

The PL includes alternative texts for different legal status in different countries as follows:

- [Boxed texts] are only applicable for OTC versions.

- [Grey-shaded texts in brackets] are only applicable for prescription versions.

For OTC use in Sweden, please refer to the approved Swedish package leaflet published on MPA's web site.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Gentazetan 100 mg gastro-resistant tablets

Acetylsalicylic acid

[<Read all of this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.>]

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

This medicine is available without prescription. However, you still need to take Gentazetan carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.>

<[To be completed nationally]>

In this leaflet:

1. What Gentazetan is and what it is used for
2. Before you take Gentazetan
3. How to take Gentazetan
4. Possible side effects
5. How to store Gentazetan
6. Further information

1. WHAT GENTAZETAN IS AND WHAT IT IS USED FOR

Gentazetan contains acetylsalicylic acid, which in low doses belong to a group of medicines called anti-platelet agents. Platelets are tiny cells in the blood that cause the blood to clot and are involved in thrombosis. When a blood clot occurs in an artery it stops the blood flowing and cuts off the oxygen supply. When this happens in the heart it can cause a heart attack or angina; in the brain it can cause a stroke.

Gentazetan is taken to reduce the risk of blood clots forming and thereby prevent further:

- heart attacks
- strokes

- cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain).

Gentazetan is also used to prevent the formation of blood clots after certain types of heart surgery in order to widen or to unblock the blood vessels.

This medicinal product is not recommended for emergencies. It can only be used as a preventive treatment.

2. BEFORE YOU TAKE GENTAZETAN

Do not take Gentazetan if you

- are allergic to acetylsalicylic acid or any of the ingredients in Gentazetan (see section 6 “Further information”)
- are allergic to other salicylates or non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs are often used for arthritis or rheumatism and pain
- have had an asthma attack or swelling of some parts of the body e.g. face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs
- currently have or have ever had an ulcer in your stomach or small intestine or any other type of bleeding like a stroke
- have ever had the problem of your blood not clotting properly
- have severe liver or kidney problems
- are in your last 3 months of pregnancy; you must not use higher doses than 100 mg per day (see section “Pregnancy and breast-feeding”)
- are taking a medicine called methotrexate (e.g. for cancer or rheumatoid arthritis) in doses higher than 15 mg per week

Take special care with Gentazetan

Before you take Gentazetan tell your doctor if you:

- have trouble with your kidneys, liver or heart
- have or have ever had problems with your stomach or small intestine
- have high blood pressure
- are asthmatic, have hay fever, nasal polyps or other chronic respiratory diseases; acetylsalicylic acid may induce an asthma attack
- have ever had gout
- have heavy menstrual periods

You must immediately seek medical advice, if your symptoms get worse or if you experience severe or unexpected side effects e.g. unusual bleeding symptoms, serious skin reactions or any other sign of serious allergy (see section “Possible side effects”).

Inform your doctor if you are planning to have an operation (even a minor one, such as tooth extraction) since acetylsalicylic acid is blood-thinning there may be an increased risk of bleeding.

Acetylsalicylic acid may cause Reye’s syndrome when given to children. Reye’s syndrome is a very rare disease which affects the brain and liver and can be life-threatening. For this reason, Gentazetan should not be given to children aged under 16 years, unless on the advice of a doctor.

You should take care not to become dehydrated (you may feel thirsty with a dry mouth) since the use of acetylsalicylic acid at the same time may result in deterioration of kidney function.

This medicinal product is not suitable as a pain killer or fever reducer.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of treatment may be influenced if acetylsalicylic acid is taken at the same time as some other medicines for:

- thinning of the blood/prevention of clots (e.g. warfarin, heparin, clopidogrel)
- rejection of organ after transplantation (cyclosporine, tacrolimus)
- high blood pressure (e.g. diuretics and ACE-inhibitors)
- regulation of the heart beat (digoxin)
- manic-depressive illness (lithium)
- pain and inflammation (e.g. NSAIDs such as ibuprofen, or steroids)
- gout (e.g. probenecid)
- epilepsy (valproate, phenytoin)
- glaucoma (acetazolamide)
- cancer or rheumatoid arthritis (methotrexate; in doses lower than 15 mg per week)
- diabetes (e.g. glibenclamide)
- depression (selective serotonin re-uptake inhibitors (SSRIs) such as sertraline or paroxetine).
- use as hormone replacement therapy when the adrenal glands or pituitary gland have been destroyed or removed, or to treat inflammation, including rheumatic diseases and inflammation of the intestines (corticosteroids)

Taking Gentazetan with food and drink

Drinking alcohol may possibly increase the risk of gastrointestinal bleeding and prolong bleeding time.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnant women should not take acetylsalicylic acid during pregnancy unless advised by their doctor. You should not take Gentazetan if you are in the last 3 months of pregnancy, unless you are advised to do so by your doctor and then the daily dose should not exceed 100 mg (see section “Do not take Gentazetan”). Regular or high doses of this medicinal product during late pregnancy can cause serious complications in the mother or baby.

