LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Metadon Abcur
(methadone hydrochloride)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Metadon Abcur
(methadone hydrochloride)

5 mg, 10 mg, 20 mg and 40 mg, tablet

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

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

What is Metadon Abcur and what is it used for?

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

Metadon Abcur *5 mg and 10 mg* is used for:

- treating severe chronic pain which can be adequately managed only with opioid analgesics
- substitution therapy in opiate dependent patients, given together with medical and psychological treatment and social rehabilitation.

Metadon Abcur *20 mg and 40 mg* is used for treating severe chronic pain which can be adequately managed only with opioid analgesics.

How does Metadon Abcur work?

Metadon Abcur is a morphine-like medicinal product.

Metadon Abcur *5 mg and 10 mg* is used for:

- treating severe chronic pain which can be adequately managed only with opioid analgesics
- substitution therapy in opiate dependent patients, given together with medical and psychological treatment and social rehabilitation.

Metadon Abcur *20 mg and 40 mg* is used for treating severe chronic pain which can be adequately managed only with opioid analgesics.

How is Metadon Abcur used?

The pharmaceutical form of Metadon Abcur is tablets for e.g. 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 Abcur have been shown in studies?

As methadone hydrochloride is a well-known substance, and its use in:

- treating severe chronic pain which can be adequately managed only with opioid analgesics
- substitution therapy in opiate dependent patients, given together with medical and psychological treatment and social rehabilitation

, is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of methadone hydrochloride in its use in:

- treating severe chronic pain which can be adequately managed only with opioid analgesics
- substitution therapy in opiate dependent patients, given together with medical and psychological treatment and social rehabilitation

What are the possible side effects of Metadon Abcur?

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

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

Why is Metadon Abcur approved?

The use of Metadon Abcur in:

- treating severe chronic pain which can be adequately managed only with opioid analgesics
- substitution therapy in opiate dependent patients, given together with medical and psychological treatment and social rehabilitation

, 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 Abcur'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 Abcur?

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

The marketing authorisation for Metadon Abcur was granted on 2018-02-02 in Sweden.

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

This summary was last updated in 2020-03-19.