# Taj Pharmaceuticals Ltd.

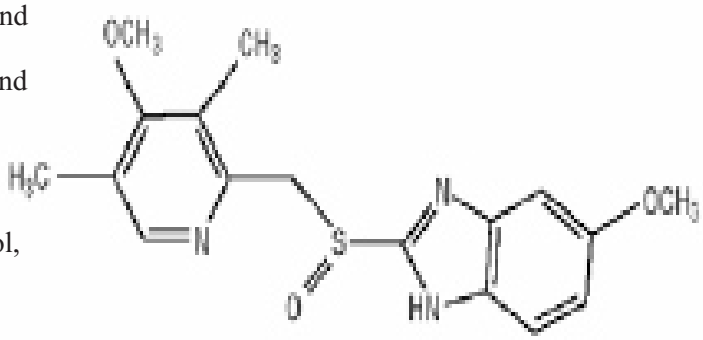
# Omeprazole Sodium

## CAS No. : 95510-70-6

**Systematic (IUPAC) name**

omeprazole/sodium bicarbonateis a combination of omeprazole, a proton-pump inhibitor, and sodium bicarbonate, an antacid. Omeprazole is a substituted benzimidazole, 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole, a racemic mixture of two enantiomers that inhibits gastric acid secretion. Its empirical formula is C17H19N3O3S, with a molecular weight of 345.42.

omeprazole is supplied as immediate-release capsules and unit-dose packets as powder for oral suspension. Each capsule contains either 40 mg or 20 mg of omeprazole and 1100 mg of sodium bicarbonate with the following excipients: croscarmellose sodium and sodium stearyl fumarate. Packets of powder for oral suspension contain either 40 mg or 20 mg of omeprazole and 1680 mg of sodium bicarbonate with the following excipients: xylitol, sucrose, sucralose, xanthan gum, and flavorings.




**Side effects**

Some of the most frequent side effects of omeprazole (experienced by over 1% of those taking the drug) are headache, diarrhea, abdominal pain, nausea, dizziness, trouble awakening and sleep deprivation, although in clinical trials the incidence of these effects with omeprazole was mostly comparable to that found with placebo.

Proton pump inhibitors may be associated with a greater risk of hip fractures, and clostridium difficile-associated diarrhea Patients are frequently administered the drugs in intensive care as a protective measure against ulcers, but this use is also associated with a 30% increase in occurrence of pneumonia.
Other side effects may include bone rebuild interference and B12 vitamin reduction.

**USES**

This medication is used to treat acid-related stomach and throat problems . It is also used to decrease the risk of stomach bleeding in very ill patients and may be used in combination with antibiotics to treat certain types of ulcers caused by bacterial infection. This medication is a combination of omeprazole and sodium bicarbonate. Omeprazole is a proton pump inhibitor that blocks acid production in the stomach. Sodium bicarbonate is an antacid added to decrease acid levels in the stomach and improve the effectiveness of omeprazole. Decreasing excess stomach acid can help relieve symptoms such as heartburn, difficulty swallowing, persistent cough, and trouble sleeping. It can also prevent serious acid damage to your digestive system (e.g., ulcers, cancer of the esophagus).

**HOW TO USE**

Take this medication by mouth, usually once daily on an empty stomach 1 hour before a meal or as directed by your doctor.
If you are using the capsule, take it with a full glass of water (8 ounces or 240 milliliters) unless your doctor directs you otherwise. Do not use other liquids. Do not open the capsule or sprinkle the contents into food.

If you are using the packet, empty the entire contents into a small cup with 1-2 tablespoons (15-30 milliliters) of water. Do not use any other liquids or foods. Stir well and drink the entire mixture immediately. Do not save it for later use. To make sure you take all the medication, add more water to the cup and drink all of it.

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CAS No 95510-70-6

If this medication is to be given through an oral or nasal tube, empty the entire contents of a packet into a small container with about 20 milliliters of water. Do not use any other liquids or foods. Stir the mixture well and give immediately into the tube using the proper syringe. Wash the mixture through the tube with more water (about 20 milliliters). For patients receiving continuous tube feedings, the tube feeding should be stopped for 3 hours before and 1 hour after giving this medication.

**SIDE EFFECTS**

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

Remember that your doctor has prescribed this medication because 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: swelling of hands/feet, unexplained sudden weight gain.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

**PRECAUTIONS**

Before taking this medication, tell your doctor or pharmacist if you are allergic to it; or to similar drugs (e.g., lansoprazole, pantoprazole); or if you have any other allergies.

Before taking this medication, tell your doctor or pharmacist your medical history, especially of: acid-base balance problems (e.g., respiratory alkalosis, Bartter's syndrome), low calcium (hypocalcemia), certain heart problems (e.g., congestive heart failure), high blood pressure, liver disease, low potassium (hypokalemia), other stomach problems (e.g., tumors).This medication contains salt (sodium). Before taking this medication, tell your doctor or pharmacist if you are on a low-salt diet.
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/jaw/left arm pain (especially with trouble breathing), unexplained weight loss.
This drug may make you dizzy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.
This medication passes into breast milk. Breast-feeding while using this drug is not recommended. Consult your doctor before breast-feeding.

**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 at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

## DOSAGE


Take this medication by mouth, usually once daily on an empty stomach 1 hour before a meal or as directed by your doctor.
If you are using the capsule, take it with a full glass of water (8 ounces or 240 milliliters) unless your doctor directs you otherwise. Do not use other liquids. Do not open the capsule or sprinkle the contents into food.

If you are using the packet, empty the entire contents into a small cup with 1-2 tablespoons (15-30 milliliters) of water. Do not use any other liquids or foods. Stir well and drink the entire mixture immediately. Do not save it for later use. To make sure you take all the medication, add more water to the cup and drink all of it.

If this medication is to be given through an oral or nasal tube, empty the entire contents of a packet into a small container with about 20 milliliters of water. Do not use any other liquids or foods. Stir the mixture well and give immediately into the tube using the proper syringe. Wash the mixture through the tube with more water (about 20 milliliters). For patients receiving continuous tube feedings, the tube feeding should be stopped for 3 hours before and 1 hour after giving this medication.

If needed, other antacids may be taken along with this medication.

The dosage and length of treatment is based on your medical condition and response to therapy. Different strengths of this medication contain the same amount of sodium bicarbonate in each dose. Do not take double of any strength (e.g., two 20 milligram packets) without your doctor's approval since this may give you too much sodium bicarbonate, increasing the risk of side effects (e.g., swelling of hands/feet).
Take this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time each day. Continue to take this medication for the prescribed length of treatment, even if you are feeling better.



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.
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