LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Salfluae Forspiro
(salmeterol xinafoate, fluticasone propionate)

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Summary Public Assessment Report

Salfluae Forspiro

(salmeterol xinafoate, fluticasone propionate)

Inhalation powder, pre-dispensed
50 microgram/500 microgram/dose

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

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

What is Salfluae Forspiro and what is it used for?

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

Salfluae Forspiro is used in the treatment of:

- asthma
- chronic obstructive pulmonary disease (COPD)
  This disease is characterized by continuous breathing difficulties caused by narrowed airways, often accompanied with coughing and phlegm. This medicine reduces the number of flare ups of COPD symptoms.

How does Salfluae Forspiro work?

This medicine contains two active substances.

- Salmeterol: a long-acting substance that widens the airways
- Fluticasone: a corticosteroid which reduces swelling and inflammation in the lungs

How is Salfluae Forspiro used?

The pharmaceutical form of Salfluae Forspiro is an inhalation powder, pre-dispensed 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.

What benefits of Salfluae Forspiro have been shown in studies?

Because Salfluae Forspiro is a hybrid application and is considered to be therapeutically equivalent, to the reference product Seretide Diskus mite, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Salfluae Forspiro?

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

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

Why is Salfluae Forspiro approved?

It was concluded that, in accordance with EU requirements, Salfluae Forspiro has been shown to have comparable quality and safety and efficacy 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 Salfluae Forspiro?

A risk management plan has been developed to ensure that Salfluae Forspiro 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 Salfluae Forspiro, 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 Salfluae Forspiro

The marketing authorisation for Salfluae Forspiro was granted on 2016-02-04 in Sweden.

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

This summary was last updated in 2016-02.