Medication Information for Parents and Teachers

Asenapine—Saphris

General Information About Medication

Each child and adolescent is different. No one has exactly the same combination of medical and psychological problems. It is a good idea to talk with the doctor or nurse about the reasons a medicine is being used. It is very important to keep all appointments and to be in touch by telephone if you have concerns. It is important to communicate with the doctor, nurse, or therapist. An advanced practice nurse (APN) has additional education and training after becoming a registered nurse (RN). Your child’s medication may be prescribed by a medical doctor (MD or DO) or an APN. In addition, a physician assistant (PA) working with a physician may prescribe certain medications. In this information sheet, “doctor” includes medical doctors as well as APNs and PAs who prescribe medication. Often a nurse (RN) will be part of the team and answer questions and give information.

It is very important that the medicine be taken exactly as the doctor instructs. However, once in a while, everyone forgets to give a medicine on time. It is a good idea to ask the doctor or nurse what to do if this happens. Do not stop or change a medicine without asking the doctor or nurse first.

If the medicine seems to stop working, it may be because it is not being taken regularly. The youth may be “cheeking” or hiding the medicine or forgetting to take it (especially at school). The doses may be too far apart or a different dose or medicine may be needed. Something at school, at home, or in the neighborhood may be upsetting the youth, or he or she may need special help for learning disabilities or tutoring. Please discuss your concerns with the doctor. Do not just increase the dose. It is also very important not to decrease the dose or stop the medicine without talking to the doctor first. The problem being treated may come back, or there could be uncomfortable or even dangerous results.

All medicines should be kept in a safe place, out of the reach of children, and should be supervised by an adult. If someone takes too much of a medicine, call the doctor, the poison control center, or a hospital emergency room.

Each medicine has a “generic” or chemical name. Just like laundry detergents or paper towels, some medicines are sold by more than one company under different brand names. The same medicine may be available under a generic name and several brand names. The generic medications are usually less expensive than the brand name ones. The generic medications have the same chemical formula, but they may or may not be exactly the same strength as the brand-name medications. Also, some brands of pills contain dye or other things that can cause allergic reactions. It is a good idea to talk to the doctor and the pharmacist about whether it is important to use a specific brand of medicine.

Any medicine can cause an allergic reaction. Examples are hives, itching, rashes, swelling, and trouble breathing. Even a tiny amount of a medicine can cause a reaction in patients who are allergic to that medicine. Be sure to talk to the doctor before restarting a medicine that has caused an allergic reaction and tell the doctor about any reactions to medicine that your child has had before.

Taking more than one medicine at the same time may cause more side effects or cause one of the medicines to not work as well. Always ask the doctor, nurse, or pharmacist before adding another medicine, either prescription or bought without a prescription in a store or on the Internet. Be sure
that each doctor knows about all of the medicines your child is taking. Also tell the doctor about any vitamins, herbal medicines, or supplements your child may be taking. Some of these may have side effects alone or when taken with this medication. It is a very good idea to keep a list with you of the names and doses of all medicines that your child is taking.

Everyone taking medicine should have a physical examination at least once a year.

If you think that your child may be using drugs or alcohol, please tell the doctor right away.

Pregnancy requires special care in the use of medicine. Some medicines can cause birth defects if taken by a pregnant mother. Please tell the doctor immediately if you suspect the teenager is at risk of becoming pregnant. The doctor may wish to discuss sexual behavior and/or birth control with your daughter.

Printed information like this applies to children and adolescents in general. If you have questions about the medicine, or if you notice changes or anything unusual, please ask the doctor or nurse. As scientific research advances, knowledge increases and advice changes. Even experts do not always agree. Many medicines have not been “approved” by the U.S. Food and Drug Administration (FDA) for use in children or use for particular problems. For this reason, use of the medicine for a problem or age group often is not listed in the Physicians’ Desk Reference. This does not necessarily mean that the medicine is dangerous or does not work, only that the company that makes the medicine has not received permission to advertise the medicine for use in children. Companies often do not apply for this permission because it is expensive to do the tests needed to apply for approval for use in children. Once a medication is approved by the FDA for any purpose, a doctor is allowed to prescribe it according to research and clinical experience.

