31 May 2024
EMA/248654/2024
EMEA/H/C/000915/II/0051

Outcome of assessment to extend the use of Valdoxan (agomelatine)

The European Medicines Agency has finalised its assessment of an application to extend the use of the antidepressant Valdoxan to include the treatment of adolescents with moderate to severe depression. Although the company decided not to pursue this use, EMA agreed for the product information to be updated to include the study results submitted for the application.

What is Valdoxan and what is it used for?

Valdoxan is a medicine used to treat major depression in adults. Major depression is a condition in which patients have mood disturbances that interfere with their everyday life. Symptoms often include deep sadness, feelings of worthlessness, loss of interest in favourite activities, sleep disturbances, a feeling of being slowed down, feelings of anxiety and changes in weight.

Valdoxan has been authorised in the EU since February 2009. It contains the active substance agomelatine and is available as tablets.

Further information on Valdoxan's current uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/valdoxan.

What change had the company applied for?

The company applied to extend the use of Valdoxan to treat adolescents aged 12 to 17 years with moderate to severe depressive episodes for whom psychological therapy on its own did not work.

How does Valdoxan work?

The active substance in Valdoxan, agomelatine, is an antidepressant that works by attaching to different receptors (targets) in the brain. This increases the levels of dopamine and noradrenaline, two neurotransmitters (substances used by nerve cells to communicate with neighbouring cells) involved in the control of mood. Increasing their levels is believed to help relieve the symptoms of depression and may also help normalise sleep patterns.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What did the company present to support its application?

The company presented results of a study involving 80 children aged 7 to 11 years and 320 adolescents aged 12 to 17 years with moderate to severe depressive episodes. After three sessions of psychological therapy, they were then given Valdoxan, fluoxetine (another antidepressant) or placebo (a dummy treatment) for 12 weeks. The main aim of the study was to investigate if Valdoxan improved the severity of depressive symptoms in children and adolescents, compared with placebo.

What were EMA's conclusions?

During its assessment, EMA's human medicines committee (CHMP) had concerns on whether the study data were sufficient to show that Valdoxan works in adolescents. The company therefore decided not to pursue this extended use and to withdraw their claim, but asked for the study data to be included in the product information for Valdoxan. As this information was considered to be of interest, the CHMP agreed for the product information to be updated to include study data on the use of Valdoxan in children and adolescents.