

Package leaflet: Information for the user
(Over-the-counter medicine*)

Ultop 20 mg gastro-resistant capsules, hard
Omeprazole

Read all of this leaflet carefully before you start using 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 has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
- 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 Ultop is and what it is used for
2. What you need to know before you use Ultop
3. How to take Ultop
4. Possible side effects
5. How to store Ultop
6. Contents of the pack and other information

1. What Ultop is and what it is used for

Ultop gastro-resistant hard capsules contain the active substance omeprazole. It belongs to the group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Ultop is used in adults for short-term treatment of the symptoms of gastro-oesophageal reflux disease (such as heartburn and gastro-oesophageal reflux).

Reflux is the return of the stomach's contents into the oesophagus, causing inflammation and pain. It can cause a painful burning sensation in the chest and throat (heartburn) and a sour taste (due to the return of acidic contents of the stomach to the oesophagus).

You may need to take the capsules for 2 or 3 days in a row to relieve symptoms.

2. What you need to know before you use Ultop

Do not take Ultop

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other medicines containing proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (for HIV infection).

Do not take Ultop if any of the above applies to you. Check with your doctor or pharmacist before taking Ultop if you are not sure.

Warnings and precautions

Do not take Ultop for more than 14 days without consulting a doctor. Talk to your doctor if your symptoms do not improve or worsen.

* Clarification – 7 or 14 tablets in a pack: over-the-counter medicine
28 in a pack: prescription medicine

Ultop may hide the symptoms of other diseases. Therefore, if any of the following happens to you before you start taking Ultop 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.
- Your stools turn black (blood-stained faeces).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have a history of peptic ulcers or have undergone gastro-intestinal surgery.
- You take medication to relieve symptoms of indigestion or heartburn on a regular basis (4 weeks or longer).
- You experience regular indigestion or heartburn for more than 4 weeks.
- You have jaundice or severe liver problems.
- You are over 55 years of age and your symptoms have only recently appeared or changed.
- You have ever had a skin reaction after treatment with a medicine similar to Ultop that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as possible, as you may need to stop your treatment with Ultop. Make sure to mention any other side effects, like pain in your joints.

Do not take omeprazole as a preventive medicine.

Other medicines and Ultop

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including over-the-counter medicines. Ultop can affect the way some medicines work and some medicines can have an effect on Ultop.

Do not take Ultop if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor or pharmacist if you are taking clopidogrel (used to prevent blood clots (thrombi)).

Inform 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);
- 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 Ultop;
- 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 Ultop;
- rifampicin (used to treat tuberculosis);
- atazanavir (used to treat HIV infection);
- tacrolimus (in cases of organ transplantation);
- St. John's wort (*Hypericum perforatum*) (used to treat mild depression);
- cilostazol (used to treat intermittent claudication);
- saquinavir (used to treat HIV infection);
- 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 treatment with Ultop.

Ultop with food and drink

The capsules may be taken with meals or on an empty stomach.

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Pregnancy, breast-feeding and fertility

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.

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 Ultop if you are breast-feeding.

Driving and using machines

Ultop is unlikely to affect your ability to drive or use machines. Side effects, such as dizziness and visual disturbances, may occur (see section 4). If these occur, you should not drive or use machines.

Ultop contains sucrose

If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicine.

3. How to take Ultop

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 standard dose is one 20 mg capsule once a day for 14 days. Contact your doctor if your symptoms do not improve in this period.

You may need to take the capsules for 2 or 3 days in a row to relieve symptoms.

Taking the medicine

- It is recommended to take your capsules in the morning.
- The capsules may be taken with meals 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 granules, which stop the medicine from being broken down by the acid in your stomach. Do not crush the granules. These micro-granules contain the active substance omeprazole and have a gastro-resistant coating, which protects them from disintegration in the stomach. The granules will release the active substance in the intestines where it is absorbed by your body.

What to do if you have trouble swallowing the capsules?

If you have trouble swallowing the capsules:

- Open the capsule and mix the contents with a spoonful of water (non-carbonated), 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.
- Make sure that you have drunk all of the medicine. For this, rinse the glass well with half a glass of water and drink it. Do not use milk or carbonated water. The solid particles contain the medicine – do not chew or crush them.