Note to Teachers

It is a good idea to talk with the parent(s) about the reason(s) that a medication is being used. If the parent(s) sign consent to release information, it is often helpful for you to talk with the doctor. If the parent(s) give permission, the doctor may ask you to fill out rating forms about your experience with the student’s behavior, feelings, academic performance, and medication side effects. This information is very useful in selecting and monitoring medication treatment. If you have observations that you think are important, do not hesitate to share these with the student's parent(s) and treating clinicians (with parental consent).

It is very important that the medicine be taken exactly as the doctor instructs. However, everyone forgets to give a medicine on time once in a while. It is a good idea to ask the parent(s) in advance what to do if this happens. Do not stop or change the time you are giving a medicine at school without parental permission. If a medication is to be taken with food, but lunchtime or snack time changes, be sure to notify the parent(s) so appropriate adjustments can be made.

All medicines should be kept in a secure place and should be supervised by an adult. If someone takes too much of a medicine, follow your school procedure for an urgent medical problem.

Taking medicine is a private matter and is best managed discreetly and confidentially. It is important to be sensitive to the student’s feelings about taking medicine.

If you suspect that the student is using drugs or alcohol, please tell the parent(s) or a school counselor right away.

Please tell the parent(s) or school nurse if you suspect medication side effects.

Modifications of the classroom environment or assignments may be useful in addition to medication. The student may need to be evaluated for additional help or a 504 plan or an Individualized Education Plan for learning problems or emotional or behavioral issues.

Any expression of suicidal thoughts or feelings or self-harm by a child or adolescent is a signal of distress and should be taken seriously. These behaviors should not be dismissed as “attention seeking.” School procedures for safety issues should be followed.
What Is Asenapine (Saphris)?

This medicine is called an atypical or second-generation antipsychotic. It is sometimes called an atypical psychotropic agent, or simply an atypical. It comes in brand name Saphris sublingual tablets that are placed under the tongue and allowed to dissolve there.

How Can This Medicine Help?

Asenapine is used to treat psychosis, such as in schizophrenia, mania, or very severe depression. It can reduce positive symptoms such as hallucinations (hearing voices or seeing things that are not there); delusions (troubling beliefs that other people do not share); agitation; and very unusual thinking, speech, and behavior. It is also used to lessen the negative symptoms of schizophrenia, such as lack of interest in doing things (apathy), lack of motivation, social withdrawal, and lack of energy.

Asenapine may be used as a mood stabilizer in patients with bipolar disorder or severe mood swings. It can reduce mania and may be able to help maintain a stable mood.

Sometimes asenapine is used to reduce severe aggression or very serious behavioral problems in young people with conduct disorder, intellectual disability, or autism spectrum disorder. This medicine is very powerful and is used to treat very serious problems or symptoms that other medicines do not help. Be patient; the positive effects of this medicine may not appear for 2–3 weeks.

How Does This Medicine Work?

Cells in the brain communicate using chemicals called neurotransmitters. Too much or too little of these substances in parts of the brain can cause problems. Asenapine works by blocking the action of two of these neurotransmitters—dopamine and serotonin—in certain areas of the brain.

How Long Does This Medicine Last?

Asenapine is usually taken twice a day.

How Will the Doctor Monitor This Medicine?

The doctor will review your child’s medical history and physical examination before starting asenapine. The doctor may order some blood or urine tests to be sure your child does not have a hidden medical condition that would make it unsafe to use this medicine. The doctor or nurse may measure your child’s pulse and blood pressure before starting asenapine. The doctor may order other tests, such as baseline tests for blood sugar and cholesterol or an ECG (electrocardiogram or heart rhythm test).

Be sure to tell the doctor if anyone in the family has diabetes, high blood pressure, high cholesterol, or heart disease.
Before your child starts taking asenapine and every so often afterward, a test such as the Abnormal Involuntary Movement Scale (AIMS) may be used to check your child’s tongue, legs, and arms for unusual movements that could be caused by the medicine.

After the medicine is started, the doctor will want to have regular appointments with you and your child to see how the medicine is working, to see if a dose change is needed, to watch for side effects, to see if asenapine is still needed, and to see if any other treatment is needed. The doctor or nurse will check your child’s height, weight, pulse, and blood pressure and watch for abnormal movements. Sometimes blood tests are needed to watch for diabetes or increased cholesterol.

What Side Effects Can This Medicine Have?

