LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Tiogiva
(tiotropium bromide)

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tiotropium bromide

Inhalation powder, hard capsule, 18 mikrogram

This is a summary of the public assessment report (PAR) for Tiogiva. It explains how Tiogiva 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 Tiogiva.

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

What is Tiogiva and what is it used for?

Tiogiva is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The company has provided additional own data to demonstrate the safety and efficacy of Tiogiva regarding this difference from the reference medicine.

The reference medicine for Tiogiva, is Spiriva. Tiogiva can be used by patients who have chronic obstructive pulmonary disease (COPD) and helps them to breathe more easily.

How does Tiogiva work?

Tiogiva is a long-acting bronchodilator that helps to open the patient's airways and makes it easier to get air in and out of the lungs. Regular use of Tiogiva can also help patients when they have on-going shortness of breath related to their disease and will help them to minimize the effects of the disease on their everyday life. It also helps patients to be active longer. Daily use of Tiogiva will also help to prevent sudden, short-term worsening of the patient's COPD symptoms which may last for several days. The effect of this medicine lasts for 24 hours, so patients only need to use it once a day.

How is Tiogiva used?

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

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 in Sweden.

What benefits of Tiogiva have been shown in studies?

Because Tiogiva is a hybrid application and is considered to be therapeutically equivalent, to the reference product Spiriva, 18 µg, Inhalation powder, hard capsule, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Tiogiva?

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

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

Why is Tiogiva approved?

This medicine is similar to a reference medicine containing the same active substance but is given by inhalation. The company has provided additional own data to demonstrate the safety and efficacy of Tiogiva regarding this difference from the reference medicine.
No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Tiogiva's benefits are greater than its risks and recommended that it be approved for use.

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

A risk management plan has been developed to ensure that Tiogiva 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 Tiogiva, 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 Tiogiva

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

This summary was last updated in 2021-06.