

Decitabine 35mg and Cedazuridine 100mg Film-Coated Tablets

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What INQOVI is used for

INQOVI is an anti-cancer medicine. It contains the active substances decitabine and cedazuridine.

INQOVI is used to treat adults with myelodysplastic syndromes (MDS), including chronic myelomonocytic leukemia (CMML). These are types of blood cancers in which the bone marrow does not work properly to produce mature blood cells. This causes a lack of healthy blood cells in the body.

INQOVI is also used to treat acute myeloid leukemia (AML) in adults, when standard induction chemotherapy is not considered suitable.

AML is a type of cancer affecting white blood cells called myeloid cells. In AML, myeloid blood cells multiply and grow very quickly in bone marrow and blood, so that there are too many of them and not enough red blood cells in the blood.

You may be given INQOVI when you are first diagnosed with AML.

How INQOVI works

Decitabine in INQOVI works by stopping cancer cells from growing. It also kills cancer cells. Cedazuridine in INQOVI helps to increase the effects of decitabine.

Before you use INQOVI

-When you must not use it

Do not take INQOVI if:

- you are allergic to decitabine or cedazuridine, or any of the other

ingredients of this medicine (see *Product description*)

- breastfeeding

-Before you start to use it

Warnings and precautions

Myelosuppression

Seek urgent medical attention if you notice any of the following signs and symptoms of myelosuppression during INQOVI (see *Side effects*). These can be serious and life-threatening:

- pale skin/lips/nails
- fatigue
- feeling dizzy
- weakness
- headache
- shortness of breath or rapid breathing
- bleeding or bruising more easily than usual

Myelosuppression is a side effect of some cancer treatments, including INQOVI. This is a condition in which bone marrow activity is decreased, resulting in fewer red blood cells, white blood cells, and platelets. You may be administered growth factors and anti-infective medicines to treat myelosuppression.

Talk to your doctor or pharmacist before taking INQOVI.

Children and adolescents

Children and adolescents under 18 years of age should not be given INQOVI. This medicine has not been studied in this age group.

-Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

INQOVI may affect the way some medicines work. Tell your doctor or pharmacist **before** you begin treatment with INQOVI if you are also taking the following medicines:

- other cancer treatments, such as cytarabine, gemcitabine or azacytidine;
- medicines to treat HIV or AIDs, such as zalcitabine, zidovudine, didanosine, stavudine,

lamivudine, abacavir, emtricitabine, apricitabine or tenofovir;

- hepatitis B treatments, such as telbivudine, adefovir or entecavir;
- herpes treatments, such as idoxuridine, trifluridine or vidarabine.

-Pregnancy and breastfeeding

Pregnancy

INQOVI is **not** recommended during pregnancy. This is because it may harm your unborn baby. For women who are able to become pregnant, a pregnancy test is recommended before starting treatment with INQOVI. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, **ask your doctor for advice before taking this medicine.**

Contraception

Women who are able to become pregnant **must use** effective birth control (contraception) both during treatment with INQOVI, and for 6 months after taking the last dose of INQOVI.

Men with female partners who are able to become pregnant **must use** effective contraception both during treatment with INQOVI, and for 3 months after the last dose.

Talk to your doctor or pharmacist about the most effective methods of contraception.

Breastfeeding

Do not breastfeed during treatment with INQOVI and for 2 weeks after your last dose of INQOVI. This is because it is not known if INQOVI pass into breast milk and whether this could harm your baby.

Fertility

INQOVI may affect male fertility. The reversibility of this effect on fertility is unknown. Talk with your doctor **before** taking this medicine if you have any concerns, or if you wish to conserve your sperm before starting treatment.

-INQOVI contains lactose

INQOVI contains 322.5mg lactose monohydrate per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

How to use INQOVI

-How much to use

You will be prescribed this medicine by a doctor experienced in the use of anti-cancer medicines. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Do not change your dose or stop taking INQOVI unless your doctor tells you to.

The recommended dose is **1 tablet** (taken orally) **once a day on Days 1 to 5** of each treatment cycle. 1 cycle is 28 days.

Your doctor may tell you to decrease your dose, temporarily stop, or completely stop taking INQOVI if you get certain side effects.

-When to use it

Swallow your tablets whole, with water, at approximately same time each day.

-How long to use it

You will take INQOVI for a minimum of 4 cycles, repeating the cycles every 28 days. After 4 cycles your doctor may decide to cease INQOVI treatment if your condition worsens or if any side effects become too difficult to tolerate.

-If you forget to use it

If you miss a dose within 12 hours of the time it is usually taken, you should take the missed dose as soon as possible and resume the normal daily dosing schedule.

If you miss a dose by more than 12 hours, you should wait and take the missed dose the following day at the usual time. Make sure you take 5 conservative doses in each treatment cycle.

If you vomit after taking a dose, no additional dose should be taken that day. The next dose should be taken at the usual time the following day.

