

# GASTRIL TABLET

Ranitidine Hydrochloride (150mg)

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## What Gastril is used for

This medicine is used to treat:

- Duodenal ulcer
- Benign gastric ulcer
- Reflux oesophagitis (inflammation of the esophagus)
- Zollinger-Ellison syndrome (excess acid production in the stomach caused by growth in the pancreas)
- And the following conditions where reduction of gastric secretion and acid output is desirable
  - The prevention of gastrointestinal bleeding from stress induced ulcer in seriously ill people.
  - The prevention of bleeding from coming back in people with bleeding stomach ulcers and before general anaesthesia in people considered to be at risk of acid aspiration (Mendelson's syndrome), particularly in pregnant women during labour
  - Management of chronic indigestion.
  - Prevention of intestine ulceration associated with NSAID.

## How Gastril works

Gastril contains the active ingredient ranitidine hydrochloride. Ranitidine hydrochloride belongs to a group of medicines called H2 antagonists or H2 blockers.

It works by decreasing the amount of acid made by the stomach. This helps to reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

## Before you use Gastril

- When you must not take it

Do not take this medicine if you have an allergy to:

- ranitidine, the active ingredient, or to any of the other ingredients listed at the end of this leaflet
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged,

return it to your pharmacist for disposal.

- Before you start to use it

If you are not sure whether you should start taking this medicine, talk to your doctor.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor before taking your medicine if:

- You have gastric ulcer
- You have use in impaired kidney function
- You have bradycardia (slow heart beat)
- You have a rare condition called *porphyria* (a rare blood pigment disorder)

Tell your doctor if you have had to stop taking this or any other medicine for your ulcer or reflux.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Breast feeding is not recommended because ranitidine is distributed into breast milk.

If you have not told your doctor about any of the above, tell him/her before you start taking Gastril.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy,

supermarket or health food shop.

Some medicines and Gastril may interfere with each other such as Sucralfate (used for ulcer healing).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

### How to use Gastril

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

#### - How much to use

The dosage of Gastril depends on the condition it is being used to treat.

#### *Duodenal and Gastric Ulcer*

Treatment: 150mg 2 times daily, or 300mg at bedtime for at least 4 weeks

Maintenance: 150mg daily may be given at bedtime

#### *Reflux oesophagitis*

Maintenance: 150mg taken twice daily in the morning and at bedtime

#### *Zollinger-Ellison syndrome*

150mg taken 3 times daily initially and increased, as necessary, to 600-900 mg/day

#### *Prevention against recurrent haemorrhage in people bleeding from stomach ulceration*

150mg twice daily may be taken once oral feeding commences.

#### *Maintenance Treatment:*

Reflux oesophagitis: 150 mg taken twice daily in the morning and at bedtime

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

Follow the instructions they give you. If you take the wrong dose, Gastril may not work as well and your problem may not improve.

Experience with ranitidine tablets in children is limited. It has however, been used successfully in children aged 8-18 years in doses up to 150mg mg twice daily.

#### - When to use it

Take Gastril as your doctor has prescribed.

#### - How long to use it

The duration of treatment with Gastril depends on the condition it is being used to treat.

If you have recurrent ulcer, long period of treatment may be necessary and/or repeated.

Your pain or other symptoms may take a few days to go away. Take all the tablets your doctor has prescribed for you, even if you feel better.

Your doctor may decide to continue your treatment with Gastril, possibly at a different dosage range, in order to prevent the problem from coming back again.

#### - If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you

missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

#### - If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Gastril.

If you use too much Gastril, symptoms may include dizziness and dilation of blood vessels.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

### While you are using it

#### - Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Gastril.

If you become pregnant while taking this medicine, tell your doctor immediately.

#### - Things you must not do

Do not stop taking your medicine or lower the dosage

without checking with your doctor.

Do not take Gastril to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Gastril affects you.

### Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Some of the side effects include:

- *Central Nervous System (CNS)*: malaise, dizziness, somnolence (sleepiness), insomnia (difficult to sleep) and vertigo (a sensation of whirling and loss of balance).
- *Cardiovascular*: Fast, slow, irregular or no heart beat
- *Gastrointestinal*: constipation, diarrhoea, nausea/vomiting, abdominal discomfort/pain
- *Hepatic*: hepatitis (inflammation of the liver), yellowing of skin and eyes.
- *Musculoskeletal*: arthralgia (pain in a joint) and myalgia (pain in a muscle or group of muscles)
- *Haematologic*: low red blood cells, white blood

cells or platelet sometimes with incomplete development of a tissue or an organ

- *Endocrine*: impotence and loss of sex drive in male.
- *Integumental*: rash, vasculitis (inflammation of blood vessels) and alopecia (hair loss)
- *Others*: hypersensitivity reactions (eg; fever, chest tightness, shortness breath), anaphylactic shock, rash, eosinophilia- an increase in the number of eosinophils in the blood, small increases in blood creatinine. Acute pancreas inflammation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

### Storage and Disposal of Gastril

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 25°C. Protect from light.

Do not store Gastril or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

### Product Description

- What it looks like

Gastril Tablet 150mg – A white, 'D' shaped tablet with marking 'duo 861'.

- Ingredients

Active ingredient

- Ranitidine hydrochloride

Inactive ingredients:

- Aerosil
- Lactose
- PVP
- Talcum
- Promigel
- Cornstach
- Isopropyl alcohol
- Magnesium stearate

- MAL number

MAL19972532AZ

### Manufacturer

Duopharma (M) Sdn. Bhd. (42491-M)

Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

**Product Registration Holder**

Duopharma (M) Sdn. Bhd.  
(42491-M)  
Lot. 2599, Jalan Seruling 59,  
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41200 Klang, Selangor Darul  
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