

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **VORANIGO™**

Vorasidenib tablets

Read this carefully before you start taking **VORANIGO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VORANIGO**.

What is VORANIGO used for?

VORANIGO is used to treat adults and adolescents (12 years of age and older) with certain types of cancers of the brain called low grade astrocytoma or oligodendroglioma following surgery, who have an abnormal gene called “IDH1” or “IDH2”.

Your healthcare professional will test your cancer for abnormal isocitrate dehydrogenase-1 (IDH1) or isocitrate dehydrogenase-2 (IDH2) protein to make sure that VORANIGO is right for you.

How does VORANIGO work?

VORANIGO is a cancer medicine that contains the active drug vorasidenib. It is used to treat specific cancers of the brain with changed (mutated) genes that make proteins known as IDH1 or IDH2. VORANIGO blocks the mutated form of the IDH1 or IDH2 protein and helps to slow or stop the brain cancer from growing.

What are the ingredients in VORANIGO?

Medicinal ingredients: vorasidenib

Non-medicinal ingredients: croscarmellose sodium, hypromellose, lactose monohydrate, macrogol, magnesium stearate, microcrystalline cellulose, pharmaceutical ink, silicified microcrystalline cellulose, sodium lauryl sulfate, titanium dioxide

VORANIGO comes in the following dosage forms:

Tablets: 10 mg and 40 mg.

Do not use VORANIGO if:

- you are allergic to vorasidenib or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VORANIGO. Talk about any health conditions or problems you may have, including if you:

- have kidney problems
- have liver problems
- are a smoker

- are intolerant to lactose. This is because VORANIGO contains lactose.

Other warnings you should know about:

- **Pregnancy and breastfeeding**

Female patients

- If you are pregnant or plan to be pregnant during treatment with VORANIGO, there are important risks you should discuss with your healthcare professional.
- Do NOT become pregnant during treatment with VORANIGO. It may harm your unborn baby.
- If you are able to become pregnant:
 - Your healthcare professional should perform a pregnancy test before you start treatment.
 - Avoid becoming pregnant by using an effective barrier (non-hormonal) method of birth control during treatment and for at least 3 months after the last dose of VORANIGO.
 - If you are taking hormonal birth control methods (such as birth control pills, contraceptive patches or implants), you must also use a barrier method (such as condoms or a diaphragm) to avoid pregnancy.
 - Talk to your healthcare professional about birth control methods that may be right for you.
 - Tell your healthcare professional right away if you become pregnant while taking VORANIGO.

Breastfeeding

- Do NOT breastfeed while taking VORANIGO and for at least 2 months after the last dose. It is not known if VORANIGO passes into breast milk.
- Talk to your healthcare professional about the best way to feed your baby during treatment with VORANIGO.

Male patients

- Do NOT father a child during treatment with VORANIGO.
- If you have a partner who is able to become pregnant:
 - Use an effective barrier method of birth control during treatment and for at least 3 months after the last dose. Hormonal birth control may be used by your partner as well to prevent pregnancy.
 - Talk to your healthcare professional about birth control methods that may be right for you.
 - Tell your healthcare professional right away if your partner becomes pregnant during your treatment with VORANIGO.

- **Fertility**

VORANIGO may affect fertility. Talk to your healthcare professional if this is a concern for you.

- **Children**

- Children under 12 years of age should not be given VORANIGO. It is not known if VORANIGO is safe and effective in children below 12 years of age.
- Children (12 to 18 years of age) may be at a higher risk of side effects.

- **Check-ups and testing**
 - You will have regular visits with your healthcare professional during treatment with VORANIGO. They will:
 - Do blood tests before you start treatment with VORANIGO, and as necessary during treatment. This is to check how well your liver is working and check your blood counts.
 - Check for signs of side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VORANIGO:

- Alfentanil (used for anaesthesia in surgery)
- Carbamazepine, phenytoin (used to treat seizures)
- Ciprofloxacin (used to treat bacterial infections)
- Cyclosporine, everolimus, sirolimus, tacrolimus (medicines used after organ transplants to help control your body's immune response)
- Fentanyl (used for severe pain)
- Fluvoxamine (used to treat depression)
- Hormonal contraceptive medicines (medicines used to prevent pregnancy, such as birth control pills)
- Ifosfamide, tamoxifen (used to treat certain cancers)
- Pimozide (used to treat abnormal thoughts and feelings)
- Quinidine (used to treat abnormal heartbeat)
- Rifampicin (used to treat tuberculosis or certain other infections)
- Smoking cigarettes

How to take VORANIGO:

- Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take VORANIGO by mouth. Swallow the tablet whole with a glass of water. Do not split, crush or chew the tablet.
- Do NOT eat food at least 2 hours before and 1 hour after you take the tablet.
- If you vomit after taking your usual dose, do not take an extra dose. Take the next dose at your scheduled time.
- Do not stop taking VORANIGO unless your healthcare professional tells you to. It is important to take VORANIGO for as long as your doctor prescribes it to you.

Usual dose:

- The recommended dose for adults and adolescents (12 years of age and older) depends on your weight:
 - For patients who weigh **at least 40 kg**: take 40 mg (one 40 mg tablet) by mouth once a day at approximately the same time each day.
 - For patients who weigh **less than 40 kg**: take 20 mg (two 10 mg tablets) by mouth once a day at approximately the same time each day.
- If necessary, your healthcare provider may lower your dose or have you temporarily or permanently stop treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much VORANIGO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take VORANIGO by:

- **less than** 6 hours, take it as soon as you remember. You can take your next dose at your usual scheduled time.
- **more than** 6 hours, skip the missed dose. Wait to take your next dose at the scheduled time. Do NOT take double the dose to make up for a dose you have missed.

What are possible side effects from using VORANIGO?

These are not all the possible side effects you may have when taking VORANIGO. If you experience any side effects not listed here, tell your healthcare professional.

- decreased appetite
- stomach pain
- acid reflux or indigestion
- fatigue

VORANIGO may cause abnormal blood test results. Your health professional will tell you if your blood test results are abnormal and if you need treatment to correct these side effects.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Diarrhea	X		
Increased amount of liver enzymes in blood (alanine aminotransferase increased, aspartate aminotransferase increased and gamma-glutamyl transferase increased): yellowing of your skin or the white part of your eyes (jaundice), dark “tea-colored” urine, loss of appetite, pain on the upper right side of your stomach area and feeling very tired or weak		X	X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature (15°C to 30°C).
- Do not use this medicine after the expiry date which is stated on the bottle label and box.
- Keep out of reach and sight of children.
- Once opened, this medicine should be used within 60 days.

If you want more information about VORANIGO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.servier.ca), or by calling 1-800-363-6093.

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