PART III: CONSUMER INFORMATION
SAPHRIS®
(asenapine sublingual tablets)

This leaflet is part III of a three-part "Product Monograph" published when SAPHRIS® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about SAPHRIS®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
SAPHRIS® (asenapine) sublingual tablet is used to treat schizophrenia and manic or mixed episodes associated with bipolar I disorder in adults.

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such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech and behaviour, and emotional flatness.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.

SAPHRIS® is not a cure for your condition, but it can help manage your symptoms and reduce the risk of relapse.

What it does:
SAPHRIS® belongs to a group of medicines called atypical antipsychotic drugs.

Antipsychotic medications affect the chemicals that allow communication between nerve cells (neurotransmitters). Illnesses that affect the brain, such as schizophrenia, may be due to certain chemicals in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Doctors and scientists are not sure what causes these imbalances to occur. Exactly how SAPHRIS® works is unknown. However, it seems to adjust the balance of chemicals called dopamine and serotonin.

When it should not be used:
Do not take SAPHRIS® if you are allergic (hypersensitive) to asenapine or any of the other ingredients listed in the "Nonmedicinal Ingredients" section of this leaflet. Serious allergic reactions have been observed in patients treated with asenapine. Signs of allergic reaction may include difficulty breathing, rash, itching, swelling of the face, lips, tongue or throat, or feeling lightheaded.

What the medicinal ingredient is:
SAPHRIS® sublingual tablets contain the active ingredient called asenapine.

What the nonmedicinal ingredients are:
SAPHRIS® sublingual tablets contain the following inactive ingredients: gelatin and mannitol.

What dosage forms it comes in:
SAPHRIS® sublingual tablets are available in 5 mg and 10 mg strengths.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
Various medicines of the group to which SAPHRIS® belongs have been associated with an increased rate of death when used in elderly patients with dementia. SAPHRIS® is not indicated in elderly patients with dementia.

Serious allergic reactions have been observed in patients treated with asenapine. Signs of allergic reaction may include difficulty breathing, rash, itching, swelling of the face, lips, tongue or throat, or feeling lightheaded. In several cases, these reactions occurred after the first dose. Seek immediate emergency assistance if you develop any of these signs or symptoms.

BEFORE you use SAPHRIS® talk to your doctor or pharmacist if you:

- have ever been diagnosed with a condition whose symptoms include high body temperature and muscle stiffness (also known as Neuroleptic Malignant Syndrome)
- have ever experienced abnormal movements of the tongue or face (also known as Tardive Dyskinesia)

You should be aware that both of these conditions may be caused by this type of medicine.

- are taking any other medicines (prescription or over the counter medicines)
- have heart disease, have had a stroke or "mini" stroke, or have a family history of these conditions.
- are taking a heart disease treatment that makes you prone to low blood pressure
- are diabetic or prone to diabetes (high blood sugar or family history of diabetes)
- have epilepsy (seizures)
- experience any difficulty in swallowing (dysphagia)
- have severe liver function problems. If you do, you should not take SAPHRIS®.
- exercise vigorously, work in hot sunny places, or have difficulty controlling core body temperature
- have thoughts of suicide
- have an increased level of the hormone prolactin in your blood (hyperprolactinemia)
- have low white blood cell counts
- have risk factors for developing blood clots such as: a family history of blood clots, age over 65, smoking,

obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, take oral contraceptives ("The Pill")
- drink alcoholic beverages or use recreational drugs
- have ever abused drugs

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 if any of these conditions develops or worsens while using SAPHRIS®.

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. Certain medications, diseases or conditions can make this worse. Patients at risk for fall should be evaluated prior to prescribing asenapine.

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

Do not breast-feed when taking SAPHRIS®.

Effects on newborns
In some cases, babies born to a mother taking an antipsychotic medication during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek emergency medical attention for your newborn, if he/she has difficulty breathing, is overly sleepy, has muscle stiffness or floppy muscles (like a rag doll), is shaking or is having difficulty feeding.

INTERACTIONS WITH THIS MEDICATION

Tell all doctors, dentists and pharmacists who are treating you that you are taking SAPHRIS®.

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), as it may be necessary to change your SAPHRIS® or antidepressant drug dose.

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

Do not drink alcohol when taking SAPHRIS®.

