

SAPHRIS®

5mg and 10mg sublingual wafers

Asenapine (as maleate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SAPHRIS.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SAPHRIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What SAPHRIS is used for

SAPHRIS is used to treat the mental illnesses:

- Schizophrenia - an illness with disturbances in thinking, feelings and behaviour.
- Bipolar 1 disorder - an illness in which there are sustained mood swings either up (mania) or down (low moods). During mania, patients experience episodes of overactivity, elation or irritability. During low moods, patients may feel depressed or guilty, lack energy, lose their appetite and have trouble sleeping.

SAPHRIS belongs to a group of medicines called antipsychotics. It

helps to correct chemical imbalances in the brain, which may cause these mental illnesses.

Your doctor may have prescribed SAPHRIS for another reason.

Ask your doctor if you have any questions about why SAPHRIS has been prescribed for you.

SAPHRIS is not addictive.

This medicine is available only with a doctor's prescription.

Before you take SAPHRIS

When you must not take it

Do not take SAPHRIS if you have an allergy to:

- **asenapine the active ingredient in SAPHRIS**
- **any of the other ingredients listed at the end of this leaflet**

Some of the symptoms of an allergic reaction to SAPHRIS may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin or you may feel faint.

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. Complications of diabetes can be serious and even life-threatening. Tell your doctor if you have blood sugar problems or signs of diabetes, such as being

thirsty all the time, going to the bathroom a lot, or feeling weak or hungry.

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.

Do not take SAPHRIS if you are pregnant or breast-feeding unless your doctor tells you so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take SAPHRIS while you are pregnant. However, if you need to take SAPHRIS during your pregnancy, the doctor will discuss the risks and benefits of taking it with you.

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 contact your doctor.

It is recommended that you do not breast-feed while taking SAPHRIS.

SAPHRIS is not recommended for use in children below 18 years of age.

Do not take SAPHRIS after the expiry date printed on the pack.

Do not use SAPHRIS if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking SAPHRIS, 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) or dementia with Lewy Bodies
- 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.

The long-term safety and effectiveness of SAPHRIS beyond 12 weeks has not been assessed in Bipolar disorder.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and SAPHRIS may interfere with each other.

These may include:

- blood pressure lowering medicines
- antidepressant drugs (e.g. paroxetine, fluvoxamine or fluoxetine)

These medicines may be affected by SAPHRIS, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Other medicines not listed above may also interfere with SAPHRIS. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Use in children

SAPHRIS is not recommended for use in children below 18 years of age.

How to take Saphris

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

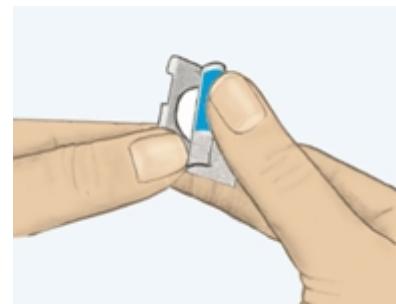
The dose of SAPHRIS is one wafer to be taken twice a day. Your doctor will tell you how many wafers you will need to take each day and how long you need to take it. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Do not remove the wafer until ready to take.

Use dry hands when handling the wafer.

Do not push the wafer through the blister. Do not cut or tear the blister. Peel back the coloured tab.



Gently remove the wafer from the blister. Do not crush the wafer.



Place the wafer under your tongue and allow it to completely dissolve.



Do not chew or swallow the wafer.

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

Otherwise SAPHRIS will not be absorbed completely and it may not work as effectively.

How long to take it

Continue taking the wafers for as long as your doctor tells you.

SAPHRIS helps control your condition, but does not cure it. Therefore you must take SAPHRIS every day.

Do not stop taking SAPHRIS unless your doctor tells you to - even if you feel better.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at the nearest hospital, if you think that you or

anyone else may have taken too much SAPHRIS. Do this even if there are no signs of discomfort or poisoning.

Keep telephone numbers for these places handy.

You may need urgent medical attention.

If you take too much SAPHRIS, you may feel restless, confused, drowsy, dizzy, sleepy or have a fast heart beat.

While you are taking SAPHRIS

Things you must do

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

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

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

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

If you are about to have any blood tests, tell your doctor that you are taking SAPHRIS. SAPHRIS 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, 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 to anyone else, even if they have the same condition as you.

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

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

If you stop taking SAPHRIS 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 you take each day before stopping completely.

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

Things to be careful of

Be careful driving or operating machinery until you know how SAPHRIS affects you.

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

If SAPHRIS 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.

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

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

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SAPHRIS.

SAPHRIS helps most people with the symptoms of schizophrenia or with manic episodes associated with Bipolar 1 disorder. But it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Therefore, it is important that you tell your doctor as soon as possible if you notice anything that is making you feel unwell, even if you think the problems are not connected with the medicine. Your doctor may then decide to adjust your dose or use a different medicine.

Ask your doctor or pharmacist to answer any questions you may have.

The following is a list of possible side effects. Do not be alarmed by

this list. You may not experience any of them.

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

- sleepiness
- increased appetite, weight gain
- drowsiness
- tremor
- sensation of numbness in the mouth
- dizziness
- change in taste
- fatigue
- dry mouth
- mouth ulcers and pain in the mouth
- increased saliva (drooling)
- nausea
- constipation
- restlessness, agitation, anxiety, excitement or difficulty concentrating
- an overwhelming urge to move such as feeling the need to pace, swing the legs while seated or rock from foot to foot
- difficulty sleeping
- headache
- hot, dry skin
- increased or decreased sweating
- signs of increased blood sugar levels such as excessive thirst, hunger, weakness, urination or onset or worsening of diabetes.
- falls 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.

These side effects are usually mild. Some of these side effects may go away after a while.

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- extremely high body temperature
- worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks, or jaw which may progress to arms and legs
- sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body
- fainting
- convulsions, fits or seizures
- severe spasms in the muscles of the shoulders, neck and upper body
- sudden increase in body temperature, with sweating, fast heart beat, muscle stiffness and fluctuating blood pressure which may lead to coma
- abnormal electrocardiogram (prolongation of the QT interval)
- 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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Saphris

Storage

Keep your wafers in the original packaging until it is time to take them to protect them from light and moisture.

If you take the wafers out of their packaging, they will not keep well.

Keep your wafers in a cool dry place where the temperature stays below 30°C.

Do not store SAPHRIS or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking SAPHRIS or the wafers have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SAPHRIS wafers come in two strengths.

5mg - white to off-white round wafer with a "5" marking on one side.

10mg - white to off-white round wafer with a "10" marking on one side.

SAPHRIS is available in Al/Al blister packs of 20, 60 and 100 wafers*.

*Not all pack sizes may be available.

Ingredients

Active ingredients:

SAPHRIS 5mg - 5mg asenapine

SAPHRIS 10mg - 10mg asenapine

Other ingredients:

- gelatin
- mannitol

Sponsor

Organon Pharma Pty Ltd
Building A, 26 Talavera Road
Macquarie Park, NSW 2113
Australia

This leaflet was revised in December 2020.

AUST R number(s):

SAPHRIS 5 mg AUST R 166562

SAPHRIS 10mg AUST R 166561

* Not all pack sizes may be marketed.

Ref no: S-CCPPI-MK8274 -SB-T-102017

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