LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Gerodolan
(hydromorphone hydrochloride)

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Summary Public Assessment Report

Gerodolan

(hydromorphone hydrochloride)

Solution for injection or infusion, 2 mg/ml, 10 mg/ml, 20 mg/ml and 50 mg/ml

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

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

What is Gerodolan and what is it used for?

Gerodolan is a 'generic medicine'. This means that Gerodolan is similar to a 'reference medicine' already authorised in the European Union (EU) called Palladon.

Gerodolan is used for the treatment of severe pain. It is intended for use in adults and adolescents over 12 years of age.

How does Gerodolan work?

Gerodolan contains the active substance hydromorphone hydrochloride, which is a potent analgesic ("painkiller") of the opioid group.

How is Gerodolan used?

The pharmaceutical form of Gerodolan is solution for injection or infusion for intravenous or subcutaneous 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 Gerodolan have been shown in studies?

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

What are the possible side effects of Gerodolan?

Because Gerodolan 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 restrictions, see the package leaflet.

Why is Gerodolan approved?

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

A risk management plan has been developed to ensure that Gerodolan 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 Gerodolan, 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 Gerodolan

The marketing authorisation for Gerodolan was granted on 2019-04-11 in Sweden.

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

This summary was last updated in 2019-12.