LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lurapena
(budesonide)

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Summary Public Assessment Report

Lurapena
budesonide

Gastro-resistant capsule, hard, 3 mg

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

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

What is Lurapena and what is it used for?

Lurapena is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for Lurapena is Budenofalk.

How does Lurapena work?

Lurapena contains the active substance budesonide, a type of locally acting steroid used to treat chronic inflammatory diseases of the intestine and the liver.

Lurapena is used in the treatment of:
- **Crohn's disease:** mild to moderate acute attacks of chronic inflammation of the intestine affecting the lower part of the small bowel (ileum) and/or upper part of the large bowel (the ascending colon).
- **Microscopic colitis:** a disease with the subtypes collagenous and lymphocytic colitis, characterised by chronic inflammation of the large bowel typically accompanied by chronic watery diarrhoea.
- **Autoimmune hepatitis:** a disease with chronic inflammation of the liver.

How is Lurapena used?

The pharmaceutical form of Lurapena is gastro-resistant capsule, hard, 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 Lurapena have been shown in studies?

Studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Budenofalk. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Lurapena?

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 Lurapena approved?

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

A risk management plan has been developed to ensure that Lurapena 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 Lurapena 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 Lurapena

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

This summary was last updated in 2022-06.