DOXEPIN HYDROCHLORIDE CAPSULES, USP
10 mg, 25 mg, 50 mg, 75 mg and 100 mg* *(Each 10 mg, 25 mg, 50 mg, 75 mg and 100 mg capsule contains 7.8 mg, 19 mg, 39 mg, 58 mg and 77 mg of doxepin, respectively)
For current labeling information, please visit https://www.fda.gov/drugsatfda

This label may not be the latest approved by FDA.

HOW SUPPLIED: Deepen Hydrochloride Capsules, USP are available containing deepen hydrochloride, USP equivalent to 10 mg, 25 mg, 50 mg, 75 mg or 100 mg of deepen.

The 10 mg capsule is a hard-shell, gelatin capsule with a buff opaque cap and buff opaque body usually printed with MYLAN over 1049 in black ink on both the cap and the body. They are available as follows:

- NDC 0378-1049-01 bottle of 100 capsules
- NDC 0378-1049-10 bottles of 1000 capsules

The 25 mg capsule is a hard-shell, gelatin capsule with an ivory opaque cap and white opaque body usually printed with MYLAN over 3212 in black ink on both the cap and the body. They are available as follows:

- NDC 0378-3212-01 bottles of 100 capsules
- NDC 0378-3212-10 bottles of 1000 capsules

The 50 mg capsule is a hard-shell, gelatin capsule with an ivory opaque cap and ivory opaque body usually printed with MYLAN over 4256 in black ink on both the cap and the body. They are available as follows:

- NDC 0378-4256-01 bottles of 100 capsules
- NDC 0378-4256-10 bottles of 1000 capsules

The 75 mg capsule is a hard-shell, gelatin capsule with a brite lite green opaque cap and brite lite green opaque body usually printed with MYLAN over 5376 in black ink on both the cap and the body. They are available as follows:

- NDC 0378-5376-01 bottles of 100 capsules
- NDC 0378-5376-10 bottles of 1000 capsules

- NDC 0378-6410-01 bottles of 100 capsules
- NDC 0378-6410-10 bottles of 1000 capsules

Store at 20° to 25°C (68° to 77°F). (See USP for Controlled Room Temperature.)

Protect from light.

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.

PHARMACIE: Dispense a Medication Guide with each prescription.

Mylan
Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

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Medication Guide
Antidepressant Medicines, Depression and Other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Read the Medication Guide that comes with your 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 illnesses

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 with in 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 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, behavior, 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 occur:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worsened depression
- new or worsened anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- 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 med icine 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 used to treat depression and other illnesses. It is important to discuss all the risks of treat ment and also the risks of not treating it. Patients and their families or other caregivers should discuss all treat ment 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.

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.

Revised 5/2014