

Consumer Medicine Information

DP-OMEPRAZOLE

Omeprazole 10 mg, 20 mg and 40 mg capsules

What is in this leaflet

This leaflet answers some of the common questions people ask about **DP-OMEPRAZOLE**. It does not contain all the information that is known about **DP-OMEPRAZOLE**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **DP-OMEPRAZOLE** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

What DP-OMEPRAZOLE is used for

Reflux Oesophagitis

DP-OMEPRAZOLE is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn, which usually occurs after eating or at night and which worsens when bending over.

DP-OMEPRAZOLE is also used to help stop reflux oesophagitis coming back or relapsing.

Acid-Related Dyspepsia

DP-OMEPRAZOLE is used to treat acid-related dyspepsia.

Dyspepsia is an uncomfortable feeling in the stomach or belching after eating. It is also known as indigestion.

Peptic Ulcers

DP-OMEPRAZOLE is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer.

A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach. They can cause pain and discomfort (indigestion) which is felt between the naval and the breast bone.

DP-OMEPRAZOLE is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with Helicobacter pylori Infection

Most people who have a peptic ulcer also have a bacteria called *Helicobacter pylori* in their stomach. When **DP-OMEPRAZOLE** is taken with antibiotics, they will kill *Helicobacter pylori* and let your peptic ulcer heal. When **DP-OMEPRAZOLE** is taken together with two antibiotics, they are more effective than taken one or two at a time. It is possible that the antibiotics may not always kill *Helicobacter pylori*. You may need further treatment.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs. These medicines are commonly taken to relieve pain, swelling and other symptoms of inflammation, including arthritis. DP-OMEPRAZOLE is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

DP-OMEPRAZOLE is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How DP-OMEPRAZOLE works

DP-OMEPRAZOLE is a type of medicine called a proton-pump inhibitor.

DP-OMEPRAZOLE works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Your doctor will have explained why you are being treated with **DP-OMEPRAZOLE** and told you what dose to take.

Follow all instructions given to you by your doctor carefully.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Before you use DP-OMEPRAZOLE

When you must not use it

Do not use DP-OMEPRAZOLE if:

- you have an allergy to omeprazole or any of the ingredients listed at the end of this leaflet
- the packaging shows signs of tampering
- the expiry date on the pack has passed.

Do not use DP-OMEPRAZOLE to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Before you start to use it

Tell your doctor if:

- you are pregnant or planning to become pregnant
- you are breastfeeding or planning to breastfeed
- you have or have had liver disease or liver problems
- you have or have had any medical conditions
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- phenytoin
- warfarin or other vitamin K antagonists
- diazepam
- ketoconazole
- itraconazole
- clarithromycin
- atazanavir
- tacrolimus
- other medicines that you buy at the chemist, supermarket or health food shop

These medicines may be affected by **DP-OMEPRAZOLE** or may affect how well it works.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

There is no evidence that **DP-OMEPRAZOLE** is addictive.

DP-OMEPRAZOLE is not likely to affect your ability to drive or use machines.

How to take DP-Omeprazole capsules

How to take it

Take DP-OMEPRAZOLE capsules as instructed by your doctor. Take one DP-OMEPRAZOLE capsule each day, unless your doctor has told you otherwise.

Swallow DP-OMEPRAZOLE capsules whole with a glass of water. Do not crush or chew.

Adults

The dose of **DP-OMEPRAZOLE** is usually 20 mg a day, but may vary depending on what condition you are being treated for and how severe it is.

Children

The recommended dose in children with reflux oesophagitis is 10 mg once a day in children weighing 10-20 kg and 20 mg in children weighing more than 20 kg.

If you have trouble swallowing **DP-OMEPRAZOLE**, open the capsule over an empty glass or cup and swallow the pellets with half a glass of liquid, or mix the pellets in a slightly acidic fluid e.g. fruit juice, yoghurt or non carbonated water and take within 30 minutes. Or, suck the capsule until it opens (1-2 minutes) and swallow the pellets with liquid. Do not crush or chew the capsules or the pellets. If the pellets in the capsules are chewed or crushed they will not work properly.

