LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salmex
(salmeterol (as xinafoate) and fluticasone propionate)

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Summary Public Assessment Report

Salmex
(salmeterol/fluticasone propionate)

50 microgram /100 microgram /dose inhalation powder, pre-dispensed
50 microgram /250 microgram /dose inhalation powder, pre-dispensed
50 microgram /500 microgram /dose inhalation powder, pre-dispensed

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

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

What is Salmex and what is it used for?

Salmex is a 'hybrid medicine'. This means that Salmex is similar to a 'reference medicine' already authorised in the European Union (EU) called Seretide Diskus.

Salmex is used to help prevent breathing problems such as:
- Asthma
- Chronic Obstructive Pulmonary Disease (COPD). Salmex, at a dose of 50/500 micrograms, reduces the number of flare ups of COPD symptoms.

How does Salmex work?

Salmex contains two medicines, salmeterol and fluticasone propionate:

- Salmeterol is a long-acting bronchodilator. Bronchodilators help the airways in the lungs to stay open. This makes it easier for air to get in and out. The effects last for at least 12 hours.
- Fluticasone propionate is a corticosteroid which reduces swelling and irritation in the lungs

How is Salmex used?

The pharmaceutical form of Salmex is pre-dispensed inhalation powder to be inhaled through the mouth into the lungs.

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 Salmex have been shown in studies?

Because Salmex is a hybrid medicine and is considered to be therapeutically equivalent to the reference product Seretide Diskus, their benefits and risks are taken as being the same as those for the reference medicine.

What are the possible side effects of Salmex?

Because Salmex is a hybrid medicine and is therapeutically equivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Salmex approved?

It was concluded that, in accordance with EU requirements, Salmex has been shown to have comparable quality and is similar to the reference medicine Seretide Diskus. Therefore, the Medical Products Agency in Sweden decided that, as for Seretide Diskus, 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 Salmex?

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

The marketing authorisation for Salmex was granted on 2018-01-12 in Sweden.

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

This summary was last updated in 2018-01.