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Saphris

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Generic name: asenapine (sublingual) [a-SEN-a-peen]

Drug class: Atypical antipsychotics

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Uses Warnings Before taking Dosage Side effects Interactions

What is Saphris?

Saphris is an antipsychotic medication. It works by changing the actions of chemicals in the brain.

Saphris sublingual tablets are used to treat schizophrenia in adults, and bipolar I disorder in adults and children who are at least 10 years old.

Saphris may used alone. In adults it may be used in conjuction with lithium or valproate.

Warnings

You should not use Saphris if you are allergic to asenapine, or if you have severe liver disease.

Saphris is not approved for use in older adults with dementia-related psychosis.

Saphris can cause serious neurologic problems. **Stop taking this medicine and call your doctor at once if you have**: very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, feeling light-headed, tremors, twitching, or uncontrollable movements of your eyes, lips, tongue, face, arms, or legs.

Before taking this medicine

You should not use Saphris if you are allergic to asenapine, or if you have:

· severe liver disease.

Asenapine may increase the risk of death in older adults with dementia-related psychosis and is not approved for this use.

To make sure Saphris is safe for you, tell your doctor if you have:

- · heart problems;
- high blood pressure;

- a heart attack or stroke;
- · diabetes (asenapine may raise your blood sugar);
- a seizure:
- · liver disease:
- breast cancer;
- trouble swallowing;
- Parkinson's disease;
- · low white blood cell (WBC) counts; or
- long QT syndrome (in you or a family member).

Taking antipsychotic medicine in the last 3 months of pregnancy may cause breathing problems, feeding problems, or withdrawal symptoms in the newborn. If you get pregnant, tell your doctor right away. Do not stop taking Saphris without your doctor's advice.

It may not be safe to breastfeed while using this medicine. Ask your doctor about any risk.

Saphris should not be given to a child younger than 10 years old. Saphris is not approved for schizophrenia in anyone younger than 18 years old.

Saphris pregnancy and breastfeeding warnings (more detail)

How should I take Saphris?

Saphris is usually taken 2 times per day. Follow all directions on your prescription label and read all medication guides or instruction sheets.

Read and carefully follow any Instructions for Use provided with your medicine. Ask your doctor or pharmacist if you do not understand these instructions.

Keep the tablet in its blister pack until you are ready to take the medicine. Using dry hands, gently remove the tablet and place it under your tongue.

Do not swallow the sublingual tablet. Allow it to dissolve under your tongue without chewing.

Do not eat or drink anything for 10 minutes after the tablet has dissolved.

Saphris may cause you to have high blood sugar (hyperglycemia). Symptoms include increased thirst, increased urination, hunger, dry mouth, fruity breath odor, drowsiness, dry skin, and blurred vision. If you are diabetic, check your blood sugar levels on a regular basis while you are taking Saphris.

Your doctor will need to check your progress while you are using Saphris.

Store at room temperature away from moisture and heat.

Dosing information

Usual Adult Dose for Schizophrenia:

Initial dose: 5 mg sublingually 2 times a day

Maintenance dose: 5 mg sublingually 2 times a day, if tolerated may increase to 10 mg sublingually 2 times a day after 1

week if necessary

Maximum dose: 20 mg/day

Comments:

- -Controlled trials revealed no added benefit with the higher dose, but a clear increase in certain adverse reactions.
- -The safety of doses above 20 mg/day has not been evaluated in clinical studies.

Use: Treatment of schizophrenia

Usual Adult Dose for Bipolar Disorder:

Monotherapy:

-Initial dose: 10 mg sublingually 2 times a day

-Maintenance dose: 5 to 10 mg sublingually 2 times a day

-Maximum dose: 20 mg/day

Adjunctive Therapy:

-Initial dose: 5 mg sublingually 2 times a day

-Maintenance dose: 5 to 10 mg sublingually 2 times a day

-Maximum dose: 20 mg/day

Comments:

- -The safety of doses above 20 mg/day has not been evaluated in clinical studies.
- -In controlled trials, the starting dose in monotherapy was 10 mg twice daily. On the second and subsequent days, the dose could be lowered to 5 mg twice daily, though approximately 90% of patients remained on the initial dose.
- -The dose should be titrated based on clinical response and tolerability.
- -There is no available evidence to answer the question of how long the patient should remain on therapy; however, it is generally recommended that responding patients be continued beyond the acute response.

Uses:

- -Acute monotherapy of manic or mixed episodes of bipolar I disorder
- -Adjunctive treatment to lithium or valproate in bipolar I disorder
- -Maintenance monotherapy treatment of bipolar I disorder

Usual Pediatric Dose for Bipolar Disorder:

10 years and older

-Initial dose: 2.5 mg sublingually 2 times a day

-Titration regimen: After 3 days, may increase to 5 mg sublingually 2 times a day, and after an additional 3 days to 10 mg sublingually 2 times a day, as needed and as tolerated

-Maintenance dose: 2.5 to 10 mg sublingually 2 times a day

-Maximum dose: 20 mg/day

Comments:

- -Pediatric patients appear to be more sensitive to dystonia with initial dosing and therefore gradual dose escalation is recommended.
- -The safety of doses above 20 mg/day has not been studied.