If you have any further questions on how to take this medicine, ask your doctor or pharmacist.

-If you use too much (overdose)

Overdose can result in myelosuppression (see *Side effects*), sepsis or pneumonia. If you take more INQOVI than you should, seek **urgent medical attention**. Signs and symptoms of an overdose may include feeling dizzy or faint, confusion or disorientation, slurred speech, weakness, headache, breathlessness, decreased urination, diarrhea, nausea/vomiting, fever, shivering or feeling very cold, clammy skin or sweating, or cough.

While you are using it

-Things you must do

Your doctor will give you a blood test to check your blood cell levels before each INQOVI treatment cycle. If, after the first treatment cycles, your blood cell levels are abnormal or if you have an infection, your doctor will delay your treatment cycle or reduce your INQOVI dose.

Your doctor may prescribe you medication to take before each INQOVI dose to minimise any potential nausea or vomiting.

-Things you must not do

- **Do not** chew, crush, or break your tablets.
- **Do not** eat 2 hours before and 2 hours after taking INQOVI.

-Things to be careful of

INQOVI may affect your ability to drive or use tools or machines. If you feel tired or dizzy after taking INQOVI, **do not** drive or use tools or machinery until you feel better.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Stop taking the medicine and seek urgent medical attention if you notice any of the following

symptoms:

- low levels of white blood cells with fever due to infection (very common – may affect more than 1 in 10 people)
- infection of the lung, symptoms include chest pain or shortness of breath (with or without fever or cough). These may be signs of pneumonia (very common – may affect more than 1 in 10 people).
- Bleeding, including blood in the stools. This may be a sign of bleeding in the stomach or gut (common – may affect up to 1 in 10 people)
- Difficulty moving, speaking, understanding or seeing; sudden severe headache, seizure, numbness or weakness in any part of the body. These may be signs of bleeding inside your head (very common – may affect up to 1 in 10 people)

Tell your doctor if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)

- Bacteria and their toxins circulating in the blood leading to organ damage and blood poisoning
- Inflammation of the deep skin tissue
- Infection in parts of the body, which collect and then passes out of the body in urine
- Other infection in any part of the body, caused by bacteria, viruses or fungi
- Low levels of white blood cells: symptoms include a fever above 38°C, chills, sweating, sore throat
- Low levels of blood platelets which can lead to bleeding and bruising
- Low levels of red blood cells which can cause tiredness and pale skin (anaemia)
- Low levels of neutrophils, a type of white blood cell that fights infection
- High blood glucose levels
- Collection of blood under the skin
- Water in the lungs – build up of excess fluid between layer of pleura outside the lungs. Symptoms include chest pain, dry

non-productive cough, shortness of breath

- Inflammation of the lining of the mouth
- Diarrhea
- Nausea and vomiting
- Abnormal blood tests showing problems with your liver
- High level of bilirubin in the blood, symptoms include yellowish appearance on the skin and whites of the eyes (jaundice)
- Fever and tiredness

Common (may affect up to 1 in 10 people)

- Bacteria present in the blood
- Inflammation of the serous tissues of the body, which are the tissue lining the lungs (pleura), heart (pericardium), and the inner lining of the abdomen (peritoneum) and organs within them
- Inflammation of the sinuses caused by fungal infection
- Nose and throat infection
- Thrush of the mouth
- Inflammation of the tissue around the teeth, often causing shrinkage of the gums and loosening of the teeth
- Inflammation and swelling of small intestine (gut) caused by a virus
- Ear infection
- Infection of the airways
- Dizziness
- Headache
- Broken blood vessel in the eye
- Lack of oxygen in body tissues
- Difficulty breathing
- Cough
- Nosebleed
- Inflamed gut (neutropenic colitis)
- Bleeding from mouth; discomfort, burning or soreness of your tongue, lips, gums or other areas of your mouth
- Rash; small red or purple spots caused by bleeding into the skin
- Blood in the urine
- Swelling of arms or legs
- Decreased appetite

If you experience any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or

adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nprra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of INQOVI

-Storage

Store in the original package in order to protect from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

-Disposal

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

Product Description

-What it looks like

INQOVI tablets are biconvex, oval-shaped, film-coated, red, and debossed with 'H35' on one side.

INQOVI is supplied in packs of 5 film-coated tablets in aluminium / aluminium foil blisters.

- Ingredients:

- Active ingredient:

The active substance of INQOVI is delcitantine and cedazuridine.

One film-coated tablet contains 35mg of the active substance decitabine and 100mg of cedazuridine.

-Inactive ingredients:

The other ingredients are lactose monohydrate, hypromellose, croscarmellose sodium, colloidal silicon dioxide, and magnesium stearate. The film coating material contains polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide red.

- MAL number(s):

MAL24106011ACRZ

Manufacturer(s)

BSP Pharmaceuticals S.P.A.

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Product Registration Holder

Pharmaforte (Malaysia) Sdn Bhd

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