If you take more Ultop than you should

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

If you forget to take Ultop

If you forget to take the medicine, take it 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

* Clarification – 7 or 14 tablets in a pack: over-the-counter medicine
28 in a pack: prescription medicine

4. Possible side effects

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body rash, fainting or difficulties swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding on 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 can occur at certain frequencies, which are classified as follows:

Very common:	in more than 1 of 10 users
Common:	in 1-10 of 100 users
Uncommon:	in 1-10 of 1000 users
Rare:	in 1-10 of 10,000 users
Very rare:	in less than 1 of 10,000 users
Not known:	cannot be estimated from the available data

Other side effects:

Common side effects

- Headache;
- effects on your stomach or intestines: diarrhoea, stomach ache, constipation, flatulence;
- nausea or vomiting;
- benign polyps in the stomach.

Uncommon side effects

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feeling, sleepiness.
- Spinning feeling (vertigo).
- Changes in blood tests that indicate the liver function.
- Skin rash, urticaria and itchy skin.
- Hip, wrist or spine fracture.
- Generally feeling unwell and lack of energy.

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, 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 mucous membranes of the mouth.
- An infection called 'thrush' which can affect the intestines and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.

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- 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).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the 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.

Side effects of unknown frequency

- Hypomagnesaemia.
If you take omeprazole for more than 3 months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can cause fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, 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.
- Intestinal inflammation (causes diarrhoea).
- Rash, possibly with pain in the joints.

Utop 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 (pain in the neck, throat or mouth or difficulties in urinating), you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important to tell your doctor about the medicines you are taking.

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 www.ravimiamet.ee. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Utop

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

Do not store above 25°C.

Store in the original package, protected from humidity.

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

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.

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28 in a pack: prescription medicine

6. Contents of the pack and other information

What Ultop contains

- The active substance is omeprazole. One hard capsule contains 20 mg of omeprazole.
- The other ingredients are:
Contents of the capsule: sucrose, maize starch, hydroxypropylcellulose, magnesium carbonate, sodium lauryl sulphate, methacrylic acid ethyl acrylate copolymer, talc, macrogol 6000 and titanium dioxide (E171).
Hull of the capsule: titanium dioxide (E171), iron oxide (E172) and gelatine.

What Ultop looks like and contents of the pack

Capsules with a brownish-pink cap and light pink body; the capsules contain white to light yellow or light pink pellets.

7 or 14 capsules with a desiccant in a plastic container.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d. d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

KRKA, d.d., Novo Mesto Eesti filiaal
Pärnu mnt 141
11314 Tallinn
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This leaflet was last revised in April 2017.

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28 in a pack: prescription medicine

Package leaflet: information for the user
(Prescription medicine*)

Ultop 20 mg gastro-resistant hard 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the similar to 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.

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1. What Ultop is and what it is used for

Ultop contains omeprazole as the active substance. It belongs in the group of medicines called proton pump inhibitors. They work by reducing the amount of acid produced in your stomach.

Ultop is used to treat the following conditions:

Adults

- Gastroesophageal reflux disease (GERD). This means that acid from the stomach escapes into the oesophagus (connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcers) or stomach (gastric ulcers).
- Ulcers that have been infected with bacteria called *Helicobacter pylori*. If you have an ulcer, 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). Ultop may also be used to prevent the formation of ulcers if you are using NSAIDs.
- Excessive production of gastric acid caused by a growth in the pancreas (Zollinger–Ellison syndrome).

Children:

Children older than 1 year whose weight is ≥ 10 kg

- Gastroesophageal reflux disease (GERD). This means that acid from the stomach escapes into the oesophagus (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), vomiting and poor weight gain.

Children over the age of 4 and adolescents

- Ulcers that have been 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.

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2. What you need to know before you take Ultop

Do not take Ultop

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6);
- If you are allergic to medicines containing other proton pump inhibitors (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are using a medicine which contains nelfinavir (used for the treatment of HIV).

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

Warnings and precautions

Ultop may mask the symptoms of other diseases. Therefore, if you have any of the following symptoms before you start taking or while you are taking Ultop, talk to your doctor immediately:

- 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 the frequency of infectious diarrhoea.
- You have severe liver problems.
- If you have ever had skin reactions after treatment with a medicine similar to Ultop, which reduces stomach acidity.
- You are about to undergo a specific blood test (chromogranin A).