Breast-feeding women should not take acetylsalicylic acid unless advised by their doctor.

Driving and using machines

Gentazetan should not affect your ability to drive and use machines.

3. HOW TO TAKE GENTAZETAN

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

Adults

Prevention of heart attacks:

- The recommended dose is 100 mg once daily.

Prevention of strokes:

- The recommended dose is 100 mg once daily.

Prevention of cardiovascular problems in patients who suffer from stable or unstable angina (a type of chest pain):

- The recommended dose is 100 mg once daily.

Prevention formation of blood clots after certain types of heart surgery:

- The recommended dose is 100 mg once daily.

The usual dose for long term use is 100 mg (one tablet) once daily. Gentazetan should not be used at higher doses unless advised by a doctor, and then the dose should not exceed 300 mg a day.

Elderly

As for adults. In general, acetylsalicylic acids should be used with caution in elderly patients who are more prone to adverse events. Treatment should be reviewed at regular intervals.

Children

Acetylsalicylic acid should not be administered to children and adolescents younger than 16 years, unless prescribed by a doctor (see section “Take special care with Gentazetan”).

Method of administration

For oral use.

The tablets should be swallowed whole with sufficient fluid (1/2 glass of water). The tablets have a gastro-resistant coating which prevents irritant effects on the gut, and should therefore not be crushed, broken or chewed.

If you take more Gentazetan than you should

If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact immediately the nearest casualty department. Show any left over medicines or the empty packet to the doctor.

Symptoms of overdose may include ringing in ears, hearing problems, headache, dizziness, confusion, nausea, vomiting and abdominal pain. A large overdose can lead to more rapid breathing than normal (hyperventilation), fever, excess sweating, restlessness, seizures, hallucinations, low blood sugar, coma and shock.

If you forget to take Gentazetan

If you miss a dose, wait until it is time for your next dose, then go on as normal.

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

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

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. This could be erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome.
- Unusual bleeding, such as coughing up blood, blood in your vomit or urine, or black stools.

Common side effects (may occur in 1 to 10 out of 100 patients):

- Indigestion.
- Increased tendency for bleeding.

Uncommon side effects (may occur in 1 to 10 out of 1,000 patients):

- Hives.
- Runny noses.
- Breathing difficulty.

Rare side effects (may occur in 1 to 10 out of 10,000 patients):

- Severe bleeding in the stomach or intestines, brain haemorrhage; altered number of blood cells.
- Nausea and vomiting.
- Cramps in the lower respiratory tract, asthma attack.
- Inflammation in the blood vessels.

- Bruising with purple spots (cutaneous bleeding).
- Severe skin reactions such as rash known as erythema multiforme and its life threatening forms Stevens-Johnson syndrome and Lyell's syndrome.
- Hypersensitivity reactions, such as swelling of e.g. lips, face or body, or shock.
- Abnormal heavy or prolonged menstrual periods

Side effects with unknown frequency

- Ringing in your ears (tinnitus) or reduced hearing ability.
- Headache.
- Vertigo.
- Ulcers in stomach or small intestine and perforation.
- Prolonged bleeding time.
- Impaired kidney function.
- Impaired liver function.
- High level of uric acid in the blood.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE GENTAZETAN

Keep out of the reach and sight of children.

Store below 25°C.

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

Do not use Gentazetan after the expiry date which is stated on the carton or blister after EXP. The expiry date refers to the last day of that month.

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. FURTHER INFORMATION

What Gentazetan contains

The active substance is acetylsalicylic acid. Each gastro-resistant tablet contains 75 or 100 mg of acetylsalicylic acid.

The other ingredients are: *tablet core*: microcrystalline cellulose, maize starch, colloidal anhydrous silica, stearic acid; *film-coating*: methacrylic acid – ethyl acrylate copolymer (1:1), polysorbate 80, sodium laurilsulfate, triethyl citrate, talc.

What Gentazetan looks like and contents of the pack

Gentazetan gastro-resistant tablets 100 mg are round, white, biconvex film-coated tablets with a diameter of 7.2 mm.

Pack sizes:

Blisters: 30 gastro-resistant tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

<[To be completed nationally]>
<[To be completed nationally]>

This leaflet was last approved in 26 May 2014