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EPAR summary for the public

Sycrest

asenapine

This is a summary of the European public assessment report (EPAR) for Sycrest. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Sycrest.

What is Sycrest?

Sycrest is a medicine that contains the active substance asenapine. It is available as sublingual tablets (5 and 10 mg). Sublingual tablets are tablets that are placed under the tongue, where they dissolve.

What is Sycrest used for?

Sycrest is used to treat moderate to severe manic episodes (extremely high mood) in adults (aged 18 years or over) with bipolar disorder, a mental illness in which patients have periods of abnormally high mood alternating with periods of normal or depressed mood.

The medicine can only be obtained with a prescription.

How is Sycrest used?

The recommended starting dose of Sycrest is 5 mg twice a day, one dose in the morning and one in the evening. This dose can be increased to 10 mg twice a day depending on how the patient responds.

Sycrest tablets should not be chewed or swallowed. When taken in combination with other medicines, Sycrest should be taken last. The patient should avoid eating or drinking for 10 minutes after taking the medicine.

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How does Sycrest work?

The active substance in Sycrest, asenapine, is an antipsychotic medicine. It is known as an 'atypical' antipsychotic because it is different from the older antipsychotic medicines that have been available since the 1950s. Its exact mechanism of action is unknown, but it attaches to several different receptors on the surface of nerve cells in the brain. This disrupts signals transmitted between brain cells by 'neurotransmitters', chemicals that allow nerve cells to communicate with each other. It is thought that Sycrest works by blocking receptors for the neurotransmitters 5-hydroxytrypamine (also called serotonin) and dopamine. Since these neurotransmitters are involved in bipolar disorder, Sycrest helps to normalise the activity of the brain, reducing the symptoms of the disease.

How has Sycrest been studied?

Four main studies looked at the use of Sycrest for manic episodes in bipolar disorder. In two of these studies, a total of 977 adult patients were given Sycrest, olanzapine (another antipsychotic medicine) or placebo (a dummy treatment) over three weeks. The other two studies lasted longer: one compared Sycrest with olanzapine over nine weeks in patients who had come from the short-term studies; and the other was a 12-week 'add on' study, in which 326 patients who were already being treated with another medicine (lithium or valproic acid) were also given either Sycrest or placebo. The main measure of effectiveness was the change in the patients' 'Young mania rating scale' (Y-MRS) score. The Y-MRS rates the severity of symptoms of manic episodes on a scale from 0 to 60.

Sycrest was also studied in patients with schizophrenia. The studies included short- and long-term studies in patients receiving Sycrest, other medicines for schizophrenia (olanzapine, risperidone or haloperidol) or placebo.

What benefit has Sycrest shown during the studies?

Sycrest was effective at treating manic episodes in patients with bipolar disorder. In the first short-term study, the reductions in Y-MRS score after three weeks were 11.5 and 14.6 points for Sycrest and olanzapine, respectively, compared with 7.8 points for placebo. The reductions for the second short-term study were 10.8 and 12.6 points for Sycrest and olanzapine, respectively, and 5.5 for placebo.

In the first long-term study, a reduction in Y-MRS score of 12.9 was seen in patients taking Sycrest compared with 16.2 in patients taking olanzapine. In the second long-term study, the reductions in Y-MRS score were 10.3 and 7.9 for Sycrest and placebo, respectively, after three weeks and 12.7 and 9.3 after 12 weeks.

The studies on schizophrenia were not considered to have shown sufficient evidence of the effectiveness in treating this disease.

What is the risk associated with Sycrest?

The most common side effects with Sycrest (seen in more than 1 patient in 10) are anxiety and somnolence (sleepiness). For the full list of side effects and restrictions, see the package leaflet.

Why has Sycrest been approved?

The CHMP decided that Sycrest's benefits are greater than its risks and recommended that it be given marketing authorisation for the treatment of moderate to severe manic episodes in patients with bipolar disorder.

The CHMP, however, did not recommend that the medicine be authorised to treat schizophrenia because of the lack of effectiveness shown in this illness.

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

A risk management plan has been developed to ensure that Sycrest 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 Sycrest, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Sycrest:

The European Commission granted a marketing authorisation valid throughout the European Union for Sycrest on 1 September 2010.

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

This summary was last updated in 10-2015.