LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Agomelatine Mylan
(agomelatine, agomelatine citric acid)

SE/H/2236/01/DC

This module reflects the scientific discussion for the approval of Agomelatine Mylan. The Summary Public Assessment Report was written in December 2018 by the previous RMS NL after initial procedure NL/H/4014/001/DC. RMS transfer from NL to SE was completed 30 August 2024.

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Summary Public Assessment Report

Generics

Agomelatine Mylan 25 mg film-coated tablets

(agomelatine)

NL/H/4014/001/DC

Date: 4 December 2018

Summary Public Assessment Report

Generics

Agomelatine Mylan 25 mg film-coated tablets

Active substance: agomelatine

This is a summary of the public assessment report (PAR) for Agomelatine Mylan. It explains how this medicine 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 Agomelatine Mylan.

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

What is Agomelatine Mylan and what is it used for?
Agomelatine Mylan is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Valdoxan 25 mg, film-coated tablets.

This medicine is used to treat depression in adults.

Depression is a continuing disturbance of mood that interferes with everyday life. The symptoms of depression vary from one person to another, but often include deep sadness, feelings of worthlessness, loss of interest in favourite activities, sleep disturbances, feeling of being slowed down, feelings of anxiety, changes in weight.

How does this medicine work?

This medicine contains the active ingredient agomelatine. It belongs to a group of medicines called antidepressants. The expected benefits of agomelatine are to reduce and gradually remove the symptoms related to depression.

How is this medicine used?
The pharmaceutical form of Agomelatine Mylan is a film-coated tablet and the route of administration is oral. The tablets should be swallowed with a drink of water and can be taken with or without food.

The medicine can only be obtained with a prescription.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Agomelatine Mylan is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Valdoxan. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Agomelatine Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Valdoxan, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine? A risk management plan has been developed to ensure that this medicine 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 Agomelatine Mylan, 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 this medicine
In the Netherlands, the marketing authorisation for Agomelatine Mylan was granted on 7 December 2018.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Agomelatine Mylan, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_4018_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in December 2018.