

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrINQOVI®

decitabine and cedazuridine tablets

Read this carefully before you start taking **Inqovi** 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 **Inqovi**.

Serious Warnings and Precautions

Inqovi should only be used under the supervision of a healthcare professional experienced in the use of drugs to treat cancer.

Side effects with Inqovi can include:

- **Neutropenia:** This is a low level of white blood cells.
- **Thrombocytopenia:** This is a low level of platelets in the blood.
- Potential for harm to your unborn baby if you take it while you are pregnant.

What is Inqovi used for?

Inqovi is used to treat adults with myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML). In MDS and CMML, the bone marrow does not make enough healthy mature blood cells. MDS and CMML are types of cancer.

How does Inqovi work?

Inqovi blocks the action of certain enzymes that are involved in the division of cancer cells. By blocking this action, it slows their growth and the progression of the disease. Inqovi also kills cancer cells.

What are the ingredients in Inqovi?

Medicinal ingredients: decitabine and cedazuridine

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, iron oxide red, magnesium stearate, polyethylene glycol, polyvinyl alcohol, talc, and titanium dioxide.

Inqovi comes in the following dosage forms:

Tablets: 35 mg decitabine and 100 mg cedazuridine per tablet

Do not use Inqovi if:

- You are allergic to decitabine, cedazuridine or any of the other ingredients in Inqovi.

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

- kidney problems
- liver problems
- a bleeding disorder. Cases of serious bleeding have been reported in patients receiving Inqovi.
- a low blood cell count (platelets, red or white blood cells). Decreased blood counts are very common with Inqovi and can be severe. Decreased blood counts are characteristic with your disease and could be improved with treatment. Your doctor will be able to assess the potential benefit of treatment versus the risks.
- an infection or flu-like symptoms. Serious infections can occur while taking Inqovi. They can cause death.
- lung disease. Cases of lung disease have been reported in patients taking intravenous decitabine.
- severe form of lactose intolerance. This is because Inqovi contains a small amount of lactose.

Other warnings you should know about:

Inqovi is a cytotoxic drug. Handle with caution. Wash your hands with soap and water immediately after handling the tablets. Return any unused Inqovi to your pharmacy or hospital for proper disposal. Check with your doctor or pharmacist if you have any questions.

Inqovi may cause cancer or damage to the genetic material in cells (DNA). Talk to your healthcare professional if you have questions about this.

Blood tests

You will need blood tests before you start Inqovi, before each cycle and as needed based on your condition. These will help your healthcare professional to know how Inqovi is affecting your blood and how well your liver and kidney are working.

Fertility, pregnancy, females of child-bearing potential, breast-feeding and male patients

Tell your doctor if you:

- are pregnant
- think you might be pregnant
- are planning to have a baby
- are breast-feeding

Inqovi can affect your ability to have a baby. This occurs in both women and men.

Your doctor will speak with you about the risks of Inqovi if you are pregnant or planning to become pregnant or breast-feed.

- You should not use Inqovi if you are pregnant as it may harm your unborn baby. Tell your doctor immediately if you become pregnant during treatment with Inqovi.

- Women must use effective contraception during treatment and for 6 months after treatment has stopped. Talk to your doctor about the best birth control for you.
- For women who can get pregnant: a pregnancy test should be done before you start Inqovi.
- Talk to your doctor if you wish to freeze your eggs before starting treatment.
- Do not breast-feed if you are using Inqovi and for at least two weeks after your last Inqovi dose. This is because it is not known if the medicine passes into the mother's milk. Talk to your doctor about the best way to feed your baby while you are being treated with Inqovi.

Men should not father a child while using Inqovi.

- Men should use effective contraception during treatment and for 3 months after treatment has stopped.
- If your partner becomes pregnant while you are taking Inqovi, tell your partner's doctor right away. Inqovi can harm your unborn baby.
- Talk to your doctor if you wish to conserve your sperm before starting treatment.

Allergic Reactions:

Allergic reactions can occur while taking Inqovi. These reactions can be severe and serious, including a reaction known as anaphylaxis. Get medical help right away if you have: rash, hives, swelling of your face, lips, tongue or throat or difficulty swallowing or breathing.

