

Summary Public Assessment Report

Clindamycin Abcur (clindamycin phosphate)

SE/H/2113/01/DC

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clindamycin phosphate

Solution for injection/infusion, 150 mg/ml

This is a summary of the public assessment report (PAR) for Clindamycin Abcur. 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 Clindamycin Abcur and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Dalacin.

Clindamycin Abcur is used to clear certain serious bacterial infections, such as: bone and joint infections, chronic sinus infections, lower respiratory tract infections, complicated abdominal infections, infections of the reproductive organs, complicated skin and soft tissue infections. Clindamycin Abcur is usually reserved for the treatment of severe infections in adults and adolescents older than 12 years when the infection is caused by bacteria that are sensitive to clindamycin, and other antibiotics have been unable to clear the infection.

How does Clindamycin Abcur work?

Clindamycin Abcur contains the active substance clindamycin and belongs to a group of medicines called antibiotics. Antibiotics are used to treat infections.

How is Clindamycin Abcur used?

The pharmaceutical form is a solution for injection/infusion for intravenous or intramuscular 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 Clindamycin Abcur have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by intramuscular injection/intravenous infusion and contains the same active substance as the reference medicine, Dalacin.

What are the possible side effects from Clindamycin Abcur?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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 Clindamycin Abcur approved?

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

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 Clindamycin Abcur

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

This summary was last updated in 2022-11.