LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Clindamycin Actavis
(clindamycin hydrochloride)

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Summary Public Assessment Report

Clindamycin Actavis
(clindamycin)
hard capsules,150 mg and 300 mg

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

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

What is Clindamycin Actavis and what is it used for?

Clindamycin Actavis is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Dalacin. Dalacin 150 mg and 300 mg hard capsule, has been authorised in Sweden since 1974.

Clindamycin Actavis is used in the treatment of
- Stomach infections
- Serious infections caused by anaerobic bacteria
- Skin and soft tissue infections
- Tonsillitis
- Dental infections

How does Clindamycin Actavis work?

Clindamycin Actavis contains the active substance clindamycin and belongs to a group of medicines called antibiotics.

How is Clindamycin Actavis used?

The pharmaceutical form of Clindamycin Actavis is hard capsules 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.

What benefits of Clindamycin Actavis have been shown in studies?

Because Clindamycin Actavis is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Dalacin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Clindamycin Actavis?

Because Clindamycin Actavis is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Clindamycin Actavis approved?

It was concluded that, in accordance with EU requirements, Clindamycin Actavis has been shown to have comparable quality and to reference medicinal product, Dalacin. Therefore, the Medical Products Agency in Sweden 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 Actavis?

A risk management plan has been developed to ensure that Clindamycin Actavis 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 Clindamycin Actavis, 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 Actavis

The marketing authorisation for Clindamycin Actavis was granted on 2016-05-26 in Sweden.

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

This summary was last updated in 2016-09.