PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ALTOSEC 20 mg capsules

Omeprazole

Contains sugar: Lactose anhydrous 8 mg; mannitol 142,5 mg

Read all of this leaflet carefully before you start taking ALTOSEC 20

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- ALTOSEC 20 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ALTOSEC 20 is and what it is used for
2. What you need to know before you take ALTOSEC 20
3. How to take ALTOSEC 20
4. Possible side effects
5. How to store ALTOSEC 20
6. Contents of the pack and other information

1. What ALTOSEC 20 is and what it is used for

ALTOSEC 20 belongs to a group of medicines called ‘proton pump inhibitors’.

They work by reducing the amount of acid that your stomach produces.

ALTOSEC 20 is used to treat the following conditions:

- Symptomatic relief of heartburn if you have 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.
- Ulcers in the upper part of the intestine (duodenal ulcer), or treatment of stomach ulcers (gastric ulcers) and treatment of inflammation of the lining of the food pipe caused by reflux.
- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor will prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Too much acid in the stomach (Zollinger-Ellison Syndrome).
- Gastric (stomach) and/or duodenal (intestinal) ulcers caused by medicines called non-steroidal anti-inflammatory drugs (NSAIDs); for reducing the risk of developing ulcers if you are taking NSAIDs or if you have previously had an ulcer and need to continue treatment with NSAIDs, ALTOSEC 20 can prevent the ulcer form coming back.

2. What you need to know before you take ALTOSEC 20

Do not take ALTOSEC 20:

- if you are hypersensitive (allergic) to omeprazole, substituted benzimidazoles or any of the other ingredients of ALTOSEC 20 (listed in section 6).
- if you are pregnant or breastfeeding your baby.
- if you are taking atazanavir or nelfinavir, used in the management of HIV.

If you are not sure, talk to your doctor or pharmacist before taking ALTOSEC 20.

Warnings and precautions

Take special care with ALTOSEC 20:

- if you experience serious skin reactions including blistering and peeling of the skin which may be due to Stevens-Johnson syndrome, Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and rapid appearance of areas of red skin studded with pinhead-sized sterile pustules (AGEP); stop using ALTOSEC 20 and seek medical attention immediately.
- seek immediate care if you experience unintentional loss of weight, repeated vomiting, difficulty swallowing, vomiting of blood, if you look pale or and feel weak (anaemia) or if you notice blood in your stool or your stool appears black (blood-stained faeces). Your doctor may decide that you need some tests to rule out malignant disease because ALTOSEC 20 also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.
- if you get stomach pain or indigestion.
- if you experience severe or persistent diarrhoea, as ALTOSEC 20 has been associated with a small increase in infectious diarrhoea. You should seek immediate help from a healthcare provider if you experience watery stools, abdominal pain and fever whilst using ALTOSEC 20.
- if you are due to have a specific blood test (Chromogranin A).
- as using ALTOSEC 20 may 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 severe liver problems.
- omeprazole, as in ALTOSEC 20, is extensively metabolised in the liver and it is recommended that the dosage should be reduced in liver impairment.

The following should be considered:

- ALTOSEC 20 may reduce the absorption of vitamin B_{12} (cyanocobalamin). This should be considered in patients with reduced body stores or risk factors for reduced vitamin B_{12} absorption on long-term therapy.
- if lesions occur, especially in sun-exposed areas of the skin, and if accompanied by pain in a joint, you should seek medical help promptly and the healthcare provider should consider stopping ALTOSEC 20. Subacute cutaneous lupus erythematosus (SCLE) (these are abnormal skin growths that are dry and evolve as ring shaped skin growths) after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.
- if you are on ALTOSEC 20 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, or 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.
- if you need to go for tests for hormonal or nervous system tumours your doctor will inform you to stop your ALTOSEC 20 treatment as the active ingredient in ALTOSEC 20 can interfere with these results.
- long-term safety of ALTOSEC 20 in patients with kidney and liver problems has not been established.
- co-administration with atazanavir and nelfinavir (used in the treatment of HIV infection) is not recommended.
- long-term use of ALTOSEC 20 has been associated with the formation of stomach glandular cysts (fluid-filled, closed sacs), but these appear to be non-cancerous and appear to be reversible on cessation of therapy.