Children and adolescents:

Inqovi is not for use in patients under the age of 18 years.

Driving and Using Machines: While using Inqovi you may feel weak, tired, or dizzy. Before driving a vehicle or using machinery wait to see how you feel after taking Inqovi.

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 Inqovi:

- Anti-cancer or chemotherapy drugs (cytarabine, gemcitabine)
- Drugs to treat HIV infection (zidovudine, abacavir, emtricitabine, tenofovir)
- Drugs to treat Hepatitis B (telbivudine, lamivudine, tenofovir, adefovir, entecavir)
- Anti-viral drugs for herpes virus (idoxuridine, trifluridine)

How to take Inqovi:

Inqovi is cytotoxic. Handle with caution. Avoid excessive handling of Inqovi with your bare hands. Wash your hands with soap and water immediately after handling the tablet.

- Take your Inqovi exactly as your doctor tells you. Check with your doctor or pharmacist if you are not sure.
- Do NOT change your dose or stop taking Inqovi unless your doctor tells you to.
- Swallow tablet whole with water on an empty stomach.
- Do NOT chew, crush or cut tablet.
- Take your dose at about the same time on each scheduled day. This will help you to remember when to take it.
- Do NOT eat 2 hours before and after taking Inqovi.
- Medicine for nausea and vomiting may be prescribed by your doctor. Take this medicine prior to taking your Inqovi dose. You and your doctor can decide if you need this or not.

Adult dose:

Usual dose:

1 tablet once a day for 5 days in a row. This is followed by 23 days with no treatment. This 28-day period is one treatment cycle. This cycle is repeated every 28 days.

Treatment will continue as long as you:

- show response,
- continue to benefit,
- are feeling well and your disease has not gotten worse.

Your doctor may delay your treatment or reduce your dose per cycle. Your doctor will tell you how many cycles you need. It will depend on how you respond to the treatment and if you have certain side effects.

If you need to take medicine to treat heartburn, acid reflux or a stomach ulcer, take it 4 hours before or after you take Inqovi. This includes:

- antacid medicine (for example calcium carbonate),
- medicines called acid reducers (for example famotidine or ranitidine), and
- medicines called proton pump inhibitors (for example omeprazole).

Overdose:

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

Missed Dose:

- If you miss a dose of Inqovi and it is within 12 hours of your usual time, take the missed dose as soon as possible. Continue with the next scheduled dose at your usual time.
- If you miss a dose by more than 12 hours, skip the dose for that day. Wait and take the missed dose the following day at your usual time. Do NOT take a double dose to make up for the missed dose. Extend your dosing period by one day for every missed dose to complete all doses in the cycle.
- Call your healthcare professional if you are not sure of what to do.

If you vomit after taking a dose of Inqovi, do not take an additional dose on that day. Take your next scheduled dose at your usual time.

What are possible side effects from using Inqovi?

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

- chills
- body aches, back pain, joint pain, muscle pain
- abdominal pain
- tiredness or feeling weak
- nausea, vomiting, constipation, diarrhea
- dizziness
- decreased appetite, weight loss
- mouth or tongue sores
- headache
- cough
- rash, skin redness, itching
- numbness or tingling
- trouble sleeping

Inqovi can cause abnormal blood test results including liver and kidney blood tests. You will have a blood test before each cycle of Inqovi and whenever needed based on your condition. Your doctor will decide when to perform blood tests and will interpret the results. You may need antibiotics, growth factors or a blood transfusion.

