EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reagila

cariprazine

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AUTHORISED
This medicine is authorised for use in the European Union.

Overview

This is a summary of the European public assessment report (EPAR) for Reagila. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Reagila.

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

What is Reagila and what is it used for?

Reagila is an antipsychotic medicine used to treat schizophrenia in adults. Schizophrenia is a mental illness with symptoms such as delusions, disorganised thinking and speech, suspiciousness and hallucinations (hearing or seeing things that are not there).

Reagila contains the active substance cariprazine.

How is Reagila used?

Reagila is available as capsules (1.5, 3, 4.5 and 6 mg) to be taken by mouth. The recommended starting dose is 1.5 mg once a day. The dose can be increased by 1.5 mg at a time up to a maximum of 6 mg per day. The lowest dose that works well for the patient should be maintained. Because the medicine's effects may take time to show, patients should be monitored for several weeks after starting treatment or changing the dose.

Reagila can only be obtained with a prescription. For further information, see the package leaflet.

How does Reagila work?

The active substance in Reagila, cariprazine, attaches to receptors (targets) in the brain for two neurotransmitters called dopamine and serotonin, which nerve cells use to communicate with neighbouring cells. Since dopamine and serotonin play a role in schizophrenia, by attaching to their receptors, cariprazine helps normalise the activity of the brain. This reduces symptoms of schizophrenia and prevents them from returning.

What benefits of Reagila have been shown in studies?

Studies showed that Reagila improves symptoms of schizophrenia and prevents symptoms from returning.

In three main studies in a total of 1,795 adults, Reagila was more effective than placebo (a dummy treatment) at reducing symptoms on a standard rating scale called PANSS (positive and negative syndrome scale). The PANSS score, which ranges from a minimum of 30 (no symptoms) to a maximum of 210 (severest symptoms), was around 96 at the start of treatment. After 6 weeks, depending on the study, the PANSS score fell by 17 to 23 points with Reagila compared with 9 to 14 points with placebo.

A fourth main study in 461 patients who mostly had 'negative' symptoms (such as lack of drive, social withdrawal, and problems with attention and memory) and only few 'positive' symptoms (such as delusions and hallucinations) showed that Reagila was effective at treating negative symptoms: after 26 weeks of treatment Reagila lowered the PANSS score for negative symptoms by around 9 points compared with around 7 points with another medicine, risperidone.

Finally, a fifth main study in 200 patients showed that Reagila was more effective than placebo at preventing symptoms from coming back after initial treatment. Over a 72 week period, symptoms returned in a quarter of patients taking Reagila compared with around half of those taking placebo.

What are the risks associated with Reagila?

The most common side effects with Reagila are akathisia (a constant urge to move) and parkinsonism (effects similar to Parkinson's disease such as shaking, muscle stiffness and slow movement). Side effects are mostly mild or moderate.

Reagila must not be taken at the same time as certain other medicines called strong or moderate CYP3A4 inhibitors or inducers.

For the full list of all side effects and restrictions with Reagila, see the package leaflet.

Why is Reagila approved?

As well as studies showing that Reagila improves the positive symptoms of schizophrenia both in the short and longer term, one study also showed that the medicine improved the negative symptoms of the disease which have a large impact on patients' quality of life. Most of the

side effects are as expected with antipsychotic medicines and many can be treated. Therefore, the European Medicines Agency decided that Reagila's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Reagila have been included in the summary of product characteristics and the package leaflet.

Other information about Reagila

The European Commission granted a marketing authorisation valid throughout the European Union for Reagila on 13 July 2017.

For more information about treatment with Reagila, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

Reagila : EPAR - Summary for the public (PDF/76.51 KB)

First published: 18/09/2017
Last updated: 18/09/2017
EMA/339882/2017

Available languages (22)

More detail is available in the summary of product characteristics

This EPAR was last updated on 05/11/2021

Authorisation details

Name
Reagila
Agency product number
EMEA/H/C/002770
Active substance
cariprazine hydrochloride
International non-proprietary name (INN) or common name
cariprazine
Therapeutic area (MeSH)
Schizophrenia
Anatomical therapeutic chemical (ATC) code

N05AX15

Additional monitoring ▼

This medicine is under additional monitoring, meaning that it is monitored even more intensively than other medicines. For more information, see Medicines under additional monitoring.

Marketing-authorisation holder

Gedeon Richter

Revision

4

Date of issue of marketing authorisation valid throughout the European Union

13/07/2017

Contact address

Gyomroi ut 19-21
1103 Budapest
Hungary

Product information

26/10/2021 Reagila - EMEA/H/C/002770 - IB/0024/G

Reagila : EPAR - Product Information (PDF/346.22 KB) (updated)

First published: 18/09/2017
Last updated: 05/11/2021

Available languages (24)

Contents

- Annex I - Summary of product characteristics
- Annex IIA - Manufacturing-authorisation holder responsible for batch release
- Annex IIB - Conditions of the marketing authorisation
- Annex IIIA - Labelling
- Annex IIIB - Package leaflet

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

Reagila : EPAR - All Authorised presentations (PDF/40.32 KB) (updated)

First published: 18/09/2017
Last updated: 05/11/2021

Available languages (24)

Pharmacotherapeutic group

Psycholeptics

Therapeutic indication

Reagila is indicated for the treatment of schizophrenia in adult patients.

Assessment history

Changes since initial authorisation of medicine

Reagila : EPAR - Procedural steps taken and scientific information after authorisation (PDF/161.65 KB) (updated)

First published: 16/02/2018
Last updated: 05/11/2021

Initial marketing-authorisation documents

Reagila : EPAR - Public assessment report (PDF/4.9 MB)

Adopted

First published: 18/09/2017
Last updated: 18/09/2017
EMA/CHMP/353055/2017

CHMP summary of positive opinion for Reagila (PDF/104.84 KB)

Adopted

First published: 19/05/2017
Last updated: 19/05/2017
EMA/309096/2017

News

- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 15-18 May 2017

19/05/2017

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