

Summary Public Assessment Report

Generics

Pivmecillinamhydrochlorid “LEO” Pivmecillinamhydrochlorid

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Pivmecillinamhydrochlorid “LEO”

Pivmecillinam hydrochloride, film-coated tablets 400 mg

This is a summary of the public assessment report (PAR) for Pivmecillinamhydrochlorid “LEO”. It explains how Pivmecillinamhydrochlorid “LEO” 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 Pivmecillinamhydrochlorid “LEO”.

For practical information about using Pivmecillinamhydrochlorid “LEO”, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pivmecillinamhydrochlorid “LEO” and what is it used for?

Pivmecillinamhydrochlorid “LEO” is a ‘generic medicine’. This means that Pivmecillinamhydrochlorid “LEO” is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Selexid.

Pivmecillinamhydrochlorid “LEO” belongs to a group of medicines called penicillins. Pivmecillinamhydrochlorid “LEO” is used to treat infections of the bladder (cystitis) in adults.

How does Pivmecillinamhydrochlorid “LEO” work?

Pivmecillinamhydrochlorid “LEO” is a type of antibiotic that works by killing germs (bacteria) that cause infections.

How is Pivmecillinamhydrochlorid “LEO” used?

The pharmaceutical form of Pivmecillinamhydrochlorid “LEO” is film-coated tablets and the route of administration is oral.

The recommended dose is 400 mg 3 times daily. The tablets should be taken at equally spaced times in the day. Pivmecillinhydrochlorid “LEO” must be taken with at least half a glass of liquid.

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 Pivmecillinamhydrochlorid “LEO” have been shown in studies?

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

The company provided data from the published literature on pivmecillinam hydrochloride.

What are the possible side effects of Pivmecillinamhydrochlorid “LEO”?

Because Pivmecillinamhydrochlorid “LEO” 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 Pivmecillinamhydrochlorid “LEO” approved?

It was concluded that, in accordance with EU requirements, Pivmecillinamhydrochlorid “LEO” has been shown to have comparable quality and to be bioequivalent to Selexid. Therefore, the member states involved in the procedure concluded that, as for Selexid, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Pivmecillinamhydrochlorid “LEO”?

A risk management plan has been developed to ensure that Pivmecillinamhydrochlorid “LEO” 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 Pivmecillinamhydrochlorid “LEO”, 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 Pivmecillinamhydrochlorid “LEO”

The marketing authorisation for Pivmecillinamhydrochlorid “LEO” was granted on 30 September 2014.

The full PAR and the package leaflet for Pivmecillinamhydrochlorid “LEO” can be found on the website <http://mri.medagencies.org/Human/>. For more information about treatment with Pivmecillinamhydrochlorid “LEO”, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 09-2015.