Any medicine can have side effects, including an allergy to the medicine. Because each patient is different, the doctor will monitor the youth closely, especially when the medicine is started. The doctor will work with you to increase the positive effects and decrease the negative effects of the medicine. Please tell the doctor if any of the listed side effects appear or if you think that the medicine is causing any other problems. Not all of the rare or unusual side effects are listed.

Side effects are most common after starting the medicine or after a dose increase. Many side effects can be avoided or lessened by starting with a very low dose and increasing it slowly—ask the doctor.

Allergic Reaction

Tell the doctor in a day or two (if possible, before the next dose of medicine):

- Hives
- Itching
- Rash

Stop the medicine and get immediate medical care:

- Trouble breathing or chest tightness
- Swelling of lips, tongue, or throat
- Feeling faint or dizzy (low blood pressure) and very fast heartbeat

Common, but Not Usually Serious, Side Effects

Discuss the following side effects with your child’s doctor when convenient. These side effects often can be helped by lowering the dose of medicine, changing the times medicine is taken, or adding another medicine.

- Daytime sleepiness or tiredness—Do not allow your child to drive, ride a bicycle or motorcycle, or operate machinery if this happens. This problem may be lessened by taking the medicine at bedtime.
- Dry mouth—Have your child try using sugar-free gum or candy.
- Constipation—Encourage your child to drink more fluids and eat high-fiber foods; if necessary, the doctor may recommend a fiber medicine such as Benefiber or a stool softener such as Colace or mineral oil.
- Dizziness—This side effect is worse when the child stands up quickly, especially when getting out of bed in the morning; try having the child stand up slowly.
- Increased appetite
• Weight gain—Seek nutritional counseling; provide your child with low-calorie snacks and encourage regular exercise.
• Increased risk of sunburn—Have your child wear sunscreen or protective clothing or stay out of the sun.
• Nausea
• Vomiting
• Insomnia (trouble sleeping)

Less Common, but Not Usually Serious, Side Effects

Discuss the following side effects with your child's doctor when convenient. These side effects often can be helped by lowering the dose of medicine, changing the times medicine is taken, or adding another medicine.

• Drooling
• Increased restlessness or inability to sit still
• Shaking of hands and fingers
• Decreased or slowed movement and decreased facial expressions
• Decreased sexual interest or ability
• Changes in menstrual cycle
• Increase in breast size or discharge from the breasts (in both boys and girls)—This may go away with time.

Less Common, but Potentially Serious, Side Effects

Call the doctor immediately:

• Stiffness of the tongue, jaw, neck, back, or legs
• Seizure (fit, convulsion)—This is more common in people with a history of seizures or head injury.
• Increased thirst, frequent urination (having to go to the bathroom often), lethargy, tiredness, dizziness, and blurred vision—These could be signs of diabetes, especially if your child is overweight or there is a family history of diabetes. Talk to a doctor within a day.

Very Rare, but Serious, Side Effects

• Extreme stiffness or lack of movement, very high fever, mental confusion, irregular pulse rate, or eye pain—This is a medical emergency. Go to an emergency room right away.
• Sudden stiffness and inability to breathe or swallow—Go to an emergency room or call 911. Tell the paramedics, nurses, and doctors that the patient is taking asenapine. Other medicines can be used to treat this problem quickly.

What Else Should I Know About Side Effects?

Most side effects lessen over time. If they are troublesome, talk with your child's doctor. Some side effects can be decreased by taking a smaller dose of medicine, by stopping the medicine, by changing to another medicine, or by adding another medicine.

Many young people who take asenapine gain weight. The weight gain may be from increased appetite and also from ways that the medicine changes how the body processes food. Asenapine may also change the way
that the body handles glucose (sugar) and cause high levels of blood sugar (hyperglycemia). People who take ase
napine, especially those who gain a lot of weight, might be at increased risk of developing diabetes and of having
increased fats (lipids—cholesterol and triglycerides) in their blood. Over time, both diabetes and increased fats in
the blood may lead to heart disease, stroke, and other complications. The FDA has put warnings on all atypical
agents about the increased risks of hyperglycemia, diabetes, and increased blood cholesterol and triglycerides
when taking one of these medicines. It is much easier to prevent weight gain than to lose weight later. When
your child first starts taking asenapine, it is a good idea to be sure that he or she eats a well-balanced diet without
“junk food” and with healthy snacks like fruits and vegetables, not sweets or fried foods. He or she should
drink water or skim milk, not pop, sodas, soft drinks, or sugary juices. Regular exercise is important for main-
taining a healthy weight (and may also help with sleep).

