PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine requires a doctor's prescription.

Read this package insert carefully in its entirety before using this medicine.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in November 2011.

SAPHRIS® 5 mg
Sublingual Tablets

SAPHRIS® 10 mg
Sublingual Tablets

COMPOSITION
Each sublingual tablet contains:
Saphris 5 mg: 5 mg of Asenapine

Saphris 10 mg: 10 mg of Asenapine

Inactive Ingredients:

Gelatin, Mannitol.

THERAPEUTIC GROUP: Antipsychotics

THERAPEUTIC ACTIVITY
Saphris is used to treat schizophrenia and manic episodes associated with bipolar I disorder.

WHEN SHOULD THE PREPARATION NOT BE USED?
- Do not use this medicine if you are allergic to asenapine or any of the other ingredients.
- 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.
- Do not use this medicine if you have severe liver function problems.
- Do not use this medicine in elderly patients with dementia.

DO NOT TAKE THIS MEDICINE WITHOUT CONSULTING A DOCTOR BEFORE STARTING TREATMENT
- if you are breastfeeding
- 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 heart disease treatment that makes you prone to low blood pressure
- if you are diabetic or prone to diabetes
- if you have epilepsy (seizures)
- if you experience any difficulty in swallowing (dysphagia)
- if you have difficulty controlling core body temperature
- if you have thoughts of suicide

- if you suffer from dehydration or low blood volume (hypovolemia)
- If you suffer from low white blood cells count
- if you have an increased level of the hormone prolactin in your 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 if any of these conditions develops or worsens while using Saphris.

Use of this medicine in patients below the age of 18 years is not recommended.

HOW WILL THIS MEDICINE AFFECT YOUR DAILY LIFE?

Use of this medicine may reduce alertness and therefore caution should be exercised when driving a car, operating dangerous machinery or performing any other activities requiring alertness.

Do not drink wine or alcoholic beverages while under treatment with this medicine.

WARNINGS

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.
This medicine may cause low blood pressure upon standing. In this case, getting up from a lying or sitting position should be gradual (see "SIDE EFFECTS").
Problem controlling core body temperature had been rarely reported while using this medicine, therefore caution should be taken while exercising strenuously, exposed to extreme heat, and taking medicines with anticholinergic activity.

DRUG INTERACTIONS

If you are taking another medicine concomitantly including medicines obtained without a prescription or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.
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 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.
Avoid taking medicines that prolong the QT interval.

SIDE EFFECTS

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example:

Very common side effects (affect more than 1 user in 10)
- Sleepiness

Common side effects (affect 1 to 10 users in 100)
- 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 (affect 1 to 10 users in 1,000)
- 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 or painful tongue
- Difficulty in swallowing

Rare side effects (affect 1 to 10 users in 10,000)
− Neuroleptic malignant syndrome (confusion, reduced or loss of consciousness, high fever, and severe muscle stiffness)
− Difficulties in focusing with the eyes

Side effects with unknown frequency
- Increased blood sugar level symptoms including excessive thirst, increased appetite and frequent urination
- Allergic reactions, infections, leakage of milk from the breast, breast enlargement, lack of regular menstrual periods, sexual dysfunction

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.

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

SIDE EFFECTS WHICH REQUIRE SPECIAL ATTENTION

Tell your doctor immediately if you experience:
− involuntary rhythmic movements of the tongue, mouth and face. Withdrawal of Saphris 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.
− serious allergic reactions (signs and symptoms of a serious allergic reaction may include difficulty breathing, rash, itching, swelling of the face, lips, tongue or throat, feeling lightheaded etc.). Seek immediate emergency assistance if you develop any of these signs and symptoms.

DOSAGE

Dosage is according to doctor's instructions only.
This medicine is not intended to be used in children.
Do not exceed the recommended dosage.
This medicine should be taken at specific time intervals as determined by the attending doctor.

If you have forgotten to take a dose at the specified time, wait and take your next dose as usual. Do not take a double dose to make up for a forgotten dose. If you miss two or more doses, contact your doctor.
If you stop taking Saphris, 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.

DIRECTIONS FOR USE

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

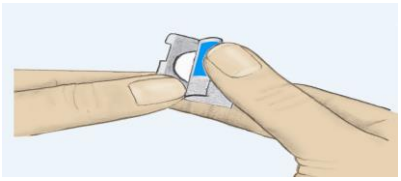

Figure 1

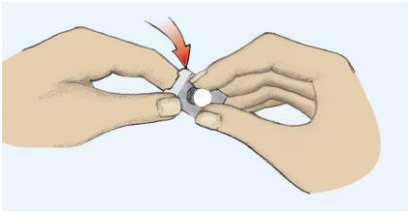

Figure 2

Figure 3

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

HOW CAN YOU CONTRIBUTE TO THE SUCCESS OF THE TREATMENT?

Complete the full course of treatment as instructed by the doctor.
Even if there is an improvement in your health, do not discontinue use of this medicine, before consulting your doctor.

AVOID POISONING!

This medicine, and all other medicines, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
Do not induce vomiting unless explicitly instructed to do so by a doctor!
This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. **Do not give this medicine to your relatives, neighbours or acquaintances.**
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

STORAGE

Store at 15ºC to 30ºC. Keep out of the reach and sight of children.
Store in the original package in order to protect from light and moisture. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package**.**
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.

DRUG REGISTRATION NUMBERS

Saphris 5 mg: 146 04 33228 00
Saphris 10 mg: 146 05 33229 00

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