Package leaflet: Information for the patient

Inaqovi 35 mg/100 mg film-coated tablets
decitabine/cedazuridine

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Inaqovi is and what it is used for

What Inaqovi is
Inaqovi is a cancer medicine. It contains the active substances decitabine and cedazuridine.

What Inaqovi is used for
Inaqovi is used alone to treat acute myeloid leukaemia (AML) in adults, when chemotherapy is not considered suitable. You will be given Inaqovi when you are first diagnosed with AML.

AML is a type of cancer affecting white blood cells called myeloid cells. In AML, myeloid cells multiply and grow very quickly in bone marrow and blood.

How Inaqovi works
Inaqovi contains two active substances that work in different ways. Decitabine works by stopping cancer cells from growing. It also kills cancer cells. Cedazuridine does not affect the cancer cells directly, but it inhibits the break down of decitabine. This increases the amount of decitabine that is available in the body, and so helps to increase the effects of decitabine.

2. What you need to know before you take Inaqovi

Do not take Inaqovi
- if you are allergic to decitabine or cedazuridine, or any of the other ingredients of this medicine (listed in section 6).
- If you are breast-feeding (see section 2, Breast-feeding).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Inaqovi if you:
- have lung problems
- have liver problems
- have kidney problems
- have heart problems

Myelosuppression and 'differentiation syndrome'
Inaqovi can cause serious myelosuppression (a condition in which the bone marrow cannot make enough blood cells), or a serious immune reaction called 'differentiation syndrome'. Both may be fatal.
Seek urgent medical attention if you notice any signs and symptoms (for symptoms see section 4)

Cardiovascular disease
Talk to your doctor if you have a history of heart problems so that you can be monitored for signs and symptoms of heart failure.

Blood tests
You will have blood tests while on treatment. These will occur before you start treatment with Inaqovi, at the start of each treatment cycle or if you notice any signs and symptoms of myelosuppression. These tests are to check that:
- you have enough blood cells, and
- your liver and kidneys are working properly

Your doctor may change or delay your dose of Inaqovi. Your doctor may also give you medicines to help prevent infections.

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

Other medicines and Inaqovi
Tell your doctor, pharmacist or nurse if you are taking, have recently taken, or might take any other medicines before you begin treatment with Inaqovi. Inaqovi may affect the way some medicines work, especially if you are also taking the following medicines to treat:
- cancer, such as cytarabine, gemcitabine or azacitidine

Pregnancy, contraception, breast-feeding and fertility

Pregnancy
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
You should not take Inaqovi during pregnancy as it may harm your unborn baby. If you are able to become pregnant, a pregnancy test is recommended before starting treatment with Inaqovi.

Contraception
Women who are able to become pregnant must use effective contraception both during treatment with Inaqovi, and for 6 months after taking the last dose of Inaqovi.

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

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

Breast-feeding
Do not breast-feed during treatment with Inaqovi. This is because it is not known if Inaqovi passes into breast milk and whether this could harm your baby.

Male and female fertility
Inaqovi may affect fertility. It is not known if the effect on fertility is permanent. Talk with your doctor before taking this medicine if you have any concerns, or if you wish to conserve your sperm or freeze your eggs before starting treatment.

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

Inaqovi contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Inaqovi

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.

The recommended dose is 1 tablet once a day for the first 5 days of a treatment cycle. This is followed by 23 days without taking this medicine. One treatment cycle has 28 days.

- Swallow your tablets whole, with water, at approximately the same time each day.
- Do not chew, crush, or break your tablets to avoid skin contact or powdered medicine in the air.
- Since taking Inaqovi with food can decrease the effectiveness of the medicine, Inaqovi must be taken without food. Take Inaqovi 2 hours before or 2 hours after a meal.

You will usually take Inaqovi for at least 4 cycles. Your doctor will do regular blood tests to check on how well you respond to the treatment. Your doctor may delay your dose and change the total number of cycles, depending on how you respond to the treatment.

If you vomit
If you vomit after taking a dose, do not take an additional dose that day. Take the next dose at the usual time the following day.

Your doctor may prescribe you additional medicine to take before each Inaqovi dose to avoid you feeling sick or having to vomit during the treatment.

If you take more Inaqovi than you should
Overdose can result in myelosuppression, sepsis or pneumonia (see section 4, Possible side effects). If you take more Inaqovi than you should, seek **urgent medical attention**.

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

If you miss a dose by 12 or more hours: Do no take a dose and take the next dose the following day at the usual time. Extend the dosing period by one day for every missed dose. Please ensure that you complete a total of 5 daily doses for each cycle.

If you stop taking Inaqovi
If you stop taking this medicine your cancer may no longer be controlled, and your symptoms from the cancer may reoccur. Therefore, you should only stop taking this medicine if your doctor tells you to.
If you have any further questions on how to take this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Tell your doctor, pharmacist, or nurse immediately if you notice any of the following serious side effects:
- **fever**: this may be a sign of an infection caused by low levels of white blood cells (**very common** - may affect more than 1 in 10 people).
- **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) or inflamed lungs (interstitial lung disease (frequency not known).
- **bleeding, including blood in the stools or nose bleed or bruising more easily**: this may be a sign of low blood cells (platelets and red blood cells) (**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 (**common** - may affect up to 1 in 10 people).
- **feeling dizzy or faint, confusion or disorientation, weakness, breathlessness, decreased urination, diarrhoea, feeling sick/vomiting, fever, shivering or feeling very cold, clammy skin or sweating, or cough**: these may be signs and symptoms of an infection of the blood (sepsis) (**very common** - may affect more than 1 in 10 people).
- **fever, cough, difficulty breathing, rash, decreased urine, hypotension (low blood pressure), swelling of the arms or legs and rapid weight gain:** these may be signs of a serious immune reaction (differentiation syndrome) (frequency not known).

Other side effects:

Very common (may affect more than 1 in 10 people)
- urinary tract infection
- infection caused by bacteria, viruses or fungi
- high blood glucose levels
- mouth or tongue ulcers because of painful inflammation of the lining of the mouth
- diarrhoea
- feeling sick and vomiting
- altered liver function tests (increased ALT, AST, alkaline phosphatase, bilirubin)

Common (may affect up to 1 in 10 people)
- inflammation of the sinuses
- headache
- inflamed gut (neutropaenic colitis)

Uncommon (may affect up to 1 in 100 people)
- a drop in the number of red blood cells, white blood cells and platelets
- sudden fever with, multiple red or bluish-red raised painful patches on the skin, usually on the arms, legs, trunk, face or neck. ('Acute Febrile Neutrophilic Dermatosis' or 'Sweet's Syndrome')
- heart muscle disease

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inaqovi

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 blister strip after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.
This medicine does not require any special temperature storage conditions.

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.

6. Contents of the pack and other information

What Inaqovi contains
- The active substances are decitabine and cedazuridine. Each film-coated tablet contains 35 mg decitabine and 100 mg cedazuridine.
- The other ingredients are:
  Inaqovi contains lactose and sodium, see section 2.
  Tablet core
  lactose monohydrate, hypromellose (E464), croscarmellose sodium (E466), silica, colloidal anhydrous, magnesium stearate (E572).
  Film-coating
  polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol (E1521), talc (E553b), iron oxide red (E172).

What Inaqovi looks like and contents of the pack
Inaqovi are red, oval biconvex shaped film-coated tablets, 14 mm diameter, plain on one side and debossed with 'H35' on the other side.

They are supplied in foil blister packs containing 5 tablets.

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