If you get a rash, especially in an area not protected from the sun, tell your doctor about it as soon as possible, as you may have to discontinue treatment with Ultop. Be sure to mention any other side effects, such as joint pain.

Your doctor will monitor your condition regularly if you are undergoing long-term treatment (longer than 1 year). Report any new and unusual symptoms and circumstances whenever you see your doctor.

Taking proton pump inhibitors like Ultop for longer than a year may slightly increase the risk of hip, wrist or spine fractures. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

Other medicines and Ultop

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Ultop may influence the effect of other medicines and other medicines may influence the effect of Ultop.

Do not take Ultop if you are taking a medicine containing **nelfinavir** (used to treat HIV).

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

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungal infections).
- Digoxin (used to treat heart diseases).
- Diazepam (used to treat anxiety, relax muscles or for epilepsy).
- Phenytoin (used for epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Ultop.
- Medicines used to thin the blood, such as warfarin or other vitamin K blockers. If you start or stop treatment with Ultop, medical supervision may be necessary.
- Rifampicin (used to treat tuberculosis).
- Atazanavir (used to treat HIV).

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- Tacrolimus (in the case of organ transplantation).
- St. John's Wart (*Hypericum perforatum*) (used to treat mild depression).
- Cilostazol (used to treat intermittent claudication).
- Saquinavir (used to treat HIV).
- Clopidogrel (used to prevent blood clots (thrombi)).
- Erlotinib (used in cancer treatment).
- Methotrexate (chemotherapeutic preparation used in large doses in cancer therapy) – if you are taking methotrexate in large doses, your doctor may temporarily stop treatment with Ultop.

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

Ultop with food and drink

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

Pregnancy, breast-feeding and fertility

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.

Omeprazole is excreted into breast milk but it is not likely to influence the child at therapeutic doses. Your doctor will decide whether you can use Ultop while breast feeding.

Driving and using machines

Ultop is not likely to affect your ability to drive or use machines. Potential side effects include dizziness and visual disturbances (see section 4). If affected, you should not drive or use machines.

Ultop contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before using this medicine.

3. How to take Ultop

Always take Ultop capsules exactly as your doctor has told you. 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 age.

The recommended doses are given below.

Adults:

To treat symptoms of GERD, such as heartburn and acid regurgitation

- If your doctor has determined that your oesophagus has been slightly damaged, the recommended dose is 20 mg once a day for 4...8 weeks. Your doctor may advise you to take a dose of 40 mg for a further 8 weeks if your oesophagus has not yet healed.
- The recommended dose once the oesophagus has healed is 10 mg once a day.
- If your oesophagus has not been damaged, the recommended dose is 10 mg once a day.

To treat upper intestinal ulcers (duodenal ulcers)

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may advise 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.

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To treat gastric ulcer

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may advise 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 gastric ulcers from recurring:

- The recommended 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 gastric ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

- The recommended dose is 20 mg once a day for 4...8 weeks.

To prevent duodenal and gastric ulcers if you are taking NSAIDs:

- The recommended dose is 20 mg once a day

To treat ulcers caused by a *Helicobacter pylori* infection and to prevent it from recurring:

- The recommended dose is 20 mg twice a day for one week.
- Your doctor will also advise you to take two antibiotics from the following: amoxicillin, clarithromycin and metronidazole.

To treat excessive production of gastric acid in the case of growth in the pancreas (Zollinger–Ellison syndrome)

- The recommended dose is 60 mg once a day.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Children:**To treat symptoms of GERD, such as heartburn and acid regurgitation**

- Children over 1 year and with a weight of more than 10 kg may take Ultop. The dose for children depends on their body weight and the correct dose will be determined by the doctor.

To treat ulcers caused by a *Helicobacter pylori* infection and to prevent it from recurring:

- Children over 4 years of age may take Ultop. The dose for children depends on their body weight and the correct dose will be determined by the doctor.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

Taking this medicine

- It is advisable to take the capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow the capsules whole with half a glass of water. Do not chew or crush the capsules. This is necessary 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 or your child have trouble swallowing the capsules?

If you or your child have trouble swallowing the capsules:

- Open the capsule and swallow the contents directly with half a glass of water or put the contents into a glass of still (noncarbonated) 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.

