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EPAR summary for the public

Thymanax

agomelatine

This is a summary of the European public assessment report (EPAR) for Thymanax. 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 Thymanax.

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

What is Thymanax and what is it used for?

Thymanax 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.

Thymanax contains the active substance agomelatine.

How is Thymanax used?

Thymanax can only be obtained with a prescription and is available as tablets (25 mg).

The recommended dose is one tablet once a day, taken at bedtime. If there is no improvement in symptoms after two weeks, the doctor may increase the dose to two tablets taken together at bedtime. Patients with depression should be treated for at least six months to make sure that they are free of symptoms.

The patient's liver function should be checked with blood tests before starting treatment and when the dose is increased, followed by further tests around 3, 6, 12 and 24 weeks later. Treatment should not be started or should be stopped in patients with abnormal liver enzyme levels in the blood (more than three times the normal level). Treatment should be discontinued immediately if the patient develops symptoms or signs of potential liver injury.

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For further information, see the package leaflet.

How does Thymanax work?

The active substance in Thymanax, agomelatine, is an antidepressant. It works in two ways, by stimulating the MT1 and MT2 receptors and by blocking the 5-HT_{2C} receptors in the brain. This is thought to lead to increases in the levels of the neurotransmitters dopamine and noradrenaline. 'Neurotransmitters' are chemicals that allow nerve cells to communicate with each other. Since dopamine and noradrenaline are involved in the control of mood, their increase between nerve cells in the brain is believed to help relieve the symptoms of depression. Thymanax might also help to normalise the patient's sleep patterns.

What benefits of Thymanax have been shown in studies?

Thymanax has been compared with placebo (a dummy treatment) in five main short-term studies involving a total of 1,893 adults with major depression. Three of these studies included some patients treated with other antidepressants, either fluoxetine or paroxetine, as an 'active comparator'. The active comparator groups were included to check that the study was able to measure the effectiveness of medicines in treating depression. The main measure of effectiveness in these five studies was the change in symptoms after six weeks, as measured on a standard scale for depression called the Hamilton Depression Rating Scale (HAM D). In the two studies where no active comparator was used Thymanax was seen to be more effective than placebo. In the other three studies, which did include an active comparator, there were no differences in scores between the patients taking Thymanax and those taking placebo. However, no effect of fluoxetine or paroxetine was seen in two of these studies, making the results difficult to interpret.

The company also presented the results of a further study comparing Thymanax with sertraline (another antidepressant), which showed that Thymanax was more effective than sertraline, with a reduction in HAM D scores after six weeks.

Two other main studies compared the ability of Thymanax and placebo to prevent symptoms returning in 706 patients whose depression had already been controlled with Thymanax. The main measure of effectiveness was the number of patients whose symptoms returned during 24 to 26 weeks of treatment. In the first study, there was no difference between Thymanax and placebo in preventing symptoms from returning during 26 weeks of treatment. However, the second study showed that symptoms returned in 21% of the patients taking Thymanax over 24 weeks (34 out of 165), compared with 41% of the patients taking placebo (72 out of 174).

What are the risks associated with Thymanax?

The most common side effects with Thymanax (seen in more than 1 patient in 100) are headache, nausea (feeling sick) and dizziness. Most side effects were mild or moderate in intensity, happened within the first two weeks of treatment and were temporary. For the full list of all side effects reported with Thymanax, see the package leaflet.

Thymanax must not be used in patients who have problems with their liver, such as cirrhosis (scarring of the liver) or active liver disease, nor in patients whose level of transaminases (liver enzymes) in the blood is more than three times the normal level. It must also not be used in patients who are taking medicines that slow down the breakdown of Thymanax in the body, such as fluvoxamine (another antidepressant) and ciprofloxacin (an antibiotic). For the full list of restrictions, see the package leaflet.

Why is Thymanax approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that Thymanax's benefits in terms of treating depression might be lower than seen with other antidepressants. However, since the medicine has a different mode of action, few side effects and a different safety profile to existing antidepressants, the Committee concluded that Thymanax could be a valuable treatment for some patients as long as their liver function is tested frequently. Therefore, the CHMP decided that Thymanax's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company that markets Thymanax will supply educational material for doctors prescribing Thymanax. This material explains the safety of the medicine, its interactions with other medicines, and includes guidance on the monitoring of liver function and management of possible symptoms of liver problems. A patient booklet will also be distributed to all patients who are prescribed Thymanax so that they are aware of the risk to the liver, the importance of monitoring liver function and the signs of liver problems to look out for.

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

Other information about Thymanax

The European Commission granted a marketing authorisation valid throughout the European Union for Thymanax on 19 February 2009.

The full EPAR for Thymanax can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Thymanax, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.