

Medication Information for Parents and Teachers

Duloxetine—Cymbalta

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.

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 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.**

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 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.

All medicines 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.

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, whether prescription or over-the-counter. 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.

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

If you suspect the youth is using drugs or alcohol, please tell the doctor right away.

Pregnancy requires special care in the use of medicine. Please tell the doctor immediately if you suspect the teenager is pregnant or might become pregnant.

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. For this reason, use of the medicine for a particular 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 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.

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 for an Individualized Education Plan for learning or behavior.

Any expression of suicidal thoughts or feelings or self-harm by a child or adolescent is a clear signal of distress and should be taken seriously. These behaviors should not be dismissed as "attention seeking."

What Is Duloxetine (Cymbalta)?

Duloxetine is a new *antidepressant*. It is known as a *serotonin-norepinephrine reuptake inhibitor* (SNRI). It comes in brand name Cymbalta capsules. Compared with the *selective serotonin reuptake inhibitors* (SSRIs), less is known about duloxetine's safety and effectiveness in children and adolescents.

How Can This Medicine Help?

Duloxetine is used to treat depression. Less is known about whether it helps anxiety disorders such as obsessive-compulsive disorder (OCD), posttraumatic stress disorder (PTSD), panic disorder, or separation anxiety disorder. It is also used to treat nerve pain in adults with diabetes.

How Does This Medicine Work?

Duloxetine increases the amount of two neurotransmitters—*serotonin* and *norepinephrine*—in parts of the brain. *Neurotransmitters* are the chemicals used by brain cells to communicate. People with depression and anxiety may have low levels of serotonin and norepinephrine in certain parts of the brain. Duloxetine helps by increasing the action of these neurotransmitters to more normal levels.

How Long Does This Medicine Last?

Duloxetine is 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 duloxetine. Be sure to tell the doctor if your child or anyone in the family has had liver problems. 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 duloxetine in youth with seizures (epilepsy), 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 illness (manic-depressive illness) 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 duloxetine 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. Duloxetine may cause small increases in blood pressure.

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

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

Common Side Effects

Tell the doctor within a week or two:

- Nausea, upset stomach, vomiting
- Decreased appetite
- 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.
- Insomnia (trouble sleeping)
- Daytime sleepiness or tiredness—Do not allow your child to drive, ride a bicycle or motorcycle, or operate machinery if this happens.
- 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.
- Excessive sweating

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)

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 some medicines for migraine headaches—triptans) are taken by the same person. *Very* rarely, it can happen at high doses of just one medicine. The early signs are restlessness, confusion, shaking, skin turning red, 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

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

Duloxetine interacts with many other 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. Cipro and Tagamet both increase the level of duloxetine. When switching from fluvoxamine, paroxetine, or fluoxetine to duloxetine, lower doses of duloxetine are needed, because those other antidepressants increase the levels of duloxetine. The herbal medicine St. John's wort also increases serotonin and can cause serious side effects if taken with duloxetine.

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

Duloxetine does not usually cause problems when taken with decongestant cold medicines.

Duloxetine can be taken with or without food.

Caffeine may increase side effects.

What Could Happen if This Medicine Is Stopped Suddenly?

If duloxetine is stopped suddenly, there may be uncomfortable withdrawal feelings, including dizziness, headache, irritability, and nightmares. Do not stop this medicine suddenly, and ask the doctor if these symptoms happen as the medicine is being tapered (dose decreased).

How Long Will This Medicine Be Needed?

Duloxetine may take up to 1–2 months to reach its full effect. If your child has a good response to duloxetine, it is a good idea to continue the medicine for at least 6 months.

What Else Should I Know About This Medicine?

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

Smoking may lower the levels of duloxetine, making it not work as well.

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 duloxetine, 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.

Duloxetine capsules should not be crushed, chewed, sprinkled on food, or mixed with juice but should be swallowed whole.

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.

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