LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Isicort
(dexamethasone)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Isicort
dexamethasone

Orodispersible film, 4 mg, 6 mg, 8 mg

This is a summary of the public assessment report (PAR) for Isicort. 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 Isicort 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 but is available as orodispersible film.

The reference medicine for the product is a so called European Reference Product, Fortecortin, approved in Spain.

Isicort is used in the treatment of:
- Swelling of the brain causedby brain tumours, neurosurgery or abscesses
- Acute severe asthma
- Severe acute skin diseases
- Autoimmune diseases
- Rheumatoid arthritis
- Prevention and treatment of nausea and vomiting due to treatment with anti-cancer drugs
- Croup
- Allergic reactions, including acute allergic reactions
- Treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight of at least 40 kg) with difficulty breathing and need of oxygen therapy.

How does Isicort work?

Isicort contains the active substance dexamethasone, which belongs to a group of medicinal products called corticosteroids (cortisones). Corticosteroids reduce inflammation and symptoms of allergic reactions and suppress the immune system.

How is Isicort used?

The pharmaceutical form is orodispersible film 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 Isicort have been shown in studies?

Studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine mentioned above.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Isicort?

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 Isicort approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine mentioned above. Therefore, the Swedish Medical Products Agency decided that, as for the reference product, 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 Isicort?

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 Isicort

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

This summary was last updated in 2022-08.