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- Make sure that you have drunk all of the medicine. For this, rinse the glass carefully with another half a glass of water and drink it. The solid pellets contain the medicine, do not chew or crush them.

If you take more Ultop than you should

If you take more Ultop than prescribed by your doctor, talk to your doctor or pharmacist immediately.

If you forget to take Ultop

Do not use a double dose to make up for a forgotten dose. Take the forgotten dose as soon as you remember it. If it is almost time for the next dose, skip the forgotten dose.

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 everybody gets them.

If you notice any of the following rare but severe side effects, stop taking Ultop and contact your doctor immediately.

- Sudden dyspnoea, swelling of the lips, tongue and throat or rash on your body, fainting or difficulties in swallowing (severe allergic reaction).
- Redness of the skin along with blistering or scaling of the skin. There may also be severe blistering and bleeding on the lips, eyes, mouth, nose and genitals. This could be Stevens–Johnson Syndrome or toxic epidermal necrolysis.
- Yellow discoloration of the skin, dark urine and tiredness, which can be symptoms of liver problems.

Other side effects

Common side effects (*can affect up to 1 person in 10*):

- Headache.
- Effects affecting digestion: diarrhoea, abdominal pain, constipation, abdominal bloating.
- Nausea or vomiting.
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 person in 100)

- Swelling of the feet and ankles.
- Sleep disorders (insomnia).
- Dizziness, tingling sensation, drowsiness.
- Vertigo.
- Changes in blood tests for liver function.
- Skin rash, hives (urticaria) and itchy skin.
- Hip, wrist or spine fracture.
- Generally feeling unwell and lacking energy.

Rare side effects (may affect up to 1 person in 1,000)

- Blood problems, such as decreased levels of white blood 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, dyspnoea.
- Low sodium levels in the blood. This may cause weakness, vomiting and cramps.
- Feeling agitated, confused or depressed.
- Changes in the sense of taste.
- Impaired vision, such as blurred vision.

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- Sudden fits of wheezing or shortness of breath (bronchospasm).
- Dry mouth.
- Stomatitis.
- An infection called thrush, which may affect your intestine and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow discoloration of the skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash upon exposure to sunshine.
- Joint pain (arthralgia) or muscle pain (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects (may affect up to 1 person in 10,000)

- Changes in blood count, including agranulocytosis (lack of white blood cells).
- Aggressive behaviour.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Severe rash with a sudden onset, blistering or peeling of the skin. This may be associated with a high fever and joint pain (erythema multiforme, Stevens–Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlargement of the mammary glands in men.

Side effects of unknown frequency (cannot be estimated from available data)

- Enterocolitis (causes diarrhoea).
- Rash which may be accompanied with joint pain.
- If you take Ultop for longer than 3 months, your level of magnesium in the blood may decrease. Low levels of magnesium may cause fatigue, involuntary muscle spasms, disorientation, cramps, vertigo and an increase in heart rate. If you get any of these symptoms, talk to your doctor immediately. Low levels of magnesium may also lead to a decrease in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your magnesium levels.

Ultop can in very rare cases affect white blood cells, which may lead to immune deficiency. If you have an infection with symptoms such as fever and feeling **very unwell** or fever with signs of a local infection (pain in the neck, throat or mouth or difficulty urinating), you must see your doctor as soon as possible to rule out a severe lack of white blood cells (agranulocytosis). You must tell your doctor about the medicines you are taking.

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 www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ultop

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

Do not store at a temperature higher than 25 °C.

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

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

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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

What Ultop contains

- The active substance is omeprazole. One capsule contains 20 mg of omeprazole.
- The other ingredients are:
Capsule contents: sucrose, corn starch, hydroxypropyl cellulose, magnesium carbonate, sodium laureth sulfate, methacrylic acid / ethyl acrylate copolymer, talc, macrogol 6000 and titanium dioxide (E171).
Capsule: titanium dioxide (E171), iron oxide (E172) and gelatine.

What Ultop looks like and contents of the pack

The capsules are two-coloured, one side of the capsule is light pink and the other is brownish pink. The capsules contain white to light yellow or light pink pellets.

The plastic bottle contains 28 capsules and a desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

For any further information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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* Clarification – 7 or 14 tablets in a pack: over-the-counter medicine
28 in a pack: prescription medicine