DOXEPIN HYDROCHLORIDE CAPSULES USP
Rx Only

**Sodium Doxepin Hydrochloride**

NDC 0078-2820-01

**INDICATIONS AND USAGE**

Doxepin hydrochloride is a class of psychotropic agents known as tertiary amine, tricyclic antidepressants. It is a white crystalline solid

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**CONTRAINDICATIONS**

Doxepin HCl is contraindicated in patients with known Type TC2 anti- drowsiness and antihistamine effects on smooth muscle have been noted. The biochemical activity of the drug metabolizing activity among Asian, African and other populations are not yet available. Poor

The biochemical activity of the drug metabolizing enzymes in patients with diminished metabolic activity due to age, disease, or the concurrent use of drugs that inhibit or induce the activity of the drug metabolizing enzymes (CYP2D6) is not known. Since there is no experience in pregnant women who have received doxepin HCl, it is not known if it will be distributed in breast milk. Since the drug may be present in human milk, a decision should be made whether to discontinue the drug or to discontinue breastfeeding.

The pupillary dilation that occurs following use of many antidepressant drugs including doxepin hydrochloride is not known to cause any significant adverse effects and is not an indication for discontinuation of the drug. The pupillary dilation may be described as a diagnostic sign, however, that doxepin hydrochloride is acting and should be noted. Doxepin hydrochloride is not approved for use in treating bipolar disorder.

The use of doxepin HCl in children under 12 years of age is not recommended because safety for its use has not been established. PRECAUTIONS - Geriatric Use

The use of doxepin HCl on a once-a-day dosage regimen in geriatric patients should be used with caution because of the possibility for anticholinergic effects and antihistaminic activity. Analgesic Use should be reduced in older patients and in those with concomitant anticholinergic or anti-serotonin effects.

The use of doxepin HCl should be used with extreme caution in patients with a history of narrow angle glaucoma and in those with a family history of glaucoma. Certain drugs can affect the activity of this isozyme and make normal metabolic pathways. Inhibitors or substrates of CYP2D6 (i.e., quinidine, selective serotonin reuptake inhibitors [SSRIs]) can affect the metabolism of doxepin HCl. Treatment should be initiated with a small dose and increased gradually to the maintenance level.
Deaths have been reported involving overdoses of doxepin. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults who take these medicines. 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.

**NOTICE:**

The following information is about antidepressant medicines prescribed for children who are taking an antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines. Some people have had thoughts about自杀或者自杀 attempts while taking an antidepressant. Others have had thoughts about other harms, including self-harm or suicide. 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.

**DOSEAGE AND ADMINISTRATION**

Doxepin HCl capsules USP, equivalent to 150 mg of doxepin are hard gelatin capsules with white opaque body and blue opaque cap, imprinted “Par 220” on both body and cap. They are supplied in bottles of 100 (NDC # 45848-222-01), 250 (NDC # 45848-225-01), and 500 (NDC # 45848-229-01). All of these strengths are packaged with a child-resistant closure.

In patients with mild symptomatology or emotional symptoms accompanying depression, a starting daily dose of 75 mg is recommended. Dosage may subsequently be increased or decreased at appropriate intervals based on individual response. The usual optimal dose range is 75 mg to 300 mg/day. In more severely ill patients higher doses may be required with subsequent gradual increase to 300 mg/day if necessary. Additional therapeutic effect is rarely to be expected by obtaining a plasma drug level above 200 ng/mL.

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