LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ipravent
(ipratropium bromide (as monohydrate))

SE/H/1361/01/DC

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Ipravent

(ipratropium bromide (as monohydrate))

20 micrograms per actuation pressurised inhalation, solution

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

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

What is Ipravent and what is it used for?
Ipravent is a 'hybrid medicine'. This means that Ipravent is similar to a reference medicine containing the same active substance, but is given by another inhaler.

The reference medicine for Ipravent is Atrovent.

Ipravent Inhaler contains a medicine called ipratropium bromide. This belongs to a group of medicines called bronchodilators.
Ipravent is used to make breathing easier for adults with chronic asthma or 'chronic obstructive pulmonary disease' (COPD).

How does Ipravent work?
Ipravent works by opening up airways.

How is Ipravent used?
The pharmaceutical form of Ipravent is pressurised inhalation, solution for oral 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 Ipravent have been shown in studies?
Because Ipravent is a hybrid application and is considered to be therapeutically equivalent, to the reference product Atrovent, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Ipravent?
For the full list of all side effects reported with Ipravent, see section 4 of the package leaflet.

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

Why is Ipravent approved?
This medicine is similar to a reference medicine containing the same active substance, but is given by another inhaler. It was concluded that, in accordance with EU requirements, Ipravent has been shown to have comparable quality and to be bioequivalent to the reference medicine Atrovent.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Ipravent'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 Ipravent?
A risk management plan has been developed to ensure that Ipravent 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 Ipravent, 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 Ipravent
The marketing authorisation for Ipravent was granted on 2016-02-25 in Sweden.

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

This summary was last updated in 2016-02.