

**DOXEPIN HYDROCHLORIDE TABLET, USP 3 mg and 6 mg**

| S.No.                       | Category         | Question                           | Answer   |
|-----------------------------|------------------|------------------------------------|--|
| <b>Clinical Particulars</b> |                  |                                    |  |
| 1.                          | 1 Use/Indication | What is the product indicated for? | Doxepin tablets are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.  |
| 2.                          | 2 Dosage         | What is the recommended dosage?    | <ul style="list-style-type: none"> <li>• <b>Initial dose:</b><br/>6 mg, once daily for adults<br/>3 mg, once daily for the elderly.</li> <li>• Total daily dose should not exceed 6 mg.</li> </ul>   |
| 3.                          | 3 Administration | How do I take it?                  | <ul style="list-style-type: none"> <li>✓ Take doxepin tablets within 30 minutes of bedtime.</li> <li>✓ Do not take doxepin tablets within 3 hours of a meal.</li> <li>✓ Doxepin tablets may make you sleepy the next day if taken with or right after a meal.</li> </ul>   |
| 4.                          | Administration   | Use in Pediatric Population        | Safety and effectiveness have not been evaluated.  |
| 5.                          | Administration   | Use in Geriatric Population        | The recommended starting dose is 3 mg. Monitor prior to considering dose escalation.   |
| 6.                          | Mechanism        | Mechanism of Action                | The mechanism of action of doxepin in sleep maintenance is unclear; however, doxepin's effect could be mediated through antagonism of the H1 receptor.   |
| 7.                          | Warning          | Warning                            | <ol style="list-style-type: none"> <li>1. <b>Co-morbid Diagnoses:</b> Reevaluate if insomnia persists after 7–10 days of use.</li> <li>2. <b>Behavioral Changes:</b> May include "sleep-driving" and hallucinations. Assess any new behavioral changes immediately.</li> <li>3. <b>Depression:</b> Monitor for worsening depression or suicidal thoughts. Prescribe the lowest effective dose to prevent overdose.</li> <li>4. <b>CNS Depressant Effects:</b> May impair alertness and coordination. Avoid hazardous activities like driving or operating machinery.</li> <li>5. <b>Alcohol:</b> Patients should not consume alcohol with doxepin</li> <li>6. <b>Additive Effects:</b> Use with CNS depressants or sedating antihistamines may require dose reduction.</li> <li>7. <b>Severe Sleep Apnea:</b> Not recommended for patients with severe sleep apnea.</li> </ol> |
| 8.                          | Lactation        | Use in Lactation                   | Breastfeeding not recommended.   |

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| 9.                                | Pregnancy           | Use in Pregnancy                                | <ul style="list-style-type: none"> <li>Advise patients that using doxepin tablets late in pregnancy may increase the risk of neonatal complications, which could require extended hospitalization, respiratory support, or tube feeding.</li> <li>Third trimester use may increase the risk for symptoms of poor adaptation (respiratory distress, temperature instability, feeding difficulties, hypotonia, tremor, irritability) in the neonate.</li> </ul>  |
| 10.                               | Precautions         | Using alcohol                                   | Yes. (Patients should not consume alcohol with doxepin as Sedative effects of Alcohol may be increased with doxepin).  |
| 11.                               | Interaction         | Is there any interaction with other medication? | <p><b>MAO inhibitors:</b> Doxepin should not be administered in patients on MAOIs within the past two weeks.</p> <p><b>Cimetidine:</b> Increases exposure to doxepin.</p> <p><b>Alcohol:</b> Sedative effects may be increased with doxepin.</p> <p><b>CNS Depressants and Sedating Antihistamines:</b> Sedative effects may be increased with doxepin</p> <p><b>Tolazamide:</b> A case of severe hypoglycemia has been reported.</p>  |
| 12.                               | Precautions         | After taking food                               | Do not take doxepin tablets within 3 hours of a meal.  |
| 13.                               | Storage             | What are the storage conditions?                | <ul style="list-style-type: none"> <li>Store doxepin tablets at room temperature between 68° and 77° F (20° to 25°C).</li> <li>Protect from light</li> </ul>   |
| 14.                               | Dispensing          | How to Dispense?                                | As prescribed by the Physician   |
| 15.                               | Contraindication    | What are the contraindications of (medication). | <ul style="list-style-type: none"> <li>Hypersensitivity to doxepin hydrochloride, inactive ingredients, or other dibenzoxepines.</li> <li>Co-administration with Monoamine Oxidase Inhibitors (MAOIs): Do not administer if patient is taking MAOIs or has used MAOIs within the past two weeks.</li> <li>Untreated narrow angle glaucoma or severe urinary retention.</li> </ul>  |
| <b>Pharmaceutical Particulars</b> |                     |   |  |
| 16.                               | Pharmaceutical Form | How is it supplied?                             | <p>1. <b>Doxepin 3 mg tablets:</b></p> <ul style="list-style-type: none"> <li>Oval shaped, white</li> <li>Debossed markings: "134" on one side, "m" on the other</li> <li>Supplied as: <ul style="list-style-type: none"> <li>NDC 72205-052-30: Bottle of 30</li> <li>NDC 72205-052-91: Bottle of 100</li> <li>NDC 72205-052-05: Bottle of 500</li> </ul> </li> </ul> <p>2. <b>Doxepin 6 mg tablets:</b></p> <ul style="list-style-type: none"> <li>Oval shaped, light yellow</li> <li>Debossed markings: "135" on one side, "m" on the</li> </ul> |

