

**Ranitidine Hydrochloride Cas No. : 66357-35-5**

Ranitidine is used to treat ulcers of the stomach and intestines and prevent them from returning after treatment. This medication is also used to treat and prevent certain stomach and throat (esophagus) problems caused by too much stomach acid (e.g., Zollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus (gastroesophageal reflux disease-GERD).

Active Pharmaceuticals Ingredients Manufacturers



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**Taj Pharmaceuticals Ltd.****Ranitidine Hydrochloride****CAS No. : 66357-35-5****Systematic (IUPAC) name**

(N-(2-[(5-[(dimethylamino)methyl]furan-2-yl)methylthio]ethyl)-N-methyl-2-nitroethene-1,1-diamine

**Identifiers**

CAS number 66357-35-5

ATC code A02BA02

PubChem 3001055

DrugBank APRD00254

ChemSpider 571454

**Chemical data**Formula C<sub>13</sub>H<sub>22</sub>N<sub>4</sub>O<sub>3</sub>S

Mol. mass 314.4 g/mol

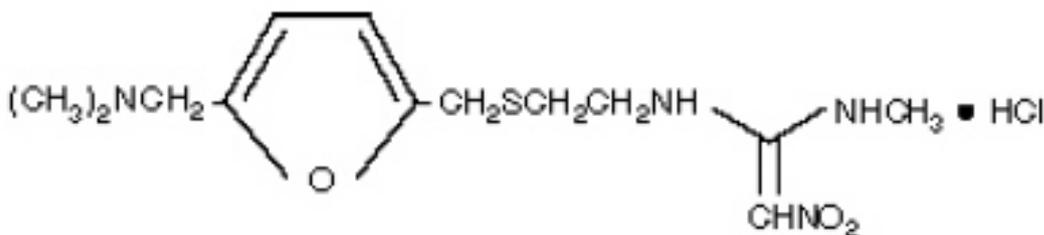
**Pharmacokinetic data**

Bioavailability 39 to 88%

Metabolism Hepatic

Half life 2–3 hours

Excretion 30–70% Renal



Zantac is used to decrease the production of stomach acid, which may reduce irritation to the stomach lining and help heal ulcers and other gastrointestinal conditions. It's prescribed for the following:

Short-term treatment (4 to 8 weeks) of active ulcers, specifically duodenal ulcers or benign stomach ulcers (also called gastric ulcers).

Maintenance therapy (at a reduced dosage) to help keep the ulcer from coming back after it has healed.

Treatment of conditions in which the stomach produces too much acid, such as Zollinger-Ellison syndrome and systemic mastocytosis.

Treatment of gastroesophageal reflux disease (also known as GERD, which occurs when stomach acid backs up into the esophagus).

Treating and maintaining healing of erosive esophagitis (severe inflammation of the esophagus).

Two over-the-counter versions, Zantac 75 and Zantac 150, are also available for relieving and preventing heartburn, acid indigestion, and sour stomach. However, the prescription version is still needed for treatment of ulcers, esophagitis, GERD, and other conditions that require monitoring by a doctor.

Most important fact about Ranitidine hydrochloride

Zantac helps to prevent the recurrence of gastric or duodenal ulcers and aids the healing of ulcers that do occur.

How should you take Ranitidine hydrochloride?

Take Ranitidine hydrochloride exactly as prescribed by your doctor. Make sure you follow the diet your doctor recommends.



Taj Pharmaceuticals Ltd.

# Ranitidine Hydrochloride

CAS No 66357-35-5



Dissolve effervescent tablets and granules in 6 to 8 ounces of water before taking them.

You can take an antacid for pain while you are taking Zantac.

## Uses

Ranitidine is used to treat ulcers of the stomach and intestines and prevent them from returning after treatment. This medication is also used to treat and prevent certain stomach and throat (esophagus) problems caused by too much stomach acid (e.g., Zollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus (gastroesophageal reflux disease-GERD).

Ranitidine is known as an H2 histamine blocker. It works by reducing the amount of acid in your stomach. This helps heal and prevent ulcers and improves symptoms such as heartburn and stomach pain.

## How to use

Take this medication by mouth with or without food, usually once or twice daily or as directed by your doctor. It may be prescribed 4 times a day for some conditions. If you are taking this medication once daily, it is usually taken after the evening meal or before bedtime.