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			
Anemia (low red blood cells): feeling weak, tired or short of breath, or looking pale.		X	
Cellulitis (infection of skin): redness, swelling, pain and tenderness, warm to touch.		X	
Edema (swelling): unusual swelling of the arms and legs.	X		
Febrile neutropenia (fever with low level of white blood cells): fever, chills. Sores in mouth, toothache. Abdominal pain. Pain near anus or when urinating. Urinating often. Cough, feeling short of breath. Any redness, swelling or pain of skin. Unusual vaginal discharge or itching. Diarrhea.		X	
Fever		X	
Infection caused by bacteria, virus or fungi – fever, sore throat, cough, runny nose, sore sinuses.		X	
Neutropenia or Leukopenia (low white blood cells): Fever or infection, fatigue, aches and pains, and flu-like symptoms.		X	
Sepsis or septic shock (infection of the blood): fever or dizziness, chills, high or low body temperature, little or no urine, low blood pressure, palpitations, rapid breathing, rapid heartbeat.		X	
Shortness of breath		X	
Thrombocytopenia (low blood platelets. These help the blood to clot): Tiny red or purple spots on the skin or inside the mouth (petechiae). Bruising or bleeding for longer than usual if you hurt yourself or more easily. Bleeding		X	

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	
from gums or nose. Blood in urine or stool. Fatigue and weakness.			
COMMON			
Arrhythmia (abnormal heart rhythms): rapid, slow or irregular heartbeat		X	
Bleeding events Bleeding a lot or uncontrollably, blood in stool or urine, coughing up blood, nose bleeds. bleeding gums, vaginal bleeding, heavy menstrual bleeding, bleeding into the eye, unexpected bruising, red-purple-brown spots on the skin, blood blisters in the mouth.		X	
CNS hemorrhage (bleeding in the brain): sudden severe headache. Weak, numb or cannot move arms, legs or face. Difficulty talking. Fainting or passing out. Dizziness, blurred vision, seizure (fit).			X
Genito-urinary hemorrhage (bleeding in the bladder or urinary tract): including blood in the urine.		X	
GI hemorrhage (bleeding in the stomach or bowels): severe abdominal pain or swelling. Vomit blood, black or bloody bowel movement, diarrhea. Feel dizzy or weak, loss of consciousness. Shortness of breath.			X
Hypotension (low blood pressure): dizziness, fainting, lightheadedness.		X	
Pneumonia (infection of the lungs): chest pain or shortness of breath. Difficult and painful breathing, cough, wheezing, or fever.			X
Pulmonary hemorrhage (bleeding in the lungs) or edema (fluid in the lungs): Coughing up blood,			X

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	
shortness of breath, blue tinged lips, blood-tinged froth.			
Upper respiratory infection (a cold): runny or stuffy nose, sore throat, cough, sinus congestion, body aches, headache, sneezing, fever, generally feeling unwell		X	
UNCOMMON			
Kidney failure/problems nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, mental status changes (drowsiness, confusion, coma)		X	
Sweet's syndrome, or acute febrile neutrophilic dermatosis (a rare skin condition): Sore red spots or blisters on the head, neck, legs, and arms. They are particularly on the back of the hands and fingers. Fever, joint pain, and sore eyes.		X	
Tumor Lysis syndrome (the sudden, rapid death of cancer cells due to the treatment): nausea, shortness of breath, irregular heartbeat, heart rhythm disturbances, lack of urination, clouding of urine, muscle spasms or twitching, tiredness and/or joint pain, severe muscle weakness, and seizures. Metabolic disorders (kidney failure, abnormal heartbeat) and abnormal blood tests due to rapid breakdown of cancer cells.		X	

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	
UNKNOWN FREQUENCY			
Anaphylaxis (severe allergic reaction): Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.		X	
Differentiation syndrome (A blood and lymphatic system disorder): dyspnea, fever, weight gain, hypotension and pulmonary infiltrates		X	
Enterocolitis (inflammation of the digestive tract): abdominal swelling, diarrhea, bloody stool, vomiting		X	
Interstitial lung disease (diseases that inflame or scar lung tissue): sudden shortness of breath, tiredness, dry cough. Generally feeling unwell.			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.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 Inqovi tablets in original packaging at room temperature (15 to 30°C).
- Do NOT store Inqovi outside of the original blisters.
- Keep out of reach and sight of children.
- Do NOT throw away any medicines via wastewater or household waste. Return any unused Inqovi to your pharmacy or hospital for disposal. Check with your doctor, nurse or pharmacist if you have any questions.

If you want more information about Inqovi:

- 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.taihopharma.com, or by calling 1-844-648-2446.

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