor may increase

Description	Omeprazole 20 mg Capsules		
Client	wavepharma- RIA Generics	Market	UK
Component	Leaflet	Version	2
Actual Size	160 x 280 mm		
Colors	<div></div> BLACK		
Track Date	02/02/2021		

Artwork Same Size
Size : 160 x 280 mm

Kaypee Design
(kaypeedesign@gmail.com)
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the dose depending on how you respond to treatment. To stop your ulcer coming back, the recommended dose is omeprazole 10 mg once daily unless your symptoms return. If your symptoms return, your doctor may increase the dose.

Treatment and prevention of stomach ulcers, duodenal ulcers and associated symptoms caused by NSAIDs
If you have previously had trouble with an ulcer and need to continue taking a NSAID the recommended dose is omeprazole 20 mg once daily. Your doctor will advise how long you need to take the capsules for.

Treatment of Ulcers caused by infection with the bacteria called Helicobacter Pylori
The recommended dose is omeprazole 40 mg once a day or 20 mg taken twice a day for a period of 1 - 2 weeks. Your doctor will also tell you to take one or two of the following antibiotics; amoxicillin, clarithromycin, metronidazole or tinidazole. For children over 4 years the dosage is based on weight and the recommended dose is 10mg or 20mg twice a day for 1 week. Your child will also be given the following antibiotic at the same time as Omeprazole Capsules: amoxicillin and clarithromycin. Follow the directions for taking your medicine very carefully and if you are unsure about anything, ask your doctor or pharmacist.

Before a hospital operation when you are to be given a general anaesthetic
The recommended dose is omeprazole 40 mg taken the evening before surgery, and another 40 mg dose two to six hours before surgery.

Zollinger - Ellison Syndrome
The recommended starting dose is omeprazole 60 mg once a day. If the dose is more than 80 mg a day, half the dose should be taken in the morning and half at night. Your doctor will tell you how many capsules to take and when to take them.

If you take more Omeprazole capsules than you should:
If you swallow too many tablets or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

If you forget to take Omeprazole capsules:
If you forget to take a dose, take it as soon as you remember. If it is nearly time for your next dose just take the next dose and forget about the one you missed. Do not take a double dose to make up for a forgotten dose.

If you stop taking Omeprazole capsules:
Do not stop taking Omeprazole capsules without first discussing it with your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible Side Effects

Like all medicines, this medicine can cause side effects, although not everyone gets them. These side effects are usually mild and go away when you stop taking this medicine.

If you notice any of following serious side effects, stop taking Omeprazole Capsules and tell a doctor or contact the casualty department at your nearest hospital straight away:
An allergic reaction (angioedema): swelling of the face, lips, tongue, throat or difficulty breathing or swallowing. Reddening of skin with blisters or peeling. There may also be severe blisters and bleeding in lips, eyes, mouth, nose and genitals. This could be 'Stevens Johnson-syndrome' or 'toxic epidermal necrolysis'. Yellow skin, dark urine and tiredness which can be symptoms of liver problems. These effects are rare, affecting less than 1 in 1000 people.

Other Side effects

Common: may affect up to 1 in 10 people

- Headache
- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence)
- Feeling sick (nausea) or being sick (vomiting)
- Benign polyps in the stomach

These may occur at the beginning of the treatment. If these signs do not get better after a few days then contact the doctor.

Uncommon: may affect up to 1 in 100 people

- Disturbed sleep (Insomnia)
- Dizziness
- Tingling feelings such as 'pins and needles'
- Feeling sleepy
- Spinning feeling (Vertigo)
- Feeling light headed or faint
- Skin rash, lumpy rash (hives), itchy skin and dermatitis
- Changes in blood tests that show how well your liver is working
- Generally feeling unwell
- Fracture of the hip, wrist or spine
- Swelling of the feet and ankles

Rare: may affect up to 1 in 1,000 people

- Dry or sore mouth
- An infection called 'thrush' which can affect the mouth or gullet and is caused by a fungus
- An inflammation of the inside of the mouth
- Taste changes
- Feeling anxious, confused or depressed
- Aggression

- Seeing, feeling or hearing things that are not there (hallucinations)
- Skin rash on exposure to sunshine
- Blurred vision
- Hair loss (alopecia)
- Painful swollen joints
- Aching muscles or muscle weakness
- Increased sweating
- Kidney problems (interstitial nephritis)
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness
- Severe liver problems leading to liver failure and inflammation of brain
- Enlarged breasts in men
- Being unable to get an erection (impotence)
- Low levels of sodium in blood. this may cause weakness, being sick (vomiting) and cramps
- Blood problems such as reduced number white cells or platelets. This can cause weakness, bruising or make infections more likely
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing
- Suddenly feeling wheezy or short of breath (bronchospasm)

Very rare: may affect up to 1 in 10,000 people

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression
- Seeing, feeling or hearing things that are not there (hallucinations)
- Severe liver problems leading to liver failure and inflammation of brain
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Muscle weakness
- Enlarged breasts in men

Not known: frequency cannot be estimated from the available data
If you are on Omeprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

- Rash, possibly with pain in the joints

In these cases consult with your doctor or pharmacist.

Do not be concerned by this list of possible side effects. You may not get any of them.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omeprazole Capsules

Keep this medicine out of the sight and reach of children.
Do not store above 30°C. Store in the original package.
Do not use Omeprazole Capsules after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Omeprazole Capsules contain

The active substance is omeprazole and each capsule contains 20mg of omeprazole as gastro resistant granules.
The other ingredients are sugar spheres, sodium starch glycollate, sodium lauryl sulfate, povidone, potassium oleate, oleic acid, hypromellose, methacrylic acid and ethyl acrylate copolymer, triethyl citrate, titanium dioxide and talc.
The capsule coating also contains gelatine, titanium dioxide (E171), quinoline yellow (E104), indigo carmine (E132) and erythrosine (E127). The printing ink contains shellac, anhydrous ethyl alcohol, isopropyl alcohol, propylene glycol, N-butyl alcohol, polyvinylpyrrolidone, sodium hydroxide and titanium dioxide (E171).

What Omeprazole 20mg Capsules look like and contents of the pack

The capsules have an orange body and blue cap and are marked with R_x20.
The capsules are supplied in bottles of 14 and 28 capsules.

Marketing Authorisation Holder:

RIA Generics Ltd
36 Ingleby Way, Wallington, Surrey, SM6 9LR, United Kingdom

Manufacturer:

RX Farma Limited, Unit 3, Colonial Way, Watford, Hertfordshire, WD24 4YR. United Kingdom.

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