LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Sirkava 18 microgram tiotropium bromide

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Summary Public Assessment Report

Sirkava

(tiotropium bromide)

Inhalation powder, hard capsule, 18 microgram

This is a summary of the public assessment report (PAR) for Sirkava. It explains how Sirkava was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Sirkava.

For practical information about using Sirkava, patients should read the package leaflet or contact their doctor or pharmacist.

What is Sirkava and what is it used for?

Sirkava is a 'hybrid medicine'. This means that Sirkava is similar to a 'reference medicine' already authorised in the European Union (EU) called Spiriva.
Sirkava 18 microgram helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing. The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a chronic disease Sirkava 18 microgram should be taken every day and not only when there is breathing problems or other symptoms of COPD.

How does Sirkava work?

Sirkava 18 microgram is a long-acting bronchodilator that helps to open the airways and makes it easier to get air in and out of the lungs. The effect of this medicine lasts for 24 hours, so it is only needed once a day.

How is Sirkava used?

The pharmaceutical form of Sirkava is inhalation powder, hard capsule for inhalation use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Sirkava have been shown in studies?

Because Sirkava is a hybrid application and is considered to be therapeutically equivalent to the reference product Spiriva, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Sirkava?

For the full list of all side effects reported with Sirkava, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Sirkava approved?

It was concluded that, in accordance with EU requirements, Sirkava has been shown to be similar to a reference medicine, Spiriva, containing the same active substance. The company has provided additional own pharmacokinetic data to demonstrate therapeutic equivalence between test and reference product. Therefore, the Medical Products Agency in Sweden decided that, as for Spiriva, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Sirkava is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Sirkava, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Sirkava

The marketing authorisation for Sirkava was granted on 2018-10-19 in Sweden.

The full PAR for Sirkava can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Sirkava, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2018-10.