

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

ULCEVAN 20 mg delayed release enteric coated tablets

Pantoprazole sodium sesquihydrate

Contains sugar: Mannitol 53,08 mg

Read all of this leaflet carefully because it contains important information for you

ULCEVAN enteric coated tablets is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ULCEVAN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ULCEVAN with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

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

1. What ULCEVAN is and what it is used for

ULCEVAN is used in adults for the temporary short-term relief of heartburn and to treat conditions where the stomach produces too much acid (hyperacidity).

2. What you need to know before you take ULCEVAN

Do not take ULCEVAN:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of ULCEVAN (listed in section 6);
- if you are taking medicines for HIV known as atazanavir or nelfinavir (antiretrovirals);- These medicines may not work as well against your HIV infection if you take them with ULCEVAN;
- if you have a serious liver problem;
- If you are pregnant or breastfeeding your baby (see section 2, pregnancy and breastfeeding).

ULCEVAN should not be given to children as it is not known if it is safe and effective for them.

Warnings and precautions

Take special care with ULCEVAN

You must contact your medical doctor for advice as soon as possible (especially if you have, or ever had, stomach ulcers or digestive tract operations) if you:

- are unintentionally losing weight;
- notice you have very dark stools or blood in your stools;
- have difficulty with, or have pain, when swallowing;
- are vomiting blood;
- feel very tired.

ULCEVAN , when taken in these cases, may relieve and hide the symptoms of a serious condition which needs treatment without delay.

- ULCEVAN increases the risk of bacterial infections of the digestive tract. Contact your doctor for advice as soon as possible if you experience symptoms such as persistent loose or watery stools, especially if combined with nausea, vomiting, stomach cramps and/or fever.
- ULCEVAN can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including ULCEVAN, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with ULCEVAN. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- If you are on ULCEVAN 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, confusion, fits, 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 lower potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Contact your doctor or speak to your pharmacist before taking ULCEVAN if:

- you have or ever had liver problems or jaundice.
- you have severe kidney problems.
- you have osteoporosis.
- you have been taking continuously, for 4 weeks or longer, medication for heartburn and/or indigestion.

Since ULCEVAN may cause you to be more sensitive to sunburn, you should take precautions when exposed to sunlight.

You should not use ULCEVAN for mild complaints such as indigestion caused by stress or emotional upsets. Speak to your doctor or pharmacist.

Other medicines and ULCEVAN

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

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

- Antiretroviral medicines known as atazanavir and nelfinavir, as the effect of these medicines may be reduced.
- A medicine known as voriconazole, as this can increase the effect of ULCEVAN and voriconazole.
- Warfarin to prevent clots as your blood may become too thin if you take it with ULCEVAN. Your risk of bleeding may increase. Speak to your doctor as you may need additional tests to check your blood (INR tests).
- Ketoconazole, itraconazole and posaconazole, used for fungal disease, may not be absorbed well and may therefore be less effective. Thrush and athletes' foot are examples of fungal diseases.
- Digoxin for heart problems, when used with ULCEVAN may result in increased levels of digoxin in your blood with worsening of its unwanted effects.
- diazepam (to calm you), and/or phenytoin (for epilepsy) as your doses may have to be decreased.
- high doses of methotrexate e.g. 300 mg daily (sometimes given for psoriasis, a skin disease marked by red, itchy, scaly patches or for rheumatoid arthritis, a chronic progressive disease causing inflammation in the joints), as the levels of methotrexate in your body may be increased.
- Ampicillin (antibiotics used for infections).
- Iron supplements.

ULCEVAN with food

ULCEVAN can be taken with or without food.

Speak to your doctor or pharmacist before taking ULCEVAN if you are taking alcohol on a regular basis.

Pregnancy, breastfeeding and fertility

You should not take ULCEVAN 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 ULCEVAN.

Driving and using machines

ULCEVAN may make you feel dizzy or make you see less clearly.

Do not drive vehicles or operate any hazardous tools or machines unless you are sure that ULCEVAN will not stop you from doing so safely.

ULCEVAN contains mannitol

ULCEVAN contains mannitol which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using ULCEVAN.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take ULCEVAN

Always take ULCEVAN exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

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

ULCEVAN is for adults only.

- Take one ULCEVAN tablet per day, before or during breakfast.
- ULCEVAN should be swallowed whole with about a quarter glass of water.
- Do not break or crush the tablet.
- Do not chew the tablet.
- The maximum dose is one tablet per day for a maximum period of 14 days.
- If your symptoms have not gone away after 14 days of continuous treatment, consult your doctor.
- You should not take more than three 14-day courses of ULCEVAN in a 12-month period without consulting your doctor.
- The use of ULCEVAN for longer than 14 days, or more often than three times in a 12-month period is not advised unless you are under the supervision of your doctor.