The dosage and length of treatment are based on your medical condition and response to therapy. In children, dosage may also be based on body weight. Follow your doctor's instructions carefully. You may take other medications (e.g., antacids) for your condition as recommended by your doctor.

Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time(s) each day. Do not increase your dose or take it more often than prescribed. Do not stop taking this without your doctor's approval because this may delay healing of the ulcer.

## Side Effects

Headache, dizziness, constipation or diarrhea may occur. If any of these effects persist or worsen, notify your doctor or pharmacist promptly.

If your doctor has directed you to use this medication, remember that he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: blurred vision, mental/mood changes (e.g., agitation, confusion, depression, hallucinations). A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

## Precautions

Before taking ranitidine, tell your doctor or pharmacist if you are allergic to it; or to other H2 histamine blockers (e.g., cimetidine, famotidine); or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: a certain blood disorder (porphyria).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: immune system problems, kidney problems, liver problems, lung diseases (e.g., asthma, chronic obstructive pulmonary disease-COPD), other stomach problems (e.g., tumors).



Some symptoms may actually be signs of a more serious condition. Tell your doctor immediately if you have: heartburn combined with lightheadedness/sweating/dizziness, chest pain or shoulder/jaw pain (especially with trouble breathing), pain spreading to arms/neck/shoulders, unexplained weight loss.

This drug may make you dizzy; use caution while engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

Do not use to treat children younger than 12 unless directed by the doctor.

### **MISSED DOSE**

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

### **STORAGE**

Store the US product in a tightly closed container at room temperature between 59-86 degrees F (15-30 degrees C) away from moisture and light. Store the nonprescription medication at room temperature between 68-86 degrees F (20-30 degrees C).

Store the Canadian product in a tightly closed container between 35.6 and 86 degrees F (2 and 30 degrees C) away from moisture and light.

Do not store in the bathroom. Keep all medicines away from children and pets.

### **DOSAGE**

Take Ranitidine hydrochloride exactly as prescribed by your doctor. Make sure you follow the diet your doctor recommends.

Dissolve effervescent tablets and granules in 6 to 8 ounces of water before taking them.

Before you administer ranitidine, look at the solution closely. It should be clear and free of floating material. Gently squeeze the bag or observe the solution container to make sure there are no leaks.

Do not use the solution if it is discolored, if it contains particles, or if the bag or container leaks. Use a new solution, but show the damaged one to your health care provider.

It is important that you use your medication exactly as directed. Do not change your dosing schedule without talking to your health care provider.

Your health care provider may tell you to stop your infusion if you have a mechanical problem (such as a blockage in the tubing, needle, or catheter); if you have to stop an infusion, call your health care provider immediately so your therapy can continue.

### **DRUG DESCRIPTION**

Ranitidine hydrochloride is a histamine H<sub>2</sub>-receptor antagonist that inhibits stomach acid production. It is commonly used in treatment of peptic ulcer disease and gastroesophageal reflux disease. Ranitidine is also used alongside fexofenadine and other antihistamines for the treatment of skin conditions such as hives.

The active ingredient in ranitidine hydrochloride (HCl), USP, a histamine H<sub>2</sub>-receptor antagonist. Chemically it is N[2-[[[5-[(dimethylamino)methyl]-2-furanyl]methyl]thio]ethyl]-N'-methyl-2-nitro-1,1-ethenediamine, HCl.



The empirical formula is  $C_{13}H_{22}N_4O_3S \cdot HCl$ , representing a molecular weight of 350.87.

Ranitidine HCl is a white to pale yellow, granular substance that is soluble in water. It has a slightly bitter taste and sulfurlike odor.

Ranitidine HCl is used to decrease the production of stomach acid, which may reduce irritation to the stomach lining and help heal ulcers and other gastrointestinal conditions. It's prescribed for the following:

Short-term treatment (4 to 8 weeks) of active ulcers, specifically duodenal ulcers or benign stomach ulcers (also called gastric ulcers).

Maintenance therapy (at a reduced dosage) to help keep the ulcer from coming back after it has healed.  
Treatment of conditions in which the stomach produces too much acid, such as Zollinger-Ellison syndrome and systemic mastocytosis.

Treatment of gastroesophageal reflux disease (also known as GERD, which occurs when stomach acid backs up into the esophagus).

Treating and maintaining healing of erosive esophagitis (severe inflammation of the esophagus)

**Note /Government Notification:** These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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