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# Inaqovi (*decitabine/cedazuridine)*

An overview of Inaqovi and why it is authorised in the EU

## What is Inaqovi and what is it used for?

Inaqovi is a cancer medicine used in adults to treat newly diagnosed acute myeloid leukaemia (AML), a type of cancer affecting the white blood cells. It is used in patients who are not eligible for standard induction chemotherapy (initial treatment with cancer medicines).

Inaqovi contains two active substances, decitabine and cedazuridine.

## How is Inaqovi used?

The medicine can only be obtained with a prescription. Treatment with Inaqovi should be started and supervised by a doctor who has experience in the use of cancer treatments.

Inaqovi is available as tablets to be taken by mouth over cycles that last for 28 days. It is given once a day for the first 5 days of each cycle. The medicine is given for a minimum of 4 cycles or until the disease gets worse or side effects become unacceptable.

For more information about using Inaqovi, see the package leaflet or contact your doctor or pharmacist.

## How does Inaqovi work?

The two active substances in Inaqovi, decitabine and cedazuridine, work in different ways. Decitabine is analogous (comparable) to cytidine, a fundamental component of the DNA (genetic material) in cells. In the body, it is incorporated into the DNA where it blocks the activity of enzymes (proteins) called DNA methyltransferases (DNMTs). These enzymes promote the development and progression of cancer. By blocking DNMTs, decitabine impacts the increase of tumour cells and lead to their death.

Cedazuridine blocks the action of an enzyme which breaks down decitabine in the gut and liver. This prevents the premature breakdown of decitabine when it is given by mouth.

## What benefits of Inaqovi have been shown in studies?

The benefits of Inaqovi were evaluated in an ongoing study involving 89 adults with newly diagnosed AML. Within the study patients were divided into two groups. For the first cycle of treatment, one

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group was given Inaqovi once daily for five days while the second group was given decitabine by infusion (drip) into a vein once daily for five days. For the second cycle, the treatments were reversed (i.e. the group given Inaqovi for the first cycle was given decitabine by infusion and vice versa). For the third and subsequent cycles, all patients were given Inaqovi.

Results showed that Inaqovi achieved the same levels of decitabine in the body as those observed when decitabine was given by infusion. In addition, results showed that 21% (19 out of 87) of patients achieved a complete response (no sign of cancer). On average, patients achieved a complete response 3 months after starting treatment. Complete responses to Inaqovi lasted for an average of approximately six months.

## What are the risks associated with Inaqovi?

For the full list of side effects and restrictions with Inaqovi, see the package leaflet.

The most common side effects with Inaqovi (which may affect more than 1 in 10 people) include thrombocytopenia (low levels of blood platelets, components which help the blood to clot).

The most common serious side effects are pneumonia (infection of the lungs) and febrile neutropenia (low levels of white blood cells with fever).

Inaqovi must not be used in women who are breast-feeding.

## Why is Inaqovi authorised in the EU?

Inaqovi was shown to achieve the same levels of decitabine in the body as formulations of decitabine given by infusion; it is therefore expected to have the same effect in the treatment of adults with AML. Patients not suitable for induction therapy are often treated with medicines given by injection. As Inaqovi is a tablet given by mouth, it reduces the burden associated with receiving infusions for both patients and their caregivers. The side effects of Inaqovi are similar to those of formulations of decitabine given by infusion. Although the safety data for Inaqovi are limited, no new side effects associated with either cedazuridine or by giving decitabine by mouth were identified.

The European Medicines Agency decided that Inaqovi's benefits are greater than its risks and it can be authorised for use in the EU.

## What measures are being taken to ensure the safe and effective use of Inaqovi?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Inaqovi have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Inaqovi are continuously monitored. Suspected side effects reported with Inaqovi are carefully evaluated and any necessary action taken to protect patients.

## Other information about Inaqovi

Inaqovi received a marketing authorisation valid throughout the EU on 15 September 2023.

Further information on Inaqovi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/inaqovi

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