LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Metadon Nordic Drugs
(methadone hydrochloride)

SE/H/1352/01-25/MR

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Metadon Nordic Drugs

(methadone hydrochloride)

oral solution
10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, 45 mg, 50 mg, 55 mg, 60 mg, 70 mg, 80 mg, 90 mg, 100 mg, 110 mg, 120 mg, 130 mg, 140 mg, 150 mg, 160 mg, 170 mg, 180 mg, 190 mg, 200 mg

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

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

What is Metadon Nordic Drugs and what is it used for?

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

Metadon Nordic Drugs is used in the treatment of opiate dependent patients. The treatment should be given together with medical and psychological treatment and social rehabilitation.

How does Metadon Nordic Drugs work?

Methadone is a synthetic opiate (a morphine-like medicine). Methadone blocks the body’s opioid receptor, and supresses the symptoms of withdrawal.

How is Metadon Nordic Drugs used?

The pharmaceutical form of Metadon Nordic Drugs is solution 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 Metadon Nordic Drugs have been shown in studies?

As methadone is a well-known substance, and its use in the treatment of opiate dependent patients is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of methadone in the treatment of opiate dependent patients.

What are the possible side effects of Metadon Nordic Drugs?

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

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

Why is Metadon Nordic Drugs approved?

The use of Metadon Nordic Drugs in the treatment of opiate dependent patients 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 Nordic Drugs'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 Nordic Drugs?

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

The marketing authorisation for Metadon Nordic Drugs was granted on 2010-07-16 in Sweden.

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

This summary was last updated in 2015-01.