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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 2 years and older and weighing at least 7 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 with food 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.

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 *Mycobacterium 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 involving adults with multidrug-resistant tuberculosis in 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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

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).

An ongoing study involving children from 2 years of age with multidrug-resistant tuberculosis in the lung showed that, after 24 weeks of treatment, blood levels of Sirturo in these children were similar to those seen in adults for whom the treatment was effective. The medicine is therefore expected to be effective at treating children with multidrug-resistant tuberculosis in the lung.

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) include 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.

The most common side effects with Sirturo in children aged 5 to less than 11 years (which occurred in about 1 in 3 children in the study) include increased liver enzymes and other effects on the liver. The most common side effect with Sirturo in children aged 2 to less than 5 years (which occurred in 1 in 5 children in the study) is vomiting.

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

In the main study, the side effects in the Sirturo group were similar to 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 to 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 was later switched to a standard authorisation as the company had 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.

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