Doxepin Hydrochloride Capsules USP 10mg, 25mg, 50mg, 75mg,100mg

S.No.	Category	Question	Answer
Clinical Particulars			
1	Use/Indication	What is the product indicated for?	Doxepin Hydrochloride Capsules, USP are recommended for the treatment of: 1. Psychoneurotic patients with depression and/or anxiety. 2. Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol). 3. Depression and/or anxiety associated with organic disease (the possibility of drug interaction should be considered if the patient is receiving other drugs concomitantly). 4. Psychotic depressive disorders with associated anxiety including involutional depression and manic-depressive disorders.
2	Dosage	What is the recommended dosage?	**DOSAGE AND ADMINISTRATION** • The usual optimum dose range is 75 mg/day to 150 mg/day. • In more severely ill patient's higher doses may be required with subsequent gradual increase to 300 mg/day if necessary. Additional therapeutic effect is rarely to be obtained by exceeding a dose of 300 mg/day • For most patients with illness of mild to moderate severity, a starting daily dose of 75 mg is recommended. Dosage may subsequently be increased or decreased at appropriate intervals and according to individual response. • In patients with mild symptoms or emotional symptoms accompanied by organic diseases lower dose may be sufficient. some of the patients have been controlled with a lower dose of 25 to 50 mg a day. • After initiation of the treatment, doxepin can be maintained with maximum recommended dose of 150 mg /day at bed time.
3	Administration	Administration precautions	Patients, their families and their caregivers should be encouraged to be alert to the emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, mania, other unusual changes in behavior, worsening of depression and suicidal ideation, especially early during antidepressant treatment and when the dose is adjusted up or down. Symptoms such as these may be associated with an increased risk for suicidal thinking and behavior and indicate a need for very close monitoring and possibly changes in the

			medication.
4	Administration	How do I take?	Doxepin Hydrochloride Capsules may be taken with or without food.
5	Administration	Use in Pediatric Population	The use of doxepin hydrochloride in children under 12 years of age is not recommended because safe conditions for its use have not been established
6	Administration	Use in Geriatric Population	In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy • The extent of renal excretion of doxepin hydrochloride has not been determined. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selections. • Sedating drugs may cause confusion and over sedation in the elderly; elderly patients generally, should be started on low doses of doxepin hydrochloride and observed closely.
7	Mechanism	Mechanism of Action	The mechanism of action of doxepin hydrochloride is not definitely known. It is not central nervous system stimulant nor a monoamine oxidase inhibitor. The current hypothesis is that the clinical effects are due, at least in part, to influences on the adrenergic activity at the synapses so that deactivation of norepinephrine by reuptake into the nerve terminals is prevented. Animal studies suggest that doxepin hydrochloride does not appreciably antagonize the antihypertensive action of guanethidine. In animal studies anticholinergic, anti-serotonin and antihistamine effects on smooth muscle have been demonstrated. At higher than usual clinical doses norepinephrine response was potentiated in animals. This effect was not demonstrated in humans. At clinical dosages up to 150 mg per day, doxepin hydrochloride can be given to man concomitantly with guanethidine and related compounds without blocking the antihypertensive effect. At dosages above 150 mg per day blocking of the antihypertensive effect of these compounds has been reported. Doxepin hydrochlorides virtually devoid of euphoria as a side effect. Characteristic of this type of compound, doxepin hydrochloride has not been demonstrated to produce the physical tolerance or psychological dependence associated with addictive compounds.
8	Warning	Black Box Warning	Consist of black box warning Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders
9	Lactation	Use in Lactation	There has been a report of apnea and drowsiness occurring in a nursing infant whose mother was taking doxepin hydrochloride.

