


Starting INQOVI

Understanding your
diagnosis and starting your
treatment with INQOVI

This booklet offers some insight, and
advice on staying actively involved and
informed when it comes to your disease
and its treatment.



INQOVI[®]
(decitabine and cedazuridine)
35mg / 100mg tablets



Finding out you have myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML) can be overwhelming. Suddenly, you have a lot to learn and a lot to think about. That is why it's important to stay informed.

This booklet can introduce you to some of the important things you'll want to know about MDS or CMML and about your treatment with INQOVI: how it works, how it's taken, and what's important to talk about with your doctor.

As you read through this booklet, you may find you have questions that are not answered. Use the Notes section at the end of this booklet to write down any of these questions you may have and bring them up with your healthcare team at your next appointment.

Myelodysplastic syndromes (MDS) and chronic myelomonocytic leukemia (CMML) are types of cancer in which the bone marrow does not make enough healthy mature blood cells. Blood cells include platelets (to help blood clot), red blood cells (to carry oxygen) and white blood cells (to fight infections).

Symptoms of MDS and CMML can include:

- Fever
- Fatigue
- Dizziness
- A general feeling of discomfort or illness (called malaise)
- Abdominal discomfort or a feeling of fullness if the spleen or liver is enlarged
- Frequent infections
- Paleness
- Night sweats
- Easy bruising and bleeding
- Shortness of breath
- Weight loss

What are myelodysplastic syndromes (MDS)?

MDS are a group of diseases in which the bone marrow does not make enough healthy mature blood cells. Immature blood cells, also known as blasts, build up in the bone marrow and the blood. As a result, there are fewer healthy red blood cells, white blood cells and platelets.

What is chronic myelomonocytic leukemia (CMML)?

CMML is a disease in which too many monocytes (a type of white blood cell) develop in the bone marrow. Some of these never develop into mature white blood cells. The monocytes and immature blood cells, also known as blasts, build up in the bone marrow. As a result, there are fewer healthy red blood cells and platelets.

Why have I been prescribed INQOVI?

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 to slow their growth and the progression of the disease. INQOVI also kills cancer cells.

What should I know before starting INQOVI?

Before you begin treatment, talk to your healthcare professional about side effects and proper use. Tell them about any health conditions or problems you may have, including any:

- kidney problems
- liver problems
- bleeding disorders; 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.
- infections or flu-like symptoms; serious infections can occur while taking INQOVI which can cause death
- lung diseases; cases of lung disease have been reported in patients taking intravenous decitabine
- severe forms of lactose intolerance; this is because INQOVI contains a small amount of lactose

You should also tell your doctor if you are pregnant, think you may be pregnant, are planning to get pregnant or father a child, or are breastfeeding. 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 breastfeed. 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 starting INQOVI. Talk to your doctor if you wish to freeze your eggs before starting treatment. Do not breastfeed 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.

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.

Talking about treatment

As you begin treatment, it is important to be your own advocate, and engage with your healthcare professional about any concerns, questions or changes you notice. Here are a handful of questions you may consider asking as you prepare to begin treatment:

- How long will I be taking INQOVI?
- How will we determine if INQOVI is working?
- What can I expect from INQOVI?
- What can I do if I experience a side effect? Can I take any medications for it?
- What are the most common side effects?
- Do I need to adjust my diet?
- Is there any exercise or food I should limit?

How should INQOVI be taken?

Remember that your doctor knows you and your treatment goals. **Always take INQOVI exactly as your doctor has told you.** Check with your doctor, pharmacist, or nurse 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.

INQOVI is cytotoxic. Handle with caution, and avoid excessive handling with your bare hands. Wash your hands with soap and water immediately after handling the tablet.

Return any unused INQOVI to your pharmacy or hospital for disposal. Check with your doctor, nurse or pharmacist if you have any questions.

What is the usual adult 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.

Week 1	1 tablet once daily for 5 days	2 days rest
Week 2	Rest	
Week 3	Rest	
Week 4	Rest	

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), and
- medicines called proton pump inhibitors (for example, omeprazole).

Overdose:

If you think you have taken too much INQOVI, contact your 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.

Important safety information

Some people may experience side effects related to INQOVI. If you get any side effects, talk to your doctor, pharmacist, or nurse.

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 are other possible side effects?

- 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. Serious side effects that affect your blood count may include anemia, thrombocytopenia, neutropenia or leukopenia, and febrile neutropenia. 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 explain the results. You may need antibiotics, growth factors or a blood transfusion.

Please see the patient leaflet for more information about serious side effects and what to do about them.

Other warnings you should know about

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)

Following your treatment plan

It is important to follow your doctor's instructions and take your medication exactly as prescribed. During your treatment, you may find that it helps to have a plan and a support system in place to lift you up when you need a hand. Here is some practical advice to help you follow your treatment plan.

Knowing your network

- Identify loved ones and friends who you can depend on for support and advocacy. These are the people you want in your corner.
- If you live with other people, have them help by reminding you to take your medicine as prescribed.

Planning ahead

- Know the plan for potential pitfalls, from what to do if you miss a dose to talking with your doctor about certain side effects.
- Plan to have enough (or extra) doses when you are travelling and away from home.

Keeping track during treatment

- Keeping track during treatment can be an important part of your plan.
- Check off every dose on a calendar.
- Use a daily journal to track things like side effects or questions you have.

Other tips to keep in mind during treatment include:

- Ask your doctor about any side effects you may be experiencing.
- Follow your doctor's advice, including any warnings or precautions.
- Eat healthy meals.
- Get enough rest.



Support program for patients prescribed INQOVI



Helping patients get started with INQOVI

Personalized support services for you

Now that you have been prescribed INQOVI (decitabine and cedazuridine) and are enrolled in the CONEXUS Patient Support Program™, you will receive access to support services throughout your treatment journey, including:



Reimbursement support

Reimbursement specialists will conduct a full investigation into your public and private coverage options.



Nurse-to-patient care

You will be assigned a dedicated Nurse Case Manager, who will provide one-on-one support throughout your treatment journey with INQOVI.



Specialty pharmacy support

- Delivery of personalized prescription to your door
- 1:1 pharmacy counselling

For more information about the
CONEXUS Patient Support Program™:

 Phone: 1-833-CONEXUS (266-3987)

 Hours of operation: 8 a.m. to 8 p.m. EST

Notes

Notes

Canadian Cancer Resources

Canadian Cancer Society

cancer.ca

Leukemia & Lymphoma Society of Canada

llscanada.org

Canadian Cancer Survivor Network

survivornet.ca

Aplastic Anemia & Myelodysplasia Association of Canada (AAMAC)

aamac.ca

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Member of:

BIOTECANADA



INQOVI®
(decitabine and cedazuridine)
35mg / 100mg tablets