LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fidaxomicin SUN
(fidaxomicin)

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Film-coated tablet, 200 mg

This is a summary of the public assessment report (PAR) for Fidaxomicin SUN. 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 Fidaxomicin SUN 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. The reference medicine for the product is DIFICLIR.

The product is used in used in adults, adolescents and children with a body weight of at least 12.5 kg to treat infections of the lining of the colon (large intestine) with certain bacteria called Clostridioides difficile. This serious illness can result in painful, severe diarrhoea.

How does Fidaxomicin SUN work?

Fidaxomicin SUN is an antibiotic which contains the active substance fidaxomicin. It works by killing the bacteria that cause the infection and helps to reduce the associated diarrhoea.

How is Fidaxomicin SUN used?

The pharmaceutical form is film-coated tablet 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 Fidaxomicin SUN have been shown in studies?

Because the product is a hybrid medicine, studies have been limited to tests to determine that it is therapeutically equivalent to the reference medicine, DIFICLIR, and it is considered that the benefits and risks are the same as those of the reference medicine.

What are the possible side effects from Fidaxomicin SUN?

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 Fidaxomicin SUN approved?

t was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine.

Therefore, the Swedish Medical Products Agency decided that, as for DIFICLIR, 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 Fidaxomicin SUN?
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 Fidaxomicin SUN
The full PAR for Fidaxomicin SUN can be found on the following website: MRI - Home. For more information about treatment with Fidaxomicin SUN, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in YYYY-MM.