Anyone considering the use of amitriptyline should be aware of the risk of suicidality, particularly in children, adolescents, and young adults. The risk of suicidality increases with higher dosages and is more common in antidepressant-naive individuals. Anyone considering the use of amitriptyline should talk to their health care provider about the benefits and risks of this medicine. Prescriptions for amitriptyline hydrochloride should be written with the smallest quantity of drug consistent with proper treatment; in an ongoing treatment relationship, patients should be reviewed periodically to assess the need for continuation of therapy. Close supervision is required when amitriptyline hydrochloride is used in patients ≤18 years old, particularly in those with a history of suicide attempt or plan, depression, or another psychiatric disorder. Treatment of depressive disorders with amitriptyline hydrochloride in elderly patients is not generally recommended. Amitriptyline hydrochloride is not recommended for use during the acute stage of manic episodes of bipolar disorder. It is generally believed that the use of antidepressants can increase the risk of suicide-related symptoms in patients with depression who are not severely ill. The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, loss of interest in sexual activity, and severe depression, have been reported with antidepressant medications, including amitriptyline hydrochloride. It is generally believed that these symptoms may be the first signs of a potentially life-threatening situation. Anyone considering the use of amitriptyline hydrochloride for depression or other indication should be aware of the risk of these symptoms and should be closely monitored for them, especially at the start of treatment. In patients who are started on therapy with amitriptyline hydrochloride for depression or other indication, carefully monitor the response as therapy is started, at therapy initiation, to ongoing treatment, and after significant dose changes. Prescribers should inform patients, their families, and their caregivers about the need to monitor for the emergence of suicidality, for symptoms that may be a manifestation of such a change, and for the importance of reporting such symptoms immediately to their health care provider. Antidepressant Medicines, Depression and Other Serious Mental Health Conditions: Antidepressants effectively treat depression and other serious mental health conditions. They also may help prevent relapse of depression. While antidepressants are effective, it may be necessary to try several different types before finding the one that is most effective with the fewest side effects for a given patient. Anyone considering the use of amitriptyline hydrochloride for depression should talk to their health care provider about the benefits and risks of this medicine. In many cases, it is possible to treat depression without using an antidepressant. Anyone considering the use of amitriptyline hydrochloride for depression should talk to their health care provider about the benefits and risks of this medicine. There is a risk of serious side effects from these medicines, including life-threatening side effects. It is generally believed that these side effects are more common with higher dosages. Anyone considering the use of amitriptyline hydrochloride for depression should talk to their health care provider about the benefits and risks of this medicine.
being little unchanged drug appearing in the urine. Other meta-
hydroxylation in man, rabbit, and rat. Virtually the entire dose

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imipramine and placebo in hospitalized depressed patients,

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431 on one side and plain on the reverse side, and suppliedas:

50 mg:

• an extreme increase in activity and talking (mania)

• acting aggressive, being angry, or violent

• new or worse anxiety

member has any of the following symptoms, especially if

Never stop an antidepressant medicine without first talking

prescribed for you or your family member.

all treatment choices with the healthcare provider, not just

and other illnesses.

see if you are at risk and receive preventative treatment if

Visual problems:

...
Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Read the Medication Guide that comes with you or your family member’s antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines. Talk to your, or your family member’s, healthcare provider about:
• all risks and benefits of treatment with antidepressant medicines
• all treatment choices for depression or other serious mental illness

What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?

1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.
2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
   • Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
   • Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
• Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:
• thoughts about suicide or dying
• attempts to commit suicide
• new or worse depression
• new or worse anxiety
• feeling very agitated or restless
• panic attacks
• trouble sleeping (insomnia)
• new or worse irritability
• acting aggressive, being angry, or violent
• acting on dangerous impulses
• an extreme increase in activity and talking (mania)
• other unusual changes in behavior or mood
• Visual problems: eye pain, changes in vision, swelling or redness in or around the eye

What else do I need to know about antidepressant medicines?

• Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms.
• Visual problems: Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.
• Antidepressants are medicines used to treat depression and other illnesses. It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.

(See Reverse)
• **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.

• **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.

• **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child’s healthcare provider for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

This Medication Guide has been approved by the U.S. Food and Drug Administration for all antidepressants.

Sandoz Inc.,
Princeton, NJ 08540