Only take other medicines while you are on SAPHRIS® if your doctor tells you that you can.

PROPER USE OF THIS MEDICATION

Usual dose:
Always take SAPHRIS® 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. Peel back the colored 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 the tablet. Do not eat or drink for 10 minutes after taking the tablet (Figure 4). When taking SAPHRIS® at the same time as your other oral medication, SAPHRIS® should be taken last and only after having swallowed the other medication and had your drink of water or other liquids.

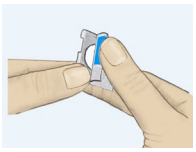
Figure 1

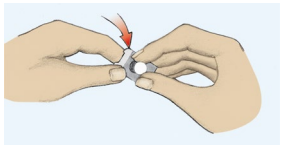
Figure 2


Figure 3

Figure 4

If you stop taking SAPHRIS®, you will lose the effects of this medicine. Even if you feel better, do not stop taking SAPHRIS® or change the times of day you take SAPHRIS® without first consulting your doctor. If your symptoms improve or disappear, it is probably because your treatment is working. SAPHRIS® should be taken for as long as you and your doctor believe it is helping you.

Do not give SAPHRIS® to anyone else. Your doctor has prescribed it for you and your condition. SAPHRIS® is not recommended for use in children under 18 years of age.

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

Overdose:

If you have taken more SAPHRIS® sublingual tablets than your doctor has recommended, contact your regional Poison Control Centre, talk to your doctor right away or go to your nearest hospital emergency department. Take the medication package with you. You may feel agitated and confused.

Missed Dose:
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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medicines, SAPHRIS® can cause some side effects. These side effects are most likely to be minor and temporary. However, some may be serious and need medical attention.

Serious allergic reactions have been observed in patients treated with asenapine. Signs of allergic reaction may include difficulty breathing, rash, itching, swelling of the face, lips, tongue or throat, or feeling lightheaded. In several cases, these reactions occurred after the first dose. Seek immediate emergency assistance if you develop any of these signs or symptoms.

The most common side effects of SAPHRIS® are:
- sleepiness
- weight gain
- increased appetite
- drowsiness
- restlessness
- slow movements and tremor
- slow or sustained muscle contractions
- dizziness
- change in taste
- involuntary muscle contractions
- sensation of numbness in the tongue or mouth
- fatigue
- increase in the level of liver proteins

Uncommon side effects include:
- fainting episode
- convulsion
- 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
- speech problems
- abnormal slow or fast heartbeat
- middle heart block
- low blood pressure upon standing
- tingling of the tongue or in the mouth
- swollen face, lips or painful tongue
- difficulty in swallowing
- mouth ulcers or blisters and pain in the mouth

Rare side effects include:
- Neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness)
- Serious allergic reactions
- Difficulties in focusing with the eyes
- Increased saliva (drooling)
- Anxiety

Your doctor should check your body weight before starting SAPHRIS® and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting SAPHRIS®. They will monitor blood sugar, and for those with certain risk factors, the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

In the early stages of treatment, some people may faint, or experience symptoms such as light-headedness and dizziness, 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.

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.

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

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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency help**
		Only if severe	**In all cases**	
Common	Muscle spasm		✓	
	Tremor (involuntary trembling or quivering)		✓	
Uncommon	Pronounced muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			✓
	Seizure (i.e. loss of consciousness with uncontrollable shaking)			✓
	Fainting			✓
	Abnormal movement of tongue or face		✓	
	Difficulty swallowing		✓	
	Allergic reaction (symptoms include difficulty breathing, rash, itching, swelling of the face, lips, tongue, throat, or feeling lightheaded)			✓
	Long-lasting (greater than 4 hours in duration) and painful erection of the penis.			✓
	New or worsening constipation			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency help**
		Only if severe	**In all cases**	
Unknown	Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations		✓	

This is not a complete list of side effects. For any unexpected effects while taking SAPHRIS®, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children.

SAPHRIS® should be stored between 2° C to 30° C. Do not use SAPHRIS® 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 in the original package.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:

- Fax to 1-866-678-6789 (toll-free), or
- Mail to: Canada Vigilance Program

Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

If you want more information about SAPHRIS®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website or by contacting Organon Canada Inc. at 1-844-820-5468.

This leaflet was prepared by Organon Canada Inc.

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