



Patient Information Sheet

Nefazodone hydrochloride

5/2007: The suicidal thoughts or actions in children and adults issue has been addressed in product labeling.

Please see: <http://www.fda.gov/cder/drug/antidepressants/default.htm>

This is a summary for patients of the most important information about nefazodone. For details, talk to your healthcare professional.

FDA ALERT [07/2005] – Suicidal Thoughts or Actions in Children and Adults

Patients with depression or other mental illnesses often think about or attempt suicide. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior (or their care givers) should contact their healthcare professional right away.

Children

Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Although nefazodone is prescribed for children, FDA has not approved nefazodone for use in children.

Adults

Several recent scientific publications report the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, FDA began a complete review of all available data to determine whether there is an increased risk of suicidal thinking or behavior in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that adults being treated with antidepressant medication, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior.

This information reflects FDA’s preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

FDA approved labeling for nefazodone contains a serious warning about the risk of liver failure.

WARNING: LIFE THREATENING LIVER FAILURE
Nefazodone may cause serious liver problems, which may lead to death. Patients with active liver disease or with high levels on liver function tests should not take nefazodone. Call your healthcare professional right away if you get any of the following symptoms while taking nefazodone because you may be getting a liver problem:

- Yellowing of the skin or whites of eyes (jaundice)
- Unusually dark urine
- Loss of appetite that lasts several days or longer
- Nausea or lower stomach (abdominal) pain

What Is Nefazodone?

Nefazodone is a medicine that is used to treat depression.

Who Should Not Take Nefazodone?

Never take nefazodone if you:

- Have liver problems
- Are allergic to the medicine Desyrel (trazodone)
- Take the following medicines:
 - Halcion (triazolam), a drug to treat trouble sleeping. Nefazodone can increase the amount of Halcion in your body, causing serious side effects.
 - Orap (pimozide), a drug to treat Tourette’s syndrome, because it can result in serious heartbeat problems.
 - Tegretol (carbamazepine), a drug to control seizures. Tegretol can reduce the amount of nefazodone in your body so that it does not help your depression.
- Take another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking a MAOI in the last 14 days. Taking nefazodone close in time to a MAOI can result in serious, sometimes fatal, reactions, including:
 - High body temperature
 - Coma
 - Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxid), and other brands.

What Are The Risks?

- Life-threatening liver failure. See Warning.
- Suicidal thought or actions. See FDA Alert.
- Low blood pressure (postural hypotension) and fainting. Low blood pressure can be serious for people with heart problems, strokes, dehydration, and who take medicines to control blood pressure.
- Mania: You may become hyperactive, excitable or elated.
- Seizures. You may have a seizure (convulsion), even if you are not taking nefazodone close in time with a MAOI.
- An erection that won't go away (priapism). Get medical help right away for an erection that lasts for more than 4 hours.
- Other side effects include sleepiness, dry mouth, nausea, dizziness, constipation, weakness, lightheadedness, vision problems, and confusion





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- **Tell your healthcare professional** about all your medical conditions especially if you have or have had heart problems, a heart attack, a stroke, or mania; if you are pregnant or plan to become pregnant; or if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Medicines Or Foods?

- **Nefazodone can interact with Xanax (alprazolam), an anti-anxiety medicine. Your dose of Xanax should be decreased if used with nefazodone.**
- Nefazodone may interact with medicines other than the ones already mentioned in this information sheet, causing serious side effects. Tell your healthcare professional about all the medicines, vitamins, and herbal supplements you take, especially medicines for mental illness, depression, seizures, and immunosuppressants.
- If you plan to drink alcohol, talk to your healthcare professional.

How Do I Take Nefazodone?

Nefazodone is taken by mouth, with or without food, twice a day.

Is There Anything Else I Need To Know?

You can get more information about antidepressants at:
www.fda.gov/cder/drug/antidepressants/default.htm

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