

# Medication Information for Parents and Teachers

## *Fluoxetine—Prozac, Symbyax*

### General Information About Medication

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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

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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 Fluoxetine (Prozac)?

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Fluoxetine is an antidepressant known as a *selective serotonin reuptake inhibitor* (SSRI). It comes in generic and brand name Prozac capsules, once-weekly extended release forms (Prozac Weekly), and generic liquid form. For very small doses or for children who cannot swallow pills, the pill form can be dissolved in cranberry or orange juice and kept in the refrigerator. Fluoxetine is also sold under the brand name Sarafem (or generic tablet) for premenstrual dysphoric disorder. There is a capsule that combines fluoxetine and olanzapine that comes in brand name Symbyax and generic.

## How Can This Medicine Help?

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Fluoxetine is used to treat depression and anxiety disorders such as obsessive-compulsive disorder (OCD), posttraumatic stress disorder (PTSD), panic disorder, separation anxiety disorder, selective mutism, social anxiety disorder, and generalized anxiety disorder. Symbyax is used to treat depression in people with bipolar disorder.

## How Does This Medicine Work?

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Fluoxetine increases the amount of a *neurotransmitter* called *serotonin* in certain parts of the brain. People with emotional and behavioral problems, such as depression and anxiety, may have low levels of serotonin in certain parts of the brain. SSRIs such as fluoxetine help by increasing the action of brain serotonin to more normal levels.

## How Long Does This Medicine Last?

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Fluoxetine lasts a very long time. It has some action in the body for as long as 4 weeks after it is stopped. It is usually taken once a day.

## How Will the Doctor Monitor This Medicine?

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The doctor will review your child's medical history and physical examination before starting fluoxetine. 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. Extra care is needed when using SSRIs in youth with seizures (epilepsy); heart, liver, or kidney problems; or diabetes. The doctor or nurse may measure your child's pulse, blood pressure, and weight before starting the medicine.

Be sure to tell the doctor if your child or anyone in the family has bipolar disorder or has tried to kill himself or herself.

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 fluoxetine is still needed, and to see if any other treatment is needed. The doctor or nurse may check your child's height, weight, pulse, and blood pressure.

Before using medicine and at times afterward, the doctor may ask your child to fill out a rating scale about depression or anxiety to help see how your child is doing.

## What Side Effects Can This Medicine Have?

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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.

For the fluoxetine-olanzapine combination Symbyax, see also the information sheet for olanzapine.

### 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

### Common Side Effects

Tell the doctor within a week or two, or sooner if the problems are getting worse:

- Nausea, upset stomach, vomiting
- Diarrhea or excessive gas
- 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.
- Headache
- Anxiety or nervousness
- Insomnia (trouble sleeping)
- Restlessness, increased activity level
- Daytime sleepiness or tiredness—Do not allow your child to drive, ride a bicycle or motorcycle, or operate machinery if this side effect is present.
- 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.
- Tremor (shakiness)

- Excessive sweating
- Apathy, lack of interest in school or friends—This may happen after an initial good response to treatment.
- Decreased sexual interest, trouble with sexual functioning
- Weight gain
- Weight loss

## Less Common, but More Serious, Side Effects

Call the doctor within a day or two:

- Significant suicidal thoughts or self-injurious behavior
- Increased activity, rapid speech, feeling “speeded up,” decreased need for sleep, being very excited or irritable (cranky), agitation, acting out of character
- Bleeding, such as bruising or nosebleeds, or bleeding with surgery

## Serious Side Effects

Call the doctor *immediately* or go to the nearest emergency room:

- Seizure (fit, convulsion)
- Stiffness, high fever, confusion, tremors (shaking)
- Overheating or heatstroke—Prevent by decreasing activity in hot weather, staying out of the sun, and drinking water.

## Serotonin Syndrome

A very serious side effect called *serotonin syndrome* can happen when certain kinds of medicines (including SSRI antidepressants, clomipramine, and other medicines, such as triptans for migraine headaches, buspirone, linezolid, tramadol, or St. John’s wort) are taken by the same person. Very rarely, serotonin syndrome can happen at high doses of just one medicine. The early signs are restlessness, confusion, shaking, skin turning red, sweating, muscle stiffness, sweating, and jerking of muscles. If you see these symptoms, stop the medicine and send or take the youth to an emergency room right away.

## Some Interactions With Other Medicines or Food

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

Fluoxetine interacts with many other prescription and over the counter medicines, including some antibiotics and other psychiatric medicines. It is especially important to tell the doctor and pharmacist about all of the medicines your child is taking or has taken in the past few months, including over-the-counter and herbal medicines. Sometimes one medicine can increase or decrease the blood level of another medicine, so that different doses are needed. Erythromycin and similar antibiotics, as well as antifungal agents such as ketoconazole, may increase levels of fluoxetine and increase side effects. Fluoxetine may increase the heart side effects of pimozide (Orap), so those two medicines should not be taken by the same person. Tryptophan or the herbal medicine St. John’s wort also increases serotonin and can cause serious side effects if taken with fluoxetine. Taking fluoxetine with aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) (medications including ibuprofen or naproxen), or anticoagulant medications (including warfarin) increases risk of abnormal bleeding.