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|------------------|-------------|---------------------------------|---|
|                  |             |                                 | <p>other</p> <ul style="list-style-type: none"> <li>• Supplied as: <ul style="list-style-type: none"> <li>▪ NDC 72205-053-30: Bottle of 30</li> <li>▪ NDC 72205-053-91: Bottle of 100</li> <li>▪ NDC 72205-053-05: Bottle of 500</li> </ul> </li> </ul> |
| 17.              | Ingredients | Active and Inactive Ingredients | <p><b>Active:</b> Doxepin hydrochloride</p> <p><b>Inactive:</b> Colloidal silicon dioxide, crospovidone, microcrystalline cellulose, and magnesium stearate.</p> <p><i>The 6 mg tablet also contains D&amp;C Yellow No. 10 alum lake.</i></p>           |
| <b>Allergens</b> |             |                                 |   |
| 18.              | Ingredients | Is it Vegetarian?               | yes   |
| 19.              | Ingredients | Does it contain Gluten?         | No  |
| 20.              | Ingredients | Does it contain Dairy Products? | No.   |
| 21.              | Ingredients | Does it contain Casein          | No  |
| 22.              | Ingredients | Does it contain Whey?           | No  |
| 23.              | Ingredients | Does it contain corn?           | No  |
| 24.              | Ingredients | Does it contain rye?            | No  |
| 25.              | Ingredients | Does it contain sugar?          | No  |
| 26.              | Ingredients | Does it contain Oats?           | No  |
| 27.              | Ingredients | Does it contain wheat?          | No  |
| 28.              | Ingredients | Does it contain spelt?          | No  |
| 29.              | Ingredients | Does it contain barley?         | No  |
| 30.              | Ingredients | Does it contain rennet?         | No  |
| 31.              | Ingredients | Does it contain starch?         | No  |
| 32.              | Ingredients | Does it contain Iodine?         | No  |
| 33.              | Ingredients | Does it contain latex?          | No  |
| 34.              | Ingredients | Does it contain alcohol?        | Yes; Doxepin HCl API contains Methonal NMT 3000 PPM & Ethanol NMT 5000 PPM  |
| 35.              | Ingredients | Does it contain dyes?           | No  |
| 36.              | Ingredients | Does it contain flavor?         | No  |
| 37.              | Ingredients | Does it contain Lactose?        | No  |
| 38.              | Ingredients | Does it contain Nuts?           | No  |
| 39.              | Ingredients | Does it contain Preservatives?  | No  |
| 40.              | Ingredients | Does it contain Soy products?   | No  |
| 41.              | Ingredients | Does it contain peanut?         | No  |

|                      |               |   |   |
|----------------------|---------------|---|---|
| 42.                  | Ingredients   | Does it contain nickel?   | No  |
| <b>Miscellaneous</b> |               |   |   |
| 43.                  | Miscellaneous | May I know the product availability?  | Novadoz Pharmaceuticals products are only available through pharmacies, wholesalers, and other authorized distributors. See our ADR (authorized distributors of record) page at NovadozPharma.com to learn more about where to find our products.       |
| 44.                  | Miscellaneous | May I know about return, refunds and reimbursement?   | Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500   |
| 45.                  | Miscellaneous | Do you have any patient's assistance program?   | Novadoz Pharmaceuticals does not offer patient assistance programs at this time. The company that produces the brand version of your product may or may not offer such a program. Please check for access & eligibility requirements with that company. |
| 46.                  | Miscellaneous | How do I report an adverse drug effect or reaction to Novadoz medication?   | To report suspected adverse reactions, contact Novadoz Pharmaceuticals LLC at 1-855-668-2369 or FDA at 1-800-FDA-1088 or <a href="http://www.fda.gov/medwatch">www.fda.gov/medwatch</a> .   |
| 47.                  | Miscellaneous | Why does my pharmacy that used to fill your generic formulation of a particular medicine, no longer fills my prescription with Novadoz formulation? | Please check with your pharmacy as to why your prescription is not a Novadoz Pharmaceuticals product. You may refer to NovadozPharma.com ADR (authorized distributor of record) page to learn where to find our products.                               |
| 48.                  | Miscellaneous | Manufacturer and Distributor  | <b>MSN Pharmaceuticals Inc</b><br>MSN Pharmaceuticals Inc<br><br>20 Duke Road, Piscataway-08854, NJ, USA  |