SAFETY DATA SHEET
Doxepin Tablets

Strength: 3 & 6 mg

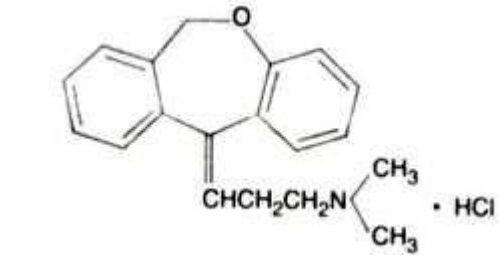
Pack Size: 30s 90s 100s 500s 1000s Tablets per bottle, 10X10 Unit dose Tablets per carton

Revision No.: 00

EMERGENCY OVERVIEW

Each **Doxepin Tablets 3 mg and 6 mg** intended for oral administration contains Doxepin Hydrochloride and excipients generally considered to be non-toxic and non-hazardous in small amounts under conditions of normal occupational exposure.

Section 1. IDENTIFICATION OF THE PRODUCT

Product Name:	**Doxepin Tablets 3 mg and 6 mg**
Active Pharmaceutical Ingredient:	**Doxepin Hydrochloride**
Formula:	C19H21NO•HCl
Chemical Name:	1-Propanamine, 3-dibenz [b,e]oxepin-11(6H)ylidene-N,N-dimethyl-hydrochloride.
Structure:	

C19H21NO•HCl Molecular Weight: 315.84

Manufacturer / supplier identification

Company:	Zydus Lifesciences Limited
Address:	Survey No. 417, 419 & 420, Sarkhej – Bavla National Highway No. 8A, Village – Moraiya, Taluka – Sanand, Dist.- Ahmedabad - 382 210, Gujarat State, India.
Contact for information:	Tel.: + 91- 2717-666200
Emergency Telephone No.	Tel. : +91-079-71800000
US Customer Service No.	Tel.: + 1 (877) 993 8779
Therapeutic Category:	Antidepressant
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.
Indications:	Doxepin hydrochloride is recommended for the treatment of: • Psychoneurotic patients with depression and/or anxiety. • Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol). • Depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly). • Psychotic depressive disorders with associated anxiety including

involutional depression and manic-depressive disorders..

Recommended usage:

Doxepin hydrochloride is recommended for the treatment of:
• Psychoneurotic patients with depression and/or anxiety. • Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol).
• Depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly).
• Psychotic depressive disorders with associated anxiety including involutional depression and manic-depressive disorders.
The target symptoms of psychoneurosis that respond particularly well to doxepin hydrochloride include anxiety, tension, depression, somatic symptoms and concerns, sleep disturbances, guilt, lack of energy, fear, apprehension and worry.
Clinical experience has shown that doxepin hydrochloride is safe and well tolerated even in the elderly patient. Owing to lack of clinical experience in the pediatric population, doxepin hydrochloride is not recommended for use in children under 12 years of age.

Restriction on Use / Contraindications:

Doxepin hydrochloride is contraindicated in individuals who have shown hypersensitivity to the drug. Possibility of cross sensitivity with other dibenzoxepines should be kept in mind.
Doxepin hydrochloride is contraindicated in patients with glaucoma or a tendency to urinary retention. These disorders should be ruled out, particularly in older patients.

Section 2. HAZARDS IDENTIFICATION

DOSAGE AND ADMINISTRATION:

The dose of doxepin tablets should be individualized

Dosing in Adults
The recommended dose of doxepin tablets for adults is 6 mg once daily. A 3 mg once daily dose may be appropriate for some patients, if clinically indicated.
Dosing in the Elderly
The recommended starting dose of doxepin tablets in elderly patients (≥ 65 years old) is 3 mg once daily. The daily dose can be increased to 6 mg, if clinically indicated.
Administration
Doxepin tablets should be taken within 30 minutes of bedtime.
To minimize the potential for next day effects, doxepin tablets should not

be taken within 3 hours of a meal

ADVERSE EFFECTS:

The most common treatment-emergent adverse reactions, reported in ≥ 2% of patients treated with doxepin, and more commonly than in patients treated with placebo, were somnolence/sedation, nausea, and upper respiratory tract infection.

The following serious adverse reactions are

- Abnormal thinking and behavioral changes
- Suicide risk and worsening of depression
- CNS Depressant effects

OVER DOSE EFFECT:

Doxepin is routinely administered for indications other than insomnia at doses 10- to 50-fold higher than the highest recommended dose of doxepin.