It can be *very dangerous* to take an SSRI at the same time as or even within a month of taking another type of medicine called a *monoamine oxidase inhibitor* (MAOI), such as selegiline (Eldepryl), phenelzine (Nardil), tranylcypromine (Parnate), or isocarboxazid (Marplan).

Fluoxetine can be taken with or without food.

Caffeine may increase side effects of fluoxetine.

## What Could Happen if This Medicine Is Stopped Suddenly?

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No known serious medical effects occur if fluoxetine is stopped suddenly, but there may be uncomfortable feelings, which should be avoided if possible. Your child might have trouble sleeping, nervousness, irritability, dizziness, and flu-like symptoms. Ask the doctor before stopping fluoxetine or if these symptoms happen while the dose is being decreased.

## How Long Will This Medicine Be Needed?

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Fluoxetine may take up to 1–2 months to reach its full effect. If your child has a good response to fluoxetine, it is a good idea to continue the medicine for at least 6–12 months. It is important to review this with your doctor.

## What Else Should I Know About This Medicine?

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In youth who have bipolar disorder or who may be at risk for bipolar disorder, any antidepressant medicine may increase the risk of hypomania or mania (excitement, agitation, increased activity, decreased sleep).

In hot weather, make sure your child drinks enough water or other liquids and does not get overheated.

Sometimes, after a person has improved while taking fluoxetine, he or she loses interest in school or friends or just stops trying. Please tell your child's doctor if this happens—it may be a side effect of the medicine. A lower dose or a different medicine may be needed.

Store the medicine away from sunlight, heat, moisture, and humidity.

Fluoxetine (Prozac) and fluvoxamine (Luvox) are sometimes confused. Be sure to check the medicine when you get it from the pharmacy.

## Black Box Antidepressant Warning

In 2004, an advisory committee to the FDA decided that there might be an increased risk of suicidal behavior for some youth taking medicines called *antidepressants*. In the research studies that the committee reviewed, about 3%–4% of youth with depression who took an antidepressant medicine—and 1%–2% of youth with depression who took a placebo (pill without active medicine)—talked about suicidal thoughts (thinking about killing themselves or wishing they were dead) or did something to harm themselves. This means that almost twice as many youth who were taking an antidepressant to treat their depression talked about suicide or had suicidal behavior compared with youth with depression who were taking inactive medicine. There were *no* completed suicides in any of these research studies, which included more than 4,000 children and adolescents. For youth being treated for anxiety, there was no difference in suicidal talking or behavior between those taking antidepressant medication and those taking placebo.

The FDA told drug companies to add a *black box warning* label to all antidepressant medicines. Because of this label, a doctor (or advanced practice nurse) prescribing one of these medicines has to warn youth and their families that there might be more suicidal thoughts and actions in youth taking these medicines.

On the other hand, in places where more youth are taking the newer antidepressant medicines, the number of adolescents who commit suicide has gotten smaller. Also, thinking about or attempting suicide is more common in surveys of teenagers in the community than it is in depressed youth treated in research studies with antidepressant medicine.

If a youth is being treated with this medicine and is doing well, then no changes are needed as a result of this warning. Increased suicidal talk or action is most likely to happen in the first few months of treatment with a medicine. If your child has recently started this medicine or is about to start, then you and your doctor (or advanced practice nurse) should watch for any changes in behavior. People who are depressed often have suicidal thoughts or actions. It is hard to know whether suicidal thoughts or actions in depressed people are caused by the depression itself or by the medicine. Also, as their depression is getting better, some people talk more about the suicidal thoughts that they had before but did not talk about. As young people get better from depression, they might be at higher risk of doing something about suicidal thoughts that they have had for some time, because they have more energy.

## What Should a Parent Do?

1. Be honest with your child about possible risks and benefits of medicine.
2. Talk to your child about whether he or she is having any suicidal thoughts, and tell your child to come to you if he or she is having such thoughts.
3. You, your child, and your child's doctor or nurse should develop a safety plan. Pick adults whom your child can tell if he or she is thinking about suicide.
4. Be sure to tell your child's doctor, nurse, or therapist if you suspect that your child is using alcohol or drugs or if something has happened that might make your child feel worse, such as a family separation, breaking up with a boyfriend or girlfriend, someone close dying or attempting suicide, physical or sexual abuse, or failure in school.
5. Be sure that there are no guns in the home and that all medicines (including over-the-counter medicines like Tylenol) are closely supervised by an adult and kept in a safe place.
6. Watch for new or worse thoughts of suicide, self-harm, depression, anxiety (nerves), feeling very agitated or restless, being angry or aggressive, having more trouble sleeping, or anything else that you see for the first time, seems worse, or worries your child or you. If these appear, contact a mental health professional **right away**. Do not just stop or change the dose of the medicine on your own. If the problems are serious, and you cannot reach one of your clinicians, call a 24-hour psychiatry emergency telephone number or take your child to an emergency room.

Youth taking antidepressant medicine should be watched carefully by their parent(s), clinician(s) (doctor, advanced practice nurse, nurse, therapist), and other concerned adults for the first weeks of treatment. It is a good idea to have regular contact with the doctor, APN, nurse, or therapist for the first months to check for feelings of depression or sadness, thoughts of killing or harming himself or herself, and any problems with the medication. If you have questions, be sure to ask the doctor, APN, nurse, or therapist.

For more information, see <http://www.parentsmedguide.org/>.