Use: Acute monotherapy of manic or mixed episodes of bipolar I disorder

Detailed Saphris dosage information

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if it is almost time for your next dose. Do not take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What to avoid

Avoid becoming overheated or dehydrated during exercise and in hot weather. Drink plenty of fluids, especially in hot weather and during exercise. It is easier to become dangerously overheated and dehydrated while you are taking Saphris.

Avoid driving or hazardous activity until you know how this medicine will affect you. Your reactions could be impaired. Avoid getting up too fast from a sitting or lying position, or you may feel dizzy.

Saphris side effects

Get emergency medical help if you have **signs of an allergic reaction to Saphris:** hives; fast heartbeats, feeling light-headed; wheezing, difficult breathing; swelling of your face, lips, tongue, or throat.

High doses or long-term use of Saphris can cause a serious movement disorder that may not be reversible. The longer you use Saphris, the more likely you are to develop this disorder, especially if you are a woman or an older adult.

Call your doctor at once if you have:

- uncontrolled muscle movements in your face (chewing, lip smacking, frowning, tongue movement, blinking or eye movement);
- ulcers, blisters, swelling, o peeling in your mouth;
- · a light-headed feeling, like you might pass out;
- breast pain or swelling, nipple discharge;
- low white blood cell counts fever, chills, mouth sores, skin sores, sore throat, cough, trouble breathing; or
- severe nervous system reaction very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, feeling like you might pass out.

Common Saphris side effects may include:

- dizziness, drowsiness, tiredness;
- feeling restless or agitated;

- numbness or tingling in or around your mouth;
- muscle stiffness, jerky muscle movements;
- nausea, altered sense of taste; or
- increased appetite, weight gain.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Saphris side effects (more detail)

Related/similar drugs

Lybalvi

Lybalvi is used to treat adults with manic or mixed episodes associated with bipolar I disorder ...

Reviews & ratings

8.1 / 10

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Fanapt

Fanapt (iloperidone) is an antipsychotic medication used to treat schizophrenia. Includes Fanapt ...

Reviews & ratings

6.4 / 10

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Caplyta

Caplyta (lumateperone) may be used to treat schizophrenia or depression associated with bipolar ...

Reviews & ratings

6.6 / 10

184 Reviews

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Abilify

Abilify is an antipsychotic medicine used to treat the symptoms of schizophrenia and bipolar ...

Reviews & ratings

6.1 / 10

1,187 Reviews

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Olanzapine

Olanzapine (brand name Zyprexa) is an atypical antipsychotic that may be used to treat adults and ...

Reviews & ratings

5.9 / 10

1,091 Reviews

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Aripiprazole

Easy-to-read patient leaflet for aripiprazole. Includes indications, proper use, special ...

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6.1 / 10

1,540 Reviews

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Quetiapine

Quetiapine is an atypical antipsychotic used to treat schizophrenia, bipolar disorder, and major ...

Reviews & ratings

7.2 / 10

2,249 Reviews

View more

Seroquel

Seroquel is used to treat the symptoms of schizophrenia, bipolar

disorder and major depressive ...

Reviews & ratings

7.0 / 10

694 Reviews

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Lamictal

Lamictal is an anti-epileptic medication used treat seizures in adults and children over 2 years ...

Reviews & ratings

8.0 / 10

792 Reviews

View more

What other drugs will affect Saphris?

Taking Saphris with other drugs that make you sleepy or slow your breathing can cause dangerous side effects or death. Ask your doctor before using opioid medication, a sleeping pill, a muscle relaxer, or medicine for anxiety or seizures.

Other drugs may interact with asenapine, including prescription and over-the-counter medicines, vitamins, and herbal products. Tell your doctor about all your current medicines and any medicine you start or stop using.

Saphris drug interactions (more detail)

Does Saphris interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

Saphris
+
Enter a drug name
Add

References

1. Saphris Product Label

More about Saphris (asenapine)

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- Drug class: atypical antipsychotics
- Breastfeeding
- En español

Patient resources

Other brands

Secuado

Professional resources

- Saphris prescribing information
- Asenapine (AHFS Monograph)

Other brands

Secuado

Related treatment guides

- Bipolar Disorder
- Schizophrenia

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Saphris only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

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DRUG STATUS

Availability

Rx Prescription only

Pregnancy & Lactation

প্ Risk data available

CSA Schedule*

N/A Not a controlled drug

Approval History

10+ years FDA approved 2009

User Reviews & Ratings

7.4 / 10

318 Reviews

Images

Saphris 10 mg (sublingual) (10)



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