The medicine may increase the level of prolactin, a natural hormone made in the part of the brain called the
pituitary. This may cause side effects such as breast tenderness or swelling or production of milk in both
boys and girls. It also may interfere with sexual functioning in teenage boys and with regular menstrual cycles
(periods) in teenage girls. A blood test can measure the level of prolactin. If these side effects do not go away
and are troublesome, talk with your child's doctor about substituting another medicine for asenapine.

One very rare side effect that may not go away is tardive dyskinesia (or TD). Patients with tardive dyskinesia
have involuntary movements (movements that they cannot help making) of the body, especially the mouth
and tongue. The patient may look as though he or she is making faces over and over again. Jerky movements
of the arms, legs, or body may occur. There may be fine, wormlike, or sudden repeated movements of the
tongue, or the person may appear to be chewing something or swallowing or puckering his or her lips. The
fingers may look as though they are rolling something. If you notice any unusual movements, be sure to tell
the doctor. The doctor may use the AIMS test to look for these movements.

Neuroleptic malignant syndrome is a very rare side effect that can lead to death. The symptoms are severe
muscle stiffness, high fever, increased heart rate and blood pressure, irregular heartbeat (pulse), and sweating.
It may lead to unconsciousness. If you suspect this, call 911 or go to an emergency room right away.

Sometimes this medicine can cause a dystonic reaction. This is a sudden stiffening of the muscles, most often
in the jaw, neck, tongue, face, or shoulders. If this happens, and your child is not having trouble breathing,
you may give a dose of diphenhydramine (Benadryl). Follow the dose instructions on the package for your
child's age. This should relax the muscles in a few minutes. Then call your doctor to tell him or her what hap-
pened. If the muscles do not relax, take your child to the emergency department.

Some Interactions With Other Medicines or Food

Please note that the following are only the most likely interactions with other medicines or food.

Asenapine should be taken without food and one should not eat or drink for at least 10 minutes after taking
this medicine. The tablet should be allowed to dissolve and should not be chewed or swallowed.

Fluoxetine (Prozac), fluvoxamine (Luvox), and other selective serotonin reuptake inhibitor (SSRI) antide-
pressants can increase the levels of asenapine and increase the risk of side effects.

Heart problems are more common if other medicines that affect the heart are being taken as well. Be sure
to tell all your child's doctors and your pharmacist about all medications your child is taking.

It is better to limit drinks with caffeine (coffee, tea, soft drinks) because caffeine works in the opposite way
from this medicine, and the positive effects might be decreased.
What Could Happen if This Medicine Is Stopped Suddenly?

Involuntary movements, or withdrawal dyskinesias, may appear within 1–4 weeks of lowering the dose or stopping the medicine. Usually these go away, but they can last for days to months. If asenapine is stopped suddenly, emotional disturbance (such as irritability, nervousness, moodiness, or oppositional behavior) or physical problems (such as stomachache, loss of appetite, nausea, vomiting, diarrhea, sweating, indigestion, trouble sleeping, trembling, or shaking) may appear. These problems usually last only a few days to a few weeks. If they happen, you should tell your child’s doctor. The medicine dose may need to be lowered more slowly (tapered). Always check with the doctor before stopping a medicine.

How Long Will This Medicine Be Needed?

How long your child will need to take this medicine depends partly on the reason that it was prescribed. Some problems last for only a few months, whereas others last much longer. It is important to ask the doctor whether medicine is still needed, especially with medicines as powerful as this one. Every few months, you should discuss with your child’s doctor the reasons for using the medicine and whether the medicine may be stopped or the dose lowered.

What Else Should I Know About This Medicine?

There are other medicines that are used for the same kinds of problems. If your child is having bad side effects or the medicine does not seem to be working, ask the doctor if another medicine might work as well or better and have fewer side effects for your child. Each person reacts differently to medicines.

Taking this medicine could make overheating or heatstroke more likely. Have your child decrease activity in hot weather, stay out of the sun, and drink water to prevent this.

Notes

Use this space to take notes or to write down questions you want to ask the doctor.
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