treatment. Dosage can then be increased by increments of up to 20 mg/week, if needed and tolerated, to a maximum recommended dosage of 60 mg/day. Daily dosage should be divided into two to four dosages. After maximum clinical response is achieved, an attempt should be made to reduce the dosage slowly over a period of several weeks without jeopardizing the therapeutic response. Beneficial effect may not be seen in some patients for 3 to 6 weeks. If no response is obtained by then, continued administration is unlikely to help.

Because of the limited experience with systematically monitored patients receiving Marplan at the higher end of the currently recommended dose range of up to 60 mg/day, caution is indicated in patients for whom a dose of 40 mg/day is exceeded (see ADVERSE REACTIONS).

## HOW SUPPLIED

Tablets, 10 mg isocarboxazid each, peach-colored, scored—bottles of 100 (NDC 30698-032-01). **RX only.** 

## Medication Guide 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

## 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.
- 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.
- **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.

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



Manufactured by Amneal Pharmaceuticals, Paterson, New Jersey 07504 for Validus Pharmaceuticals, Inc. Parsippany, New Jersey 07054 Printed in U.S.A.

©Validus Pharmaceuticals All rights reserved Revised: June 2007