- ALTOSEC 20 can cause an increased risk of kidney disease leading to kidney failure. This is called tubulointerstitial nephritis and you may have increased urine output, blood in your urine or dark urine, changes in mental status, such as drowsiness or confusion, swelling of any area of your body.

Children and adolescents

There is no experience with ALTOSEC 20.

Other medicines and ALTOSEC 20

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

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

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- 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 ALTOSEC 20.
- Medicines that are used to prevent blood clots, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking ALTOSEC 20.
- Rifampicin (used to treat tuberculosis).
- Saquinavir (used to treat HIV infection).
- Tacrolimus (in cases of organ transplantation).
- St John's wort (*Hypericum perforatum*) (used to treat mild depression).
- Clopidogrel and cilostazol (used to prevent blood clots (thrombi)).

- Methotrexate (used in the treatment of certain cancers and autoimmune diseases) if you are taking a high dose of methotrexate, your doctor may temporarily stop your ALTOSEC 20 treatment.

ALTOSEC 20 with food and alcohol

The absorption of ALTOSEC 20 is not affected by alcohol or food.

Pregnancy and breastfeeding

You should not take ALTOSEC 20 if you are pregnant or breastfeeding your baby. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking ALTOSEC 20.

Driving and using machines

It is not always possible to predict to what extent ALTOSEC 20 may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ALTOSEC 20 affects you (see section 4).

ALTOSEC 20 contains lactose and mannitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ALTOSEC 20.

ALTOSEC 20 contains mannitol and may have a laxative effect.

3. How to take ALTOSEC 20

Always take ALTOSEC 20 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not share medicines prescribed for you with any other person.

Do not suddenly stop taking ALTOSEC 20 without consulting with your doctor first.

If you have the impression that the effect of ALTOSEC 20 is too strong or too weak, tell your doctor or pharmacist.

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

The usual dose is 20 mg once a day for two to four weeks. If the ulcer is not fully healed, your doctor may tell you to increase the dose to 40 mg once a day.

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

Your doctor will tell you to take specific antibiotics with the prescribed ALTOSEC 20 to treat this infection.

Gastric ulcer (ulcers in the stomach) and acid reflux

The usual dose is 20 mg once daily for 4 to 8 weeks.

Depending on your response, your doctor may decide to increase your dose to 40 mg once daily.

If you have severe or symptomatic recurrent acid regurgitation, the doctor will indicate if treatment can be continued with ALTOSEC 20 at a dosage of 20 mg once daily.

Symptomatic gastro-oesophageal reflux disease (acid reflux disease)

The usual dose is 20 mg daily.

If you do not get an adequate response with 20 mg after 2 weeks of treatment, your doctor may decide to do further investigations.

Zollinger-Ellison Syndrome (A condition where you have too much acid in the stomach caused by a growth in the pancreas)

The usual dose is 60 mg daily. Your doctor will adjust the dose depending on your needs and will also indicate for how long you need to take the medicine for.

NSAID associated gastric (stomach) ulcers and duodenal (intestinal) ulcers.

The usual dose is 20 mg once daily.

If you are not fully healed after the initial course your doctor may extend your treatment period.

ALTOSEC 20 can also be used to prevent gastric and duodenal ulcers.

Method of administration

It is recommended to take ALTOSEC 20 capsules in the morning, preferably without food, swallowed whole with half a glass of water. The capsules must not be chewed or crushed.

For patients with swallowing difficulties

The capsule can be opened, and the contents swallowed directly with half a glass of water or after mixing the contents in a slightly acidic fluid, for example fruit juice or applesauce, or in non-carbonated water. The dispersion should be taken immediately (or within 30 minutes). Always stir just before drinking. Rinse it down with half a glass of water. Alternatively, patients can suck the capsule and swallow the pellets with half a glass of water. Ingest without chewing the enteric coated pellets.

