

SAPHRIS[®] SUBLINGUAL TABLET

Asenapine (5mg, 10mg)

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What SAPHRIS SUBLINGUAL TABLET is used for

SAPHRIS SUBLINGUAL TABLET belongs to a group of medicines called antipsychotics. SAPHRIS SUBLINGUAL TABLET is used to treat schizophrenia, acute treatment of manic or mixed episodes associated with bipolar I disorder.

Schizophrenia is a disease with symptoms such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech and behaviour, and emotional flatness. People with this disease may also feel depressed, anxious, guilty or tense.

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.

How SAPHRIS SUBLINGUAL TABLET works

SAPHRIS SUBLINGUAL TABLET is thought to work by blocking receptors in the brain for treatment of schizophrenia and bipolar I disorder.

Before you take SAPHRIS SUBLINGUAL TABLET

When you must not take it

- if you are allergic (hypersensitive) to asenapine or any of the other ingredients.
- If you have diabetes or risk factors for diabetes, such as being overweight or a family history of diabetes, your blood sugar should be tested at the beginning of and throughout treatment with SAPHRIS SUBLINGUAL TABLET.
- If you are pregnant or breastfeeding, unless your doctor tells you so.
- If you are below 18 years of age.

If you are not sure whether you should start taking SAPHRIS SUBLINGUAL TABLET, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if:

you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

you have or have had any medical conditions, especially the following:

- dementia (in elderly patients)
- Parkinson's disease
- heart disease / low blood pressure
- liver disease
- diabetes or family history of diabetes
- difficulty in swallowing
- epilepsy (seizures)
- higher levels of the hormone, prolactin, in your blood
- neuroleptic malignant syndrome - a reaction to some medicines with a sudden increase in body temperature, extremely high blood pressure and severe convulsions
- tardive dyskinesia - a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaws which may progress to the arms and legs

Depression and other mental illnesses can lead to suicide. It is important to discuss all the risks of treating depression and mental illness as well as the risks of not

treating it. You should discuss all treatment choices with your doctor, not just the use of anti-depressants. Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present.

If you have not told your doctor about any of the above, tell him/her before you start taking SAPHRIS SUBLINGUAL TABLET.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should tell your doctor if you are taking antidepressant drugs (specifically fluvoxamine, paroxetine or fluoxetine), as it may be necessary to change your SAPHRIS SUBLINGUAL TABLET or antidepressant drug dose.

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

Taking SAPHRIS SUBLINGUAL TABLET with food and drink

Do not eat or drink for 10 minutes after taking the tablet.

Do not drink alcohol when taking SAPHRIS SUBLINGUAL TABLET.

Take special care with SAPHRIS SUBLINGUAL TABLET
SAPHRIS SUBLINGUAL TABLET has not been studied in

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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. SAPHRIS SUBLINGUAL TABLET is not approved for the treatment of elderly patients with dementia and is not recommended for use in this particular group of patients.

In the early stages of treatment, some people may faint, especially when getting up from a lying or sitting position. This is more likely to happen if you are elderly. This will usually pass on its own but if it does not, tell your doctor.

Children and adolescents

Use of SAPHRIS SUBLINGUAL TABLET below the age of 18 years is not recommended due to lack of information on whether it is safe and effective in this age group.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

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

The following symptoms may occur in newborn babies, of mothers that have used antipsychotics 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 SAPHRIS SUBLINGUAL TABLET.

Driving and using machines

SAPHRIS SUBLINGUAL TABLET may affect your concentration or alertness. Make sure these abilities are not affected before you drive or operate machinery.

How to take SAPHRIS SUBLINGUAL TABLET

How much to take

Always take SAPHRIS SUBLINGUAL TABLET exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is a tablet of 5 or 10 mg two times a day.

Do not remove a tablet until ready to take it. Use dry hands when touching the tablet. Do not push the tablet through the tablet pack. Do not cut or tear the tablet pack. Peel back the colored tab (Figure 1).

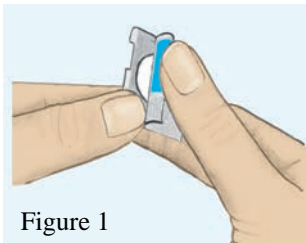


Figure 1

Gently remove the tablet (Figure 2). Do not crush the tablet.

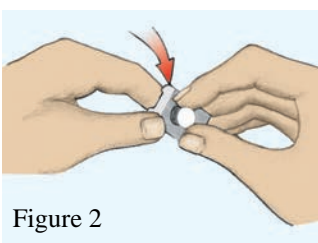


Figure 2

To ensure optimal absorption, place the tablet under the tongue and wait until it dissolves completely (Figure 3).

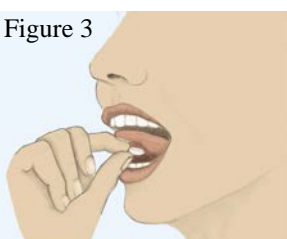


Figure 3

The tablet will dissolve in saliva within seconds. Do not swallow or chew the tablet. Do not eat or drink for 10 minutes after taking the tablet.

When to take it

Use as directed by your doctor or pharmacist.

How long to take it

Continue taking SAPHRIS for as long as your doctor recommends.

If you forget to take it

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.