Take DP-OMEPRAZOLE at the same time each day, preferably in the morning.

Keeping a regular time for taking DP-OMEPRAZOLE will help remind you to take it.

In most patients, DP-OMEPRAZOLE relieves symptoms rapidly and healing is usually complete within 4 weeks.

Although DP-OMEPRAZOLE heals ulcers very successfully, it may not prevent them coming back at a later date. DP-OMEPRAZOLE can be taken to prevent these relapses. If you are taking DP-OMEPRAZOLE with antibiotics, it is possible that the antibiotics may not kill *Helicobacter pylori*. You may need further treatment with antibiotics.

Tell your doctor if your symptoms return.

It does not matter whether you take DP-OMEPRAZOLE with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

If you or anyone else has taken too much DP-OMEPRAZOLE, immediately contact a doctor or Poisons Information Centre (telephone 0800 Poison or 0800 764 766), or go to the nearest Accident & Emergency department or clinic. It is important to do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

While you are using DP-OMEPRAZOLE

You must use DP-OMEPRAZOLE exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking DP-OMEPRAZOLE.

Tell your doctor if you become pregnant while you are taking DP-OMEPRAZOLE.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DP-OMEPRAZOLE.

DP-OMEPRAZOLE helps most people with stomach or duodenal ulcers or reflux disease, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- diarrhoea, wind (flatulence) or constipation
- nausea and/or vomiting
- stomach pain or discomfort
- dry mouth
- skin rash, itching
- headache and/or dizziness
- breast enlargement in men
- unusual hair loss or thinning

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- muscle pain or weakness, joint pain
- "pins and needles" (tingling or numbness of the hands and feet)
- changes in sleep patterns
- changes in mood
- hallucinations or confusion
- bleeding or bruising more easily than normal, nose bleeds

- frequent infections such as fever, severe chills, sore throat or mouth ulcers

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- severe skin reaction which may include redness, blistering and peeling of the skin, accompanied with fever and chills, aching muscles
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking DP-OMEPRAZOLE.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion occurs during treatment with **DP-OMEPRAZOLE**
- you begin to vomit blood or food
- you pass black (blood-stained) motions.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **DP-OMEPRAZOLE capsules**.

Storage conditions

Keep your DP-OMEPRAZOLE capsules in the bottle with the lid tightly closed until it is time to take them. If you leave DP-OMEPRAZOLE capsules out of the original bottle they will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Use capsules within 3 months of first opening the bottle.

Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy medicines.

Do not use DP-OMEPRAZOLE after the expiry date printed on the label and carton.

Keep out of the reach and sight of children. Do not leave DP-OMEPRAZOLE in the car on hot days.

Disposal

If your doctor tells you to stop taking DP-OMEPRAZOLE or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What DP-OMEPRAZOLE looks like

10 mg: Opaque yellow cap and body, No. 3, hard gelatin capsules containing off-white (ivory) to cream-white spherical microgranules.

20 mg: Opaque yellow cap and body, No. 2, hard gelatin capsules containing off-white (ivory) to cream-white spherical microgranules

40 mg: Opaque blue cap and white body, No.0, hard gelatin printed capsules containing off-white (ivory) to cream-white spherical microgranules.

Ingredients

Each **DP-OMEPRAZOLE** capsule contains omeprazole 10, 20 or 40 mg as the active ingredient plus:

Capsule shell:

Gelatin, Titanium dioxide (E171), Quinoline yellow (E104) (not present in 40 mg strength)

Capsules content:

Hypromellose 6 cP, Methacrylic acid – ethyl acrylate copolymer, Talc, Sugar spheres (consisting of maize starch and sucrose), Polysorbate 80, Disodium phosphate, anhydrous, Mannitol, Macrogol 6000, Sodium laurilsulfate, titanium dioxide E171

DP-OMEPRAZOLE does not contain gluten.

Sponsor

Douglas Pharmaceuticals Limited

P O Box 45 027

Te Atatu Peninsula

Auckland 0651

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