

VOZAN FILM COATED TABLETS

Vonoprazan (10mg, 20mg)

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What Vozan is used for

Your doctor may prescribe Vozan 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 Vozan works

Vozan 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 Vozan

• When you must not use it

Do not take Vozan 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 Vozan, 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

Vozan passes into breast milk. Do not breastfeed during treatment with Vozan.

- 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 Vozan may affect or be affected by these drugs:
 - Clarithromycin (used to treat infections)
 - Atazanavir or rilpivirine (used to treat HIV)
 - Midazolam

How to use Vozan

• How much to use

The dose of Vozan depends on your condition. The usual doses of Vozan 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 Vozan together with

amoxicillin and clarithromycin

- 20 mg Vozan 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

Vozan can be taken without regard to food or timing of food.

• How long to use it

Take Vozan exactly as your 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 Vozan at the same time.

• If you use too much (overdose)

- If you take more Vozan 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

- Vozan should be swallowed whole.
- Contact your doctor immediately if you notice the following:
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• Things you must not do

- Vozan should not be chewed.

• Things to be careful of

- Symptomatic response to Vozan 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.

Side Effects

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

Common side effects of Vozan including:

- Diarrhea
- Constipation

Uncommon side effects of Vozan including:

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- 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 Vozan

- **Storage**
Store below 30°C.

Keep Vozan 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

Vozan 10mg Film Coated Tablets – Yellow, oval shaped tablet with beveled edges, debossed with “H2” on one side and plain on the other side.

Vozan 20mg Film Coated Tablets – Pink, oval shaped tablet, with beveled edges, scored on both side and debossed with “H3” on one side and plain on the other side.

Ingredients

- Active ingredients: Vonoprazan Fumarate
- Inactive ingredients
Tablet core:
 - Mannitol
 - Microcrystalline cellulose
 - Hydroxypropyl cellulose
 - Malic acid
 - Croscarmellose sodium
 - Magnesium stearate

Film coat:

Vozan 10mg Film Coated Tablets: Opadry Complete Film Coating System 03F620167 Yellow

Vozan 20mg Film Coated Tablets: Opadry Complete Film Coating System 03F640104 Pink

MAL number(s):

Vozan 10 mg Film Coated Tablet: MALXXXXXXXXX

Vozan 20 mg Film Coated Tablet: MALXXXXXXXXX

Manufacturer

Novugen Pharma Sdn.Bhd.
No. 27, Jalan Lengkok Teknologi 2,
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Product Registration Holder

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