

Vocinti Film-Coated Tablet

Vonoprazan 10mg and 20mg

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What Vocinti is used for

Your doctor may prescribe Vocinti for the following indication in adults:

- Treatment of stomach and duodenal ulcer.
- Treatment and maintenance of inflammation of your esophagus (reflux esophagitis) up to 52 weeks.
- Prevention of recurrence of stomach or duodenal ulcer in patients requiring continued NSAID treatment (NSAID treatment is used against pain or inflammation)
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy

How Vocinti works

Vocinti is a Vonoprazan is a potassium competitive acid blocker (PCAB) and inhibits H⁺, K⁺-ATPase in a reversible and potassium-competitive manner. It does not require activation by acid.

Before you use Vocinti

• When you must not use it
Do not take Vocinti if you are allergic to vonoprazan or any of the other ingredients of this medicine. (see Product Description).

If you are currently taking a medicine containing the active substance atazanavir or rilpivirine.

• Before you start to use it
Warning and precautions

Before you take Vocinti, tell your doctor if you:

- Have liver problems
- Have kidney problems
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed. It is not known if Vocinti passes into breast milk. Do not breastfeed during treatment with Vocinti.

• Taking other medicines

- Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Contact your doctor before you start or stop other types of medicines.
- Especially tell your doctor if you are taking any medication containing following active substance as Vocinti may affect or be affected by these drugs:
 - Clarithromycin (used to treat infections)
 - Atazanavir or rilpivirine (used to treat HIV)
 - Midazolam

How to use Vocinti

• How much to use

The dose of Vocinti depends on your condition. The usual doses of Vocinti for adults are given below:

- Treatment of stomach ulcer: One 20mg tablet every day for 8 weeks.
- Treatment of duodenal ulcer: One 20mg tablet every day for 6 weeks.
- Treatment of inflammation of your esophagus (reflux

esophagitis): one 20mg tablet every day for 4 weeks. If your symptoms persist or not relieved within 4 weeks, please contact your doctor. For maintenance of healing of inflammation of your esophagus, one 10mg tablet every day. Your doctor may increase the dose to one 20mg for efficacy inadequate. Duration to be taken can be up to 52 weeks.

- Prevention of recurrence of stomach or duodenal ulcer in patients requiring continued NSAID treatment: one 10mg tablet every day.
- Treatment of infections caused by the bacteria *Helicobacter pylori* when given in combination with antibiotic therapy: one 20mg tablet in combination with two different antibiotics twice daily at the same time for 7 days. The recommended combinations of antibiotics are:
 - 20 mg Vocinti together with amoxicillin and clarithromycin
 - 20 mg Vocinti together with amoxicillin and metronidazole

If you are being treated for infection because you have an ulcer, it is unlikely that your ulcer will return if the infection is successfully treated.

• When to use it
Vocinti can be taken without regard to food or timing of food.

• How long to use it
Take Vocinti exactly as your

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doctor tells you to take it.

- If you forget to use it
 - If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose, and take the next dose at your regular time. Do not take 2 doses of Vocinti at the same time.
- If you use too much (overdose)
 - If you take more Vocinti than your doctor tells you to take, call your doctor right away or go to the nearest hospital emergency room right away.

While you are using it

- Things you must do
 - Vocinti should be swallowed whole.
 - Contact your doctor immediately if you notice the following:
 - Sudden breathing or swallowing difficulties, swelling of your face, lips, tongue and throat or body, fainting (severe allergic reaction)
 - Yellow color skin or eyes, dark urine and tiredness which can be symptoms of liver problems (see side effects)
- Things you must not do
 - Vocinti should not be chewed.
- Things to be careful of
 - Symptomatic response to Vocinti does not prevent the presence of gastric cancer.

- There is increased risk for bone fracture for people who received high-doses, or used more than a year or longer.
- There is an increased risk of bacteria infection.
- Increased chromogranin A (CgA) level

Side Effects

Like all medicines, Vocinti may cause side effects, although not everybody gets them.

Common side effects of Vocinti including:

- Diarrhea
- Constipation

Uncommon side effects of Vocinti including:

- Nausea
- Abdominal (stomach area) distension
- Changes in liver function test values

Frequency unknown:

- Hypersensitivity (allergic reaction) including anaphylactic shock (severe allergic reaction)
- Skin reactions such as eruption, rash and itching
- Liver problems (may include nausea or vomiting, stomach pain, unusual or unexplained tiredness, loss of appetite, dark urine) and jaundice (yellowing of the skin and the white of the eyes)

If you get any side effects, including any side effects not listed in this leaflet, talk to your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse

Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Vocinti

- Storage
Store below 30°C.
Keep Vocinti and all medicines out of the reach of children.

- Disposal
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like
Vocinti is supplied as an oval film-coated tablet and are distinguished both by colours and imprinted markings on the body:
 - 10mg – pale yellow tablet imprinted with “B217” on the upperside
 - 20mg – pale red tablet imprinted with “B218” on the upperside

Ingredients

Active ingredient

Vonoprazan fumarate

Inactive ingredients

D-mannitol, crystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, fumaric acid, magnesium stearate, hypromellose, macrogol 6000, titanium oxide (contained in 10mg and 20mg tablet), yellow ferric oxide (contained in 10mg tablet), iron sesquioxide (contained in 20mg tablet).

- MAL Number
MAL19056002ARZ (10mg)

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Manufacturer

Takeda Pharmaceutical
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Product Registration Holder

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Date of Revision

1/4/2025

Serial Number

NPRA (R1/3) 16042025/074