LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Zoreeda
(salmeterol and fluticasone propionate)

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Summary Public Assessment Report

Zoreeda

(salmeterol/fluticasone propionate)

Pressurised inhalation, suspension;
25 micrograms /125 micrograms /dose and 25 micrograms /250 micrograms /dose

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

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

What is Zoreeda and what is it used for?

Zoreeda is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance. The reference medicine for Zoreeda is Seretide Evohaler.

The doctor has precribed this medicine to help prevent breathing problems such as asthma. You must use Zoreeda every day as directed by your doctor. This will make sure that it works properly in controlling your asthma.

Zoreeda helps to stop breathlessness and wheeziness coming on. It does not work once you are breathless or wheezy. If that happens you need to use a fast acting 'reliever' medication, such as salbutamol.

How does Zoreeda work?

Zoreeda contains two medicines, salmeterol and fluticasone propionate

- Salmeterol is a long- acting bronchodilator. Bronchodilators help the airways in the lung 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 Zoreeda used?

The pharmaceutical form of Zoreeda is pressurised inhalation, suspension 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 Zoreeda have been shown in studies?

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

What are the possible side effects of Zoreeda?

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

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

Why is Zoreeda approved?

This medicine is similar to a reference medicine containing the same active substance. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Zoreeda'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 Zoreeda?

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

The marketing authorisation for Zoreeda was granted on 2016-07-14 in Sweden.

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

This summary was last updated in 2016-07.