Package leaflet: Information for the patient

Sycrest® 5 mg sublingual tablets
Sycrest® 10 mg sublingual tablets
asenapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Sycrest is and what it is used for

Sycrest contains the active substance asenapine. This medicine belongs to a group of medicines called antipsychotics. Sycrest is used to treat moderate to severe manic episodes associated with bipolar I disorder in adults. Antipsychotic medicines affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain, such as bipolar I disorder, may be due to certain chemicals in the brain, such as dopamine and serotonin, being out of balance and these imbalances may cause some of the symptoms you may be experiencing. Exactly how this medicine works is unknown, however, it is believed to adjust the balance of these chemicals.

Manic episodes associated with bipolar I disorder is a condition with symptoms such as feeling “high”, having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability.

2. What you need to know before you take Sycrest

Do not take Sycrest
If you are allergic to asenapine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Sycrest.

Sycrest has not been studied in elderly patients with dementia. However, elderly patients with dementia, who are treated with other similar types of medicine, may have an increased risk of stroke or death. Sycrest is not approved for the treatment of elderly patients with dementia and is not recommended for use in this particular group of patients.

Sycrest may cause low blood pressure. In the early stages of treatment, some people may faint, especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor. Your dose may need to be adjusted.

Asenapine may cause sleepiness, sudden drops in blood pressure when you stand up, dizziness and changes in your ability to move and balance, which may lead to falls and, consequently, fractures or other injuries. Patients at risk for fall should be evaluated prior to prescribing asenapine.

Tell your doctor immediately if you experience
- involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Sycrest may be needed.
- fever, severe muscle stiffness, sweating or a lowered level of consciousness (a disorder called "neuroleptic malignant syndrome"). Immediate medical treatment may be needed.

Check with your doctor or pharmacist before taking Sycrest:

- if you have ever been diagnosed with a condition whose symptoms include high body temperature and muscle stiffness (also known as neuroleptic malignant syndrome).
- if you have ever experienced abnormal movements of the tongue or face (tardive dyskinesia). You should be aware that both of these conditions may be caused by this type of medicine.
- if you have a heart disease or a treatment for heart disease that makes you prone to low blood pressure
- if you are diabetic or prone to diabetes
- if you have Parkinson's disease or dementia
- if you have epilepsy (seizures)
- if you experience any difficulty in swallowing (dysphagia)
- if you have severe liver problems. If you do, you should not take Sycrest
- if you have difficulty controlling core body temperature
- if you have thoughts of suicide
- if you have abnormally high levels of prolactin in the blood (hyperprolactinaemia)

Be sure to tell your doctor if you meet any of these conditions as he/she may want to adjust your dose or monitor you for a while. Also contact your doctor immediately if any of these conditions develops or worsens while using Sycrest.

Children and adolescents
Sycrest is not recommended for use in patients below the age of 18 years.

Other medicines and Sycrest
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines may reduce or increase the effect of Sycrest.

If you are taking other medicines, Sycrest should be taken last.

You should tell your doctor if you are taking antidepressant medicines (specifically fluvoxamine, paroxetine or fluoxetine), as it may be necessary to change your Sycrest or antidepressant medicine dose.

You should tell your doctor if you are taking medicines for Parkinson's disease (such as levodopa), as this medicine may make them less effective.

Since Sycrest works primarily in the brain, interference from other medicines (or alcohol) that work in the brain could occur due to an additive effect on brain function.

Since Sycrest can lower blood pressure, care should be taken when Sycrest is taken with other medicines that lower blood pressure.

Sycrest with food, drink and alcohol
Do not eat or drink for 10 minutes after taking this medicine.
You should avoid drinking alcohol when taking this medicine.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Sycrest while you are pregnant, unless your doctor tells you so. If you are taking this medicine and you become pregnant or you plan to get pregnant, ask your doctor as soon as possible whether you may continue taking Sycrest.

The following symptoms may occur in newborn babies, of mothers that have used Sycrest in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not breast-feed when taking Sycrest.

Driving and using machines
Sycrest may cause sleepiness or sedation. Therefore, make sure your concentration and alertness are not affected before you drive or operate machinery.

3. How to take Sycrest

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is a sublingual tablet of 5 mg or 10 mg two times a day. One dose should be taken in the morning and one dose should be taken in the evening.

Instructions for use
Sycrest is for sublingual use.
Sycrest is not advised if you are unable to take the tablet as described below. If you are unable to take this medicine as is described below, the treatment may not be effective for you.
- Do not remove a sublingual tablet from the blister until ready to take it.
- Use dry hands when touching the tablet.
- Do not push the tablet through the blister. Do not cut or tear the blister.
- Peel back the coloured tab (Figure 1).
- Gently remove the tablet (Figure 2). Do not crush the tablet.
- To ensure optimal absorption, place the tablet under the tongue and wait until it dissolves completely (Figure 3). The tablet will dissolve in saliva within seconds.
- Do not swallow or chew on the tablet.
- Do not eat or drink for 10 minutes after taking the tablet.