The signs and symptoms associated with doxepin use at doses several-fold higher than the maximum recommended dose (Excessive dose) of doxepin for the treatment of insomnia are described . as are signs and symptoms associated with higher multiples of the maximum recommended dose (Critical overdose)

PREGNANCY COMMENTS:

Advise patients that doxepin use late in pregnancy may increase the risk for neonatal complications requiring prolonged hospitalization, respiratory support or tube feeding

WARNINGS & PRECAUTIONS:

Need to Evaluate for Co-morbid Diagnoses: Reevaluate if insomnia persists after 7 to 10 days of use.

Abnormal thinking, behavioral changes, complex behaviors: May include "Sleep-driving" and hallucinations. Immediately evaluate any new onset behavioral changes

Depression: Worsening of depression or suicidal thinking may occur. Prescribe the least amount feasible to avoid intentional overdose

CNS-depressant effects: Use can impair alertness and motor coordination. Avoid engaging in hazardous activities such as operating a motor vehicle or heavy machinery after taking drug.Do not use with alcohol.

Potential additive effects when used in combination with CNS depressants or sedating antihistamines. Dose reduction may be needed.

Patients with severe sleep apnea: Doxepin is ordinarily not recommended for use in this population

Drug Interactions:

MAO inhibitors: Doxepin should not be administered in patients on MAOIs within the past two weeks. (4.2)

• Cimetidine: Increases exposure to doxepin.

Alcohol: Sedative effects may be increased with doxepin.

CNS Depressants and Sedating Antihistamines: Sedative effects may be increased with doxepin.
Tolazamide: A case of severe hypoglycemia has been reported.

Section 3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Exposure	CAS No.
Principle Component :		
Doxepin	Not Found	1229-29-4
Inactive ingredients :		
lactose monohydrate	Not Found	10039-26-6
FD&C Blue No.1 aluminium lake	Not Found	68921-42-6
pregelatinized starch	Not Found	9005-25-8
Magnesium stearate	Not Found	557-04-0
sodium starch glycolate	Not Found	9063-38-1
talc	Not Found	14807-96-6
D&C Yellow No. 10 aluminium lake.	Not Found	14807-96-6

Section 4. FIRST - AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Section 5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all firefighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

Section 6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7. HANDLING AND STORAGE

Storage	Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. protected from light. Dispense in a tight, light resistant container.
Specific end use	Pharmaceutical drug product
Precautions for safe handling	If Tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Environmental Exposure Controls:	Refer to specific Member State legislation for requirements under Community environmental legislation.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state **Tablets**

Description **Doxepin Tablets**

Doxepin tablets, 3 mg are light blue color round shaped, uncoated biconvex tablets having mottled surface and debossed with '393' on one side and plain on the other, and are supplied as:

NDC-72578-181-06 in bottle of 30 tablets with child-resistant closure
NDC-72578-181-16 in bottle of 90 tablets with child-resistant closure
NDC-72578-181-01 in bottle of 100 tablets
NDC-72578-181-05 in bottle of 500 tablets
NDC-72578-181-10 in bottle of 1,000 tablets
NDC-72578-181-77 in unit-dose blister cartons of 100 (10 x 10) unit dose tablets
Doxepin tablets, 6 mg are light green color round shaped, uncoated biconvex tablets having mottled surface and debossed with '394' on one side and plain on the other, and are supplied as:
NDC-72578-182-06 in bottle of 30 tablets with child-resistant closure
NDC-72578-182-16 in bottle of 90 tablets with child-resistant closure
NDC-72578-182-01 in bottle of 100 tablets
NDC-72578-182-05 in bottle of 500 tablets
NDC-72578-182-10 in bottle of 1,000 tablets
NDC-72578-182-77 in unit-dose blister cartons of 100 (10 x 10) unit dose tablets

Pure/Mixture Mixture

Section 10. STABILITY AND REACTIVITY

The product is stable

Section 11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility Carcinogenesis, mutagenesis, and impairment of fertility studies have not been conducted with doxepin hydrochloride.

Section 12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number 202761

Section 16. OTHER INFORMATION

Refer Product Packing Insert for more details

Date of issue: 27th July, 2024 **Supersedes edition:** NA

The information presented in the safety data sheet is, to the best of our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.