If you take more ALTOSEC 20 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ALTOSEC 20

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ALTOSEC 20 can have side effects.

Not all side effects reported for ALTOSEC 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ALTOSEC 20, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking ALTOSEC 20 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth and or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes, and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalized Exanthematous Pustulosis (AGEP).

These are all very serious side effects. If you have them, you may have had a serious reaction to ALTOSEC 20. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Liver problems, including jaundice, which can cause yellow skin, dark urine, and tiredness,
- watery stools, abdominal pain and fever, as these can be signs of a serious stomach infection,
- blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make you more prone to infections,

- fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate,
- 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),
- fracture of the hip, wrists or spine,
- painful urination and lower back pain as these may be symptoms of severe kidney problems, including kidney failure, (interstitial nephritis),
- changes in blood count including agranulocytosis (lack of white blood cells). ALTOSEC 20 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 lack of white blood cells (agranulocytosis) can be ruled out by a blood test,
- severe liver problems leading to liver failure and inflammation of the brain.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache (severe enough to cause discontinuation in some patients),
- effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence),
- feeling sick (nausea) or being sick (vomiting),
- stomach pain or colic (which could be benign polyps in the stomach),
- sudden wheezing or shortness of breath (bronchospasm).

Less frequent side effects:

- Blood problems, such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely,
- feeling agitated, confused, or depressed,
- taste changes,
- dizziness, ‘pins and needles’ feeling on the skin, drowsiness, difficulty in sleeping,
- ringing in the ears,
- 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,
- hair loss (alopecia),
- skin rash on exposure to sunshine,
- joint pains (arthralgia) or muscle pains (myalgia),
- muscle weakness,
- increased sweating,
- a feeling of general discomfort or uneasiness,
- the abnormal development of large breasts in males,
- swelling of the hands and feet due to water retention,
- spinning feeling (vertigo),
- eyesight problems, such as blurred vision,
- aggression,
- seeing, feeling or hearing things that are not there (hallucinations).

Side effects with an unknown frequency:

- Inflammation in the gut (leading to diarrhoea),

- if you are on ALTOSEC 20 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, or 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to: Acino Pharma (Pty) Ltd **E-mail:** drugsafety_ZA@acino.swiss or

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

By reporting side effects, you can help provide more information on the safety of ALTOSEC 20.

5. How to store ALTOSEC 20

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in the original packaging until required for use.

HDPE bottle, replace cap firmly after use.

Do not use after the expiry date stated on the label.

Do not store in a bathroom.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ALTOSEC 20 contains

The active substance is 20 mg of omeprazole.

The other ingredients are disodium hydrogen phosphate dihydrate, gelatin, hydroxypropylcellulose, hydroxypropyl methylcellulose, lactose anhydrous, magnesium stearate, mannitol, methacrylic acid copolymer Type C, microcrystalline cellulose, polyethylene glycol, red iron oxide (C.I. 77491), silicon dioxide colloidal anhydrous, sodium lauryl sulphate, titanium dioxide.

Contains sugar: Lactose anhydrous 8 mg; mannitol 142,5 mg

What ALTOSEC 20 looks like and contents of the pack

ALTOSEC 20 are hard gelatin capsule size '2' opaque pink body and opaque reddish brown cap, imprinted with "F51" on cap and body in black ink and capsule containing white to slightly beige enteric coated Omeprazole pellets.

14 or 28 capsules are packed into a white high-density polyethylene bottle sealed with a white polypropylene screw cap with a safety ring together with a white low-density polyethylene desiccant capsule. The bottle is placed in an outer cardboard carton together with a leaflet.
14 or 28 capsules are packed into polyvinyl chloride blister strips sealed with an aluminium foil backing. The blister strips are packed into an outer cardboard carton together with a leaflet.
Not all packs and pack sizes are necessarily marketed.

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Access to the corresponding Professional Information

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https://www.sahpra.org.za/pi-pil-repository/

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