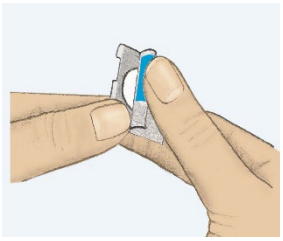
Figure 1


Figure 2

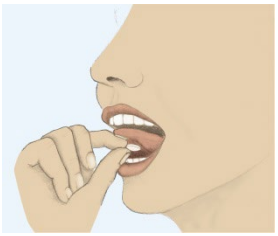
Figure 3

If you take more Sycrest than you should
If you take too much Sycrest, contact a doctor straight away. Take the medicine pack with you. In case of overdose you may feel sleepy or tired, or have abnormal body movements, problems with standing and walking, feel dizzy due to low blood pressure and feel agitated and confused.

If you forget to take Sycrest
Do not take a double dose to make up for a forgotten dose. If you miss one dose, take your next dose as usual. If you miss two or more doses, contact your doctor or pharmacist.

If you stop taking Sycrest
If you stop taking Sycrest, you will lose the effects of this medicine. You should not stop taking this medicine, unless your doctor tells you as your symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects have been reported with this medicine. Seek medical attention immediately if you have any of the following symptoms:
- allergic reactions (These usually involve a combination of effects such as difficulty in breathing or swallowing, swollen face, lips, tongue or throat, skin rash, itching and increased heart rate.)
- sudden increase in body temperature, with sweating, fast heartbeat, severe muscle stiffness, confusion and fluctuating blood pressure which may lead to coma
- convulsions, fits or seizures
- fainting
- falls which may occur as a result of one or more adverse events such as: sleepiness, sudden drops in blood pressure when you stand up, dizziness and changes in your ability to move and balance.

Tell your doctor right away if you have:
- signs of increased blood sugar levels such as excessive thirst, hunger or urination, weakness or onset of worsening of diabetes
- worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to arms and legs

Other side effects reported with this medicine include:

Very common side effects (may affect more than 1 in 10 people)
- anxiety
- sleepiness

Common side effects (may affect up to 1 in 10 people)
- weight gain
- increased appetite
- slow or sustained muscle contractions
- restlessness
- involuntary muscle contractions
- slow movements, tremor
- sedation
- dizziness
- nausea
- change in taste
- numb feeling of the tongue or in the mouth
- increased saliva (drooling)
- muscle tightness
- fatigue
- increase in the level of liver proteins

Uncommon side effects (may affect up to 1 in 100 people)
- abnormal muscle movements: a collection of symptoms known as extrapyramidal symptoms (EPS) which may include one or more of the following: abnormal movements of muscles, tongue, or jaw, slow or sustained muscle contractions, muscle spasms, tremor (shaking), abnormal movements of the eyes, involuntary muscle contractions, slow movements, or restlessness
- unpleasant sensations in the legs (also called restless legs syndrome)
- speech problems
- abnormal slow or fast heartbeat
- middle heart block
- abnormal electrocardiogram (prolongation of the QT interval)
- low blood pressure upon standing
- low blood pressure
- tingling of the tongue or in the mouth
- swollen or painful tongue
- difficulty in swallowing
- ulcers, soreness, redness, swelling, and blisters within the mouth
- sexual dysfunction
- lack of regular menstrual periods

Rare side effects (may affect up to 1 in 1,000 people)
- changes in the levels of white blood cells
- difficulties in focusing with the eyes
- blood clots in blood vessels to the lungs causing chest pain and difficulty in breathing
- muscle disease presenting as unexplained aches and pains
- male breast enlargement
- leakage of milk or fluid from the breast

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sycrest

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton. The expiry date refers to the last day of that month.

Store this medicine in the original package in order to protect from light and moisture.

This medicinal product does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sycrest contains
– The active substance is asenapine.
– Each Sycrest 5 mg sublingual tablet contains 5 mg asenapine.
– Each Sycrest 10 mg sublingual tablet contains 10 mg asenapine.
– The exact amount is shown on your Sycrest tablet pack.

– The other ingredients are gelatin and mannitol (E421).

What Sycrest looks like and contents of the pack
The 5 mg sublingual tablets are round white to off-white tablets marked with “5” on one side.
The 10 mg sublingual tablets are round white to off-white tablets marked with “10” on one side.

The sublingual tablets are provided in peelable blisters containing 10 tablets each. Packs may contain 20, 60 or 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holders
Marketing Authorisation Holder in Great Britain: Organon Pharma (UK) Limited, The Hewett Building, 14 Hewett Street, London EC2A 3NP, United Kingdom.

Marketing Authorisation Holder in UK (Northern Ireland): N.V. Organon, Kloosterstraat 6, NL-5349 AB Oss, The Netherlands.

Manufacturer
Organon Heist bv, Industriepark 30, 2220 Heist-op-den-Berg, Belgium.

For any information about this medicine, please contact:

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medicalinformationuk@organon.com

This leaflet was last revised in December 2022.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

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