



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Sirturo (*bedaquiline*)

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

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

Sirturo is a tuberculosis medicine that contains the active substance bedaquiline. Tuberculosis is an infection caused by the bacterium *Mycobacterium tuberculosis*.

Sirturo is used in combination with other tuberculosis medicines in adults and children (aged 5 years and older and weighing at least 15 kg) with tuberculosis in the lung that is resistant to at least isoniazid and rifampicin, the two standard tuberculosis medicines.

### How is Sirturo used?

Sirturo can only be obtained with a prescription. Treatment should be started and monitored by a doctor who is experienced in the treatment of tuberculosis that is resistant to at least isoniazid and rifampicin. In addition, it is recommended that a healthcare professional watches the patients as they take the medicine.

The medicine is available as tablets to be taken once a day for the first 2 weeks, and then 3 times a week for the next 22 weeks. In adults, treatment may be continued for up to 40 weeks. In children, the dose depends on the child's weight. The tablets should be taken with food.

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

### How does Sirturo work?

The active substance in Sirturo, bedaquiline, blocks an enzyme inside the *M. tuberculosis* bacteria called ATP synthase, which the bacteria need to generate energy. Without the ability to generate energy, the bacteria die and the patient's condition starts to improve.

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

In a main study in patients with multi-drug resistant tuberculosis affecting the lung, Sirturo was compared with placebo (a dummy treatment) when added to combination treatment with other standard tuberculosis medicines. The study showed that after 24 weeks, 79% of the patients given Sirturo (52 out of 66 patients) tested negative for *M. tuberculosis* in the sputum (phlegm) compared with 58% of patients given placebo (38 out of 66 patients). The average time it took to clear the

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bacteria from the sputum was also shorter for patients in the Sirturo group than for those in the placebo group (83 days versus 125 days).

The way Sirturo is handled in the body in children has been shown to be the same as in adults; it is therefore also expected to be effective at treating tuberculosis in children.

A follow-up study compared the benefits of Sirturo plus other tuberculosis medicines taken by mouth with another combination that included a tuberculosis medicine given by injection. The study showed that after 76 weeks, around 82% of the patients given the Sirturo combination (162 out of 196 patients) tested negative for *M. tuberculosis* in the sputum compared with 71% of patients given the combination with an injectable medicine (133 out of 187 patients).

## **What are the risks associated with Sirturo?**

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

The most common side effects with Sirturo in adults (which may affect more than 1 in 10 people) are QT prolongation (abnormal electrical activity of the heart that affects its rhythm), nausea (feeling sick), vomiting, arthralgia (joint pain), increased blood levels of liver enzymes (a sign of possible liver problems), dizziness and headache. Overall, the side effects in adolescents are similar to those in adults. Blood tests showing increased liver enzymes and other effects on the liver occur in about 1 in 3 younger children.

## **Why is Sirturo authorised in the EU?**

The main study showed that Sirturo increased the number of patients who tested negative for the tuberculosis bacteria and shortened the average time it took to clear *M. tuberculosis* bacteria from the sputum. Furthermore, Sirturo was the first of a new class of medicines for which cross-resistance had not yet occurred. Cross-resistance is when bacteria resistant to one medicine are also resistant to a different medicine not used previously, which is often the case with multi-drug resistant tuberculosis.

The side effects in the Sirturo group in the main study were not markedly different from those in the placebo group, though there were higher levels of liver enzymes and some reports of alterations in the heart's electrical activity (known as prolonged QT interval). Also, a higher number of deaths was reported in the Sirturo group. Although an analysis did not conclude that Sirturo caused these deaths, the company was asked provide more information from a long-term follow-up study to address any concerns.

The follow-up study confirmed the benefits of a Sirturo-containing regimen when compared with an injectable-containing regimen. The number of deaths in the Sirturo group was not higher than in the control group in this study and no new safety issues for Sirturo were identified. The known safety issues including liver toxicity and QT-prolongation were shown to be clinically manageable.

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

Sirturo was originally given 'conditional authorisation'. The authorisation has now been switched to a standard authorisation as the company has provided the additional data requested by the Agency.

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

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

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

## **Other information about Sirturo**

Sirturo received a conditional marketing authorisation valid throughout the EU on 5 March 2014. The conditional marketing authorisation was switched to a standard marketing authorisation on 17 June 2024.

Further information on Sirturo can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/sirturo](https://ema.europa.eu/medicines/human/EPAR/sirturo)

This overview was last updated in 06-2024.