10	Pregnancy	Use in Pregnancy	The use of doxepin hydrochloride in children under 12 years of age is not recommended because safe conditions for its use have not been established.
11	Precautions	Is there any interaction between medication and alcohol?	It should be borne in mind that alcohol ingestion may increase the danger inherent in any intentional or unintentional doxepin hydrochloride over dosage. This is especially important in patients who may use alcohol excessively.
12	Storage	What are the storage conditions?	tore at 20º to 25ºC (68º to 77ºF); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from light. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure.
13	Dispensing	How to Dispense?	As prescribed by the Physician
14	Contraindication	What are the contraindications of (medication)?	Doxepin hydrochloride capsules are contraindicated in individuals who have shown hypersensitivity to the drug. Possibility of cross sensitivity with other di benzoxepines should be kept in mind. Doxepin hydrochloride capsules are contraindicated in patients with glaucoma or a tendency to urinary retention. These disorders should be ruled out, particularly in older patients.
Pharmaceutical Particulars			
15	Pharmaceutical Form	How Supplied	Doxepin Hydrochloride Capsules, USP are available containing doxepin hydrochlorides equivalent to 10 mg,25 mg, 50 mg, 75 mg or 100 mg of doxepin. The 10 mg capsule is a yellow opaque body imprinted with “10 mg” in black ink and yellow opaque cap imprinted with “MD12” in black ink filled with white to off white powder. They are available as follows: NDC 72205-088-91lbottles of 100 capsules NDC 72205-088-99 bottles of 1000 capsules The 25 mg capsule is a white opaque body imprinted with “25 mg” in black ink and yellow opaque cap imprinted with “MD13” in black ink filled with white to off white powder. They are available as follows: NDC 72205-089-91 bottles of 100 capsules NDC 72205-089-99 bottles of 1000 capsules The 50 mg capsule is a ivory opaque body imprinted with “50 mg” in black ink and ivory opaque cap imprinted with “MD14” in black ink filled with white to off white powder. They are available as follows: NDC 72205-090-91 bottles of 100 capsules NDC 72205-090-99 bottles of 1000 capsules The 75 mg capsule is a green opaque body imprinted with “75 mg” in black ink and green opaque cap imprinted with “MD15” in black ink filled with white to off white powder. They are available as follows: NDC 72205-091-91 bottles of 100 capsules. NDC 72205-091-99 bottles of 1000 capsules.

			The 100 mg capsule is a white opaque body imprinted with “100 mg” in black ink and green opaque cap imprinted with “MD16” in black ink filled with white to off white powder. They are available as follows: NDC 72205-092-91bottles of 100 capsules NDC 72205-092-99 bottles of 1000 capsules.
16	Ingredients	Active and Inactive	**Active ingredient:** Doxepin hydrochloride **Inactive ingredients:** starch, Corn, sodium lauryl sulfate, magnesium stearate, titanium dioxide, FD&C yellow no.6, D&C yellow No.10, Gelatin, shellac, ferrosoferric oxide, propylene glycol, potassium hydroxide.
Allergens			
17	Ingredients	Does it contain Gluten?	No
18	Ingredients	Does it contain alcohol?	No
19	Ingredients	Does it contain dyes?	No
20	Ingredients	Does it contain Lactose?	No
21	Ingredients	Does it contain Nuts?	No
22	Ingredients	Does it contain Preservatives?	No
23	Ingredients	Does it contain Soy products?	No
24	Ingredients	Does it contain peanut?	No
25	Ingredients	Does it contain any derivatives from tree nuts or any other type of nuts?	No
26	Ingredients	Does it contain Corn?	Starch used which is derived from maize starch.
27	Ingredients	Does it contain Alcohol?	API contains solvents within the limits as per ICH
28	Ingredients	Does it contain Animal products?	Bovine gelatin used for capsule manufacturing.
29	Ingredients	Does it contain wheat?	Starch used which is derived from maize starch
Miscellaneous			
30	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
31	Miscellaneous	May I know about return, refunds and reimbursement?	Contact Novadoz Pharmaceuticals Customer Service directly at 908-360-1500

32	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
33	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
34	Miscellaneous	May I know where is this product manufactured?	**Manufactured by**: MSN Laboratories Private Limited Telangana – 509 228, INDIA **Distributed by**: Novadoz Pharmaceuticals LLC Piscataway, NJ