LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salmeterol Orifarm
(salmeterol, salmeterol xinafoate)

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Inhalation powder, pre-dispensed, 50 microgram/dose

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Salmeterol Orifarm and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Serevent Diskus, 50 microgram/dose, inhalation powder, pre-dispensed.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

The product is used in the maintenance treatment of asthma along with inhaled steroids and in COPD (chronic obstructive pulmonary disease).

The product should be used by asthma patients.

How does Salmeterol Orifarm work?

The product is a long-acting bronchodilator. It helps the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects are usually felt within 10 to 20 minutes and last for at least 12 hours. Full effect is obtained after 2-3 hours.

How is Salmeterol Orifarm used?

The pharmaceutical form is inhalation powder, pre-dispensed dose, 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 in Sweden.

What benefits of Salmeterol Orifarm have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Serevent Diskus, 50 microgram/dose, inhalation powder, pre-dispensed, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Salmeterol Orifarm?

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Salmeterol Orifarm approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Serevent Diskus, 50 microgram/dose, inhalation powder, pre-dispensed, 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 Salmeterol Orifarm?

A risk management plan has been developed to ensure that the product 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, 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 Salmeterol Orifarm

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

This summary was last updated in YYYY-MM.
Infoga datum enligt när sPAR blir klar för publicering.