LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Roadasan Forspiro
(salmeterol xinafoate, fluticasone propionate)

SE/H/1448/01-02/DC

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Summary Public Assessment Report

Roadasan Forspiro

(salmeterol xinafoate, fluticasone propionate)

Inhalation powder, pre-dispensed
50 microgram/250 microgram/dose
50 microgram/500 microgram/dose

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

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

What is Roadasan Forspiro and what is it used for?

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

Roadasan Forspiro (50 microgram/250 microgram/dose) is used in the treatment of:

- asthma

Roadasan Forspiro (50 microgram/500 microgram/dose) 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 Roadasan 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 Roadasan Forspiro used?

The pharmaceutical form of Roadasan Forspiro is 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 Roadasan Forspiro have been shown in studies?

Because Roadasan Forspiro is a hybrid application 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 Roadasan Forspiro?

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

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

Why is Roadasan Forspiro approved?

It was concluded that, in accordance with EU requirements, Roadasan 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 Roadasan Forspiro?

A risk management plan has been developed to ensure that Roadasan 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 Roadasan 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 Roadasan Forspiro

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

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

This summary was last updated in 2016-02.