LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Metadon Pharmadone
(methadone hydrochloride)

SE/H/1311/01-20/MR

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oral solution,
10, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150 mg

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

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

What is Metadon Pharmadone and what is it used for?

Metadon Pharmadone is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Metadon Pharmadone is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Metadon Pharmadone is used for the treatment of opioid-related drug dependency. Methadone treatment is supposed to take place together with psychological treatment and social follow-up. All methadone treatment shall be according to national guidelines.

How does Metadon Pharmadone work?

Methadone blocks the body's opioid receptor, and supresses the symptoms of withdrawal.

How is Metadon Pharmadone used?

The pharmaceutical form of Metadon Pharmadone is oral solution.

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 oral solution have been shown in studies?

As methadone hydrochloride is a well-known substance, and its use in the treatment of opioid-related drug dependency is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of methadone hydrochloride in the treatment of treatment of opioid-related drug dependency.

What are the possible side effects of Metadon Pharmadone?

For the full list of all side effects reported with Metadon Pharmadone, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Metadon Pharmadone approved?

The use of Metadon Pharmadone in the treatment of opioid-related drug dependency is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Metadon Pharmadone's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Metadon Pharmadone?

A risk management plan has been developed to ensure that Metadon Pharmadone 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 Metadon Pharmadone, 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 Metadon Pharmadone

The marketing authorisation for Metadon Pharmadone was granted on 2008-12-05 in Sweden.

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

This summary was last updated in 2015-01.