If you take more ULCEVAN than you should

If you have taken more ULCEVAN tablets than you should, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

There is limited information available on the effects of very high doses.

If you forget to take ULCEVAN

Take the missed dose as soon as you remember. If, however, it is almost time for your next dose, do not take a double dose to make up for the missed dose. Continue with the normal dose of one tablet per day before or during breakfast.

If you stop taking ULCEVAN

Do not stop taking ULCEVAN unless your doctor tells you to.

4. Possible side effects

ULCEVAN can have side effects.

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

Some less frequent side effects of ULCEVAN can be serious. If any of the following happens, stop taking/using ULCEVAN and tell your doctor immediately or go to the casualty department at your nearest hospital as you will need immediate medical attention or hospitalisation:

- If you have an allergic reaction to ULCEVAN with effects such as swelling of the mouth, tongue or face and/or throat, difficulty to breathe or swallow, red lumpy skin rash (hives), dizziness (which may be as a result of a sudden fall in blood pressure leading to collapse or shock).
- If you experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), and unexplained flu-like symptoms.
- If you develop severe flu-like symptoms followed by severe skin blisters with redness around them, or a peeling rash, hives and/or mouth sores: These are symptoms of Stevens-Johnson syndrome, a sometimes fatal form of allergic skin disease.
- If you develop serious skin reactions, including shedding of scaly dead skin, extremely serious allergic skin reactions, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and toxic skin degeneration.
- Problems with passing urine or if you pass urine more often than usual and develop a fever and generally feel unwell, or if you notice blood in your urine.

- Watery stool/runny tummy that does not go away, accompanied by stomach pain and fever; these are the symptoms of infection requiring medical treatment (see section 2).

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

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

- if you lose a lot of weight for no reason and have problems swallowing,
- if you get stomach pain or indigestion,
- jaundice (yellow eyes or skin),
- if you begin to vomit food or blood,
- if you pass black stools (blood-stained faeces),
- if you have watery stools,
- fatigue, painful muscle spasm, confusion, fits, dizziness and life-threatening irregular heartbeat; these are symptoms of hypomagnesaemia (low magnesium levels),
- fracture of the hip, wrist or spine,
- painful urination and low back pain as these may be symptoms of kidney problems.

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,
- Digestive tract problems such as stomach pain, runny tummy (watery stools), constipation and bloating (gas)

Less frequent side effects:

- nausea (feeling sick),
- vomiting (being sick),
- dry mouth,
- feeling abnormally weak and tired,
- generally feeling unwell,
- swollen hands and feet,
- not seeing clearly,
- blood test results showing impaired liver function or increase of 'certain fats' in the blood (triglycerides, cholesterol), increase in bilirubin (formed when red blood cells breakdown),
- weight changes,
- increase in body temperature,
- joint pain,
- muscle pain,
- increased risk of wrist, hip and spine bone breaks,
- feeling of dizziness,
- taste disorders,
- feeling down,
- not sleeping well,
- feeling confused or baffled,
- decrease in the blood of the number of red cells, white cells, and platelets (pancytopenia), white blood cells (leukopenia) (may increase the risk of inflammation/infection), platelets (thrombocytopenia) (may increase risk of bruising or bleeding), sharp drop in circulating granular white blood cells (agranulocytosis) - an acute disease marked by high fever,

- oversensitivity to sunlight.

Side effects with an unknown frequency:

- runny tummy due to bacterial infections,
- severe liver damage that can lead to liver failure (see Section 2),
- enlarged breasts in men,
- -decrease in magnesium and sodium in the blood,
- feeling or experiencing things that seem real, but that do not in fact really happen (hallucinations).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important.

Health care providers are asked to report any suspected adverse reactions to **SAHPRA** via the "6.04 Adverse Drug Reactions Reporting Form, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store ULCEVAN

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store in a bathroom.

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

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 ULCEVAN contains

The active substance is pantoprazole.

Each enteric coated tablet contains pantoprazole sodium sesquihydrate equivalent to 20 mg pantoprazole.

The other ingredients are basic butylated methacrylate copolymer, calcium stearate, mannitol, sodium carbonate anhydrous, sodium starch glycolate.

Coating:

Hypromellose (E464), kollicoat MAE 30 DP yellow, macrogol, methacrylic acid-ethyl acrylate copolymer dispersion, propylene glycol, sodium lauryl sulfate, talc, titanium dioxide (E171), yellow iron oxide (E172).

Contains sugar: Mannitol 53,08 mg

What ULCEVAN looks like and contents of the pack

ULCEVAN is a coated (light yellow), elliptical, normal biconvex tablet.

Alu/Alu blisters containing 7 tablets per blister strip. 1 or 2 such strips are packed into a carton in pack sizes of 7 or 14 tablets.



Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

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

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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