If you take too much (overdose)

If you take too much SAPHRIS SUBLINGUAL TABLET, contact a doctor straight away. You may feel agitated and confused.

If you stop taking SAPHRIS SUBLINGUAL TABLET

If you stop taking SAPHRIS SUBLINGUAL TABLET, 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.

While you are taking SAPHRIS SUBLINGUAL TABLET

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking SAPHRIS SUBLINGUAL TABLET.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking SAPHRIS SUBLINGUAL TABLET.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking SAPHRIS SUBLINGUAL TABLET.

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If you become pregnant while taking SAPHRIS SUBLINGUAL TABLET, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking SAPHRIS SUBLINGUAL TABLET. SAPHRIS SUBLINGUAL TABLET may interfere with the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some blood tests from time to time. This helps to reduce unwanted side effects.

If you or someone you know is demonstrating any of the following warning signs of suicide while taking SAPHRIS SUBLINGUAL TABLET, contact your doctor or mental health professional immediately or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. These symptoms may continue or get worse during the early stages of treatment until the effect of the medicine becomes apparent. All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not give SAPHRIS SUBLINGUAL TABLET to anyone else, even if they have the same condition as you.

Do not take SAPHRIS SUBLINGUAL TABLET to treat any other complaints unless your doctor tells you to.

Do not stop taking SAPHRIS SUBLINGUAL TABLET, or change the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking SAPHRIS SUBLINGUAL TABLET suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of SAPHRIS SUBLINGUAL TABLET you take each day before stopping completely.

Do not take any medicines that cause drowsiness while you are taking SAPHRIS SUBLINGUAL TABLET, unless recommended by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how SAPHRIS SUBLINGUAL TABLET affects you. SAPHRIS SUBLINGUAL TABLET may cause dizziness, and tiredness, in some people. Make sure you know how you react to SAPHRIS SUBLINGUAL TABLET before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or sleepy.

If SAPHRIS SUBLINGUAL TABLET makes you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful when drinking alcohol while taking SAPHRIS SUBLINGUAL TABLET.

Combining SAPHRIS SUBLINGUAL TABLET and alcohol can make you more sleepy or dizzy.

Your doctor may suggest you to avoid alcohol while you are being treated with SAPHRIS SUBLINGUAL TABLET.

Make sure you keep cool in hot weather and keep warm in cool weather.

SAPHRIS SUBLINGUAL TABLET may affect the way your body reacts to temperature changes.

Side effects

Like all medicines, SAPHRIS SUBLINGUAL TABLET can cause side effects, although not everybody gets them.

The most common side effects of SAPHRIS SUBLINGUAL TABLET include:

- Sleepiness
- 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 or slow movements
- Restlessness
- Weight gain
- Dizziness
- Sensation of numbness in the tongue or mouth

Tell your doctor or pharmacist if you notice these or any of the following side effects and they worry you:

- dry mouth
- indigestion
- constipation or stomach discomfort
- increased saliva (drooling)
- vomiting
- tingling of the tongue or in the mouth
- swollen or painful tongue
- difficulty swallowing
- mouth ulcers and pain in the mouth
- fatigue
- irritability
- increased appetite
- anxiety
- difficulty sleeping
- depression

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- headache
- nausea
- change in taste
- joint pain, or pain in limb, hand or foot
- swelling of hands or feet
- speech problems
- difficulties focusing the eyes

Call your doctor or go to the nearest hospital emergency room right away if you have any of the following symptoms. SAPHRIS SUBLINGUAL TABLET may be associated with these serious side effects:

- Sudden increase in body temperature, with sweating, fast heart beat, severe muscle stiffness, confusion and fluctuating blood pressure which may lead to coma
- Worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to arms and legs
- Fainting
- Signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- Convulsions, fits or seizures
- Sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.

Occasionally, SAPHRIS may be associated with:

- Changes in liver function or blood such as cholesterol or triglyceride levels. These can only be found when your doctor does tests from time to time to check your progress.
- Increased blood sugar levels. Tell your doctor or pharmacist if you have excessive thirst, hunger, and/or urination, weakness, onset or worsening of diabetes.
- Changes in blood pressure (high blood pressure, or low blood pressure on standing).
- Anemia (low red blood cells or low hemoglobin) or low blood platelets.

- Low sodium levels in the blood.
- Irregular heartbeat, middle heart block.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of SAPHRIS SUBLINGUAL TABLET

Storage

- Keep out of the reach and sight of children.
- Do not use SAPHRIS SUBLINGUAL TABLET 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 at 2°-30°C.
- Store in the original package in order to protect from light and moisture.

Disposal

- Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

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 tablets are wrapped in aluminium / aluminium blister strips

in carton of 20, or 60 tablets per carton.

Not all pack sizes may be marketed.

Ingredients

The active substance is asenapine. The other ingredients are gelatin and mannitol (E421).

MAL Number

SAPHRIS SUBLINGUAL TABLET 5MG:
MAL20112129ACR

SAPHRIS SUBLINGUAL TABLET 10MG:
MAL20112130ACR

Manufacturer

Catalent UK Swindon Zydis Ltd.,
Frankland Road, Blagrove,
Swindon, Wiltshire,
SN5 8RU, United Kingdom.

Product Registration Holder

Merck Sharp & Dohme
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46100 Petaling Jaya,
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