

Summary Public Assessment Report

Metadon 2care4 (methadone hydrochloride)

SE/H/1713/01-04/DC

Summary Public Assessment Report

Metadon 2care4

(methadone hydrochloride)

Tablet, 5 mg, 10 mg, 20 mg and 40 mg

This is a summary of the public assessment report (PAR) for Metadon 2care4. It explains how Metadon 2care4 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 2care4.

For practical information about using Metadon 2care4, patients should read the package leaflet or contact their doctor or pharmacist.

What is Metadon 2care4 and what is it used for?

Metadon 2care4 is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Metadon 2care4 is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Metadon 2care4 is used to treat adults with severe chronic pain which can be adequately managed only with opioid analgesics. Lower strengths of Metadon 2care4 (5 mg and 10 mg) are also used as substitution therapy in opiate dependence, given together with medical and psychological treatment and social rehabilitation.

How does Metadon 2care4 work?

Metadon 2care4 is a narcotic pain relief medication which acts in a similar way to morphine, but has a less sedative effect. Metadon 2care4 blocks the opioid receptors, and suppresses the symptoms of withdrawal.

How is Metadon 2care4 used?

The pharmaceutical form of Metadon 2care4 is tablet 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 2care4 have been shown in studies?

As methadone hydrochloride is a well-known substance, and its use in the treatment of severe chronic pain and as substitution therapy in opiate dependence 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 severe chronic pain and as substitution therapy in opiate dependence.

What are the possible side effects of Metadon 2care4?

For the full list of all side effects reported with Metadon 2care4, see section 4 of the package leaflet.

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

Why is Metadon 2care4 approved?

The use of Metadon 2care4 in the treatment of severe chronic pain and as substitution therapy in opiate dependence 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 the benefits of Metadon 2care4 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 2care4?

A risk management plan has been developed to ensure that Metadon 2care4 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 2care4, 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 2care4

The marketing authorisation for Metadon 2care4 was granted on 2018-09-13 in Sweden.

The full PAR for Metadon 2care4 can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Metadon 2care4, please read the [package leaflet 5 mg and 10 mg](#) and [package leaflet 20 mg and 40 mg](#), respectively, or contact your doctor or pharmacist.

This summary was last updated in 2018-09-13.