

ULCID 20 mg GASTRO-RESISTANT CAPSULES

Omeprazole

Read all of this leaflet carefully before you start using 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. Do not pass it on to others. It may harm them, even if their symptoms 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 the leaflet. See section 4.

In this leaflet:

1. What Ulcid is and what it is used for
2. What you need to know before you take Ulcid
3. How to take Ulcid
4. Possible side effects
5. How to store Ulcid
6. Contents of the pack and other information

1. What Ulcid is and what it is used for

Ulcid gastro-resistant capsules contains the active substance omeprazole. It belongs to a group of medicines called 'proton-pump inhibitors'. They work by reducing the amount of acid that your stomach produces. This allows the ulcers to heal and eases the pain.

Ulcid is used to treat the following conditions:

In adults:

- 'Gastro-oesophagitis 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.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Prevention of relapse of duodenal and gastric ulcers.
- 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.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Ulcid can also be used to stop ulcers from forming if you are taking NSAIDs.
- Reflux oesophagitis. This is where acid from the stomach escapes into the gullet causing heartburn and inflammation of the lining of the gullet.
- Management of healed reflux oesophagitis.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- Reflux oesophagitis. This is where acid from the stomach escapes into the gullet causing heartburn and inflammation of the lining of the gullet.
- 'Gastro-oesophagitis 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.

Children and adolescents over 4 years of age

- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

2. What you need to know before you take Ulcid

Do not take Ulcid

- if you are allergic (hypersensitive) to omeprazole or to any of the other ingredients in Ulcid.
- if you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (for HIV infection).
- have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

If you are not sure, talk to your doctor or pharmacist before taking Ulcid.

Warnings and precautions:

Ulcid may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Ulcid or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- 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 severe liver problems.

If you take Ulcid on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

- Taking atazanavir with Ulcid is not recommended as the active omeprazole decreases the absorption of this drug.

Important information:

- If you are suffering from ulcers it should be determined if you are infected with bacteria called *Helicobacter pylori*. If you are shown to be *Helicobacter pylori*-positive, combination therapy should be used for treatment.
- If a gastric ulcer is suspected, the possibility of malignancy must be excluded before treatment with Ulcid is initiated, as treatment may alleviate symptoms and delay diagnosis.
- Your doctor should confirm your diagnosis if you are being treated for reflux oesophagitis.
- Decreased gastric acidity, due to any means – including proton-pump inhibitors – increases gastric counts of bacteria normally present in the gastro-intestinal tract. Treatment with acid reducing drugs leads to a slightly increased risk of gastrointestinal infections, such as Salmonella and Campylobacter.
- Taking a proton pump inhibitor like Ulcid, especially over a period of more than one year, may slightly increase your risk of fractures 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).

Other medicines and Ulcid

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. This is because Ulcid can affect the way some medicines work and some medicines can have an effect on Ulcid.

Do not take Ulcid if you are taking a medicine containing **nelfinavir** (used to treat HIV infection). The absorption of posaconazole (an antifungal) and erlotinib (used to treat certain types of cancer) is reduced by Ulcid and should therefore be avoided. If you are treated with a combination of Ulcid and another medicine (for NSAID related ulcers or treatment of *Helicobacter pylori*) caution should be exercised when additional medicines are administered, as interactions might be enhanced or increased.

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

- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by fungus).
- Digoxin (used to treat heart problems).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Ulcid.
- Medicines that are used to thin your blood, such as warfarin (for thinning of the blood) or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Ulcid.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV infections).
- Tacrolimus (in cases of organ transplants).
- Methotrexate (used to treat rheumatoid arthritis, psoriasis).
- 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)).
- Macrolide antibiotics e.g. clarithromycin (used for the treatment of infections).
- Ritonavir (for anti-viral activity associated with HIV).
- Ulcid may interfere with some laboratory tests. Tell your doctor you are taking omeprazole in advance of these tests.

Ulcid may reduce the oral absorption of vitamin B₁₂. This should be taken into account in those patients with low basal levels who undergo long term treatment with Ulcid. If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Ulcid to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any medicines you are taking.

Taking Ulcid with food and drink

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

Pregnancy, breast-feeding and fertility

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

Driving and using machines

Ulcid 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.

Important information about some of the ingredients of Ulcid

Ulcid gastro-resistant capsules contains a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ulcid

Always use Ulcid exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are. The usual doses are given below.

- DO NOT chew the capsules. The capsule contents should not be dispersed in water before taking.

Adults:

To treat symptoms of GORD such as **heartburn and acid regurgitation**:

- The usual dose is 20 mg once a day.
- A dose of 10 mg once daily for 4 weeks may be sufficient however if symptom control is not achieved after 4 weeks the usual dose of 20 mg Ulcid once a day should be taken.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The usual dose is Ulcid 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The usual dose is Ulcid 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To prevent the duodenal and stomach ulcers from coming back:

- The usual dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and stomach **ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The usual dose is Ulcid 20 mg once a day for 4 to 8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs**:

- The usual dose is Ulcid 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The usual dose is 20 mg Ulcid twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole. The selection of an appropriate regimen should be based on your tolerability and the therapeutic guidelines.

To treat **reflux oesophagitis**:

- The usual dose is 20 mg Ulcid once daily for 4 to 8 weeks. If needed, the dose can be increased to Ulcid 20-40 mg once daily.
- For long term management of patients with healed reflux oesophagitis the usual dose is 10 mg Ulcid once daily.

To treat too much acid in the stomach caused by a **growth in the pancreas (Zollinger-Ellison syndrome)**:

- The usual dose is Ulcid 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for. With doses above 80 mg daily, the dose should be divided and given twice daily. In patients with Zollinger-Ellison syndrome the treatment is not subject to a time limit.

Use in Children:

To treat symptoms of reflux oesophagitis or GORD such as **heartburn and acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg may take Ulcid. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- The treatment time for reflux oesophagitis is 4-8 weeks.
- The treatment time for GORD is 2-4 weeks.

To treat **ulcers caused by *Helicobacter pylori* infection** and to stop them coming back:

- Children aged over 4 years may take Ulcid. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

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 coated pellets which stop the medicines from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you or your child have trouble swallowing the capsules

- If you or your child have trouble swallowing the capsules:
 - Break the capsule and disperse it in a spoonful of water (non-fizzy), any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
 - Always stir the mixture just before drinking (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.
 - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. **Do not use** milk or fizzy water. The solid pieces contain the medicine - do not chew or crush them.

Special Populations:

To treat ulcers in patients with impaired kidney function:

- Dose adjustment is not needed. To treat ulcers in patients with impaired liver function:
- A daily dose of 10-20 mg may be sufficient. To treat ulcers in the elderly:
- Dose adjustment is not needed.

If you take more Ulcid than you should

If you take more Ulcid than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Ulcid

If you forget to take a capsule, take one as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ulcid

If you stop treatment too early your problems may reoccur. Therefore refer to the regimens given above or ask your doctor before stopping treatment. To avoid the development of resistances when treating ulcers which are infected with *Helicobacter pylori* treatment should not be shortened. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

If you notice any of the following rare but serious side effects, stop taking Ulcid and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the 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.

Side effects may occur with certain frequencies, which are defined as follows:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 to 10 people
Uncommon: may affect up to 1 to 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

Other side effects include:

Common side effects

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

Uncommon side effects

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.
- Fracture of the hip, wrist or spine.

Rare side effects

- Blood problems such as a reduced number of 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.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called "thrush" which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects

- Changes in blood count including: agranulocytosis (lack of white blood cells). Symptoms include; high fever, sore throat, mouth and anal ulcers, bleeding gums, excessive fatigue, frequent infections. Pancytopenia (lack of red and white cells and platelets). Symptoms include fatigue, infection, nose bleeding, increased menstrual bleeding, hemorrhage, pallor, rapid heartbeat and shortness of breath.
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain resulting from pre-existing liver problems.
- 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 males.

Not known:

- Hypomagnesaemia (low levels of magnesium in the blood)
- A condition resulting in profuse watery diarrhoea (microscopic colitis).

Ulcid may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a reduction in the number of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

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.

There is no information of the effect of omeprazole on puberty and growth in children. Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get 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 (see directly below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.imb.ie

e-mail: imbpharmacovigilance@imb.ie

5. How to store Ulcid

- Keep out of the reach and sight of children.
- Do not use Ulcid after the expiry date which is stated on the outer and inner pack after expiry. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original container. Keep the container tightly closed.
- 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 Ulcid contains

- The active substance is omeprazole. Each gastro-resistant capsule contains 20 mg of omeprazole.
- The other ingredients are hypromellose, lactose monohydrate, crospovidone, glycerol dibehenate, titanium dioxide, anhydrous silica, talc, triethyl citrate, methacrylic acid-ethyl acrylate copolymer (1:1). The capsule shells contain titanium dioxide (E 171), water and gelatin. Contains traces of sodium lauryl sulphate and polysorbate 80.

What Ulcid looks like and contents of the pack

- Ulcid are opaque, white hard capsules with imprint '20' on the body and 'OM' on the cap containing gastro-resistant micro tablets.
- Original packs containing 7, 14 or 28 gastro resistant capsules in tablet containers. Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Astellas Pharma Co. Ltd., 5 waterside Citywest Business Campus, Naas Road, Dublin 24, Ireland

Manufacturer:

Merckle GmbH, Ludwig-Merckle-Strasse 3,
89143 Blaubeuren, Germany

This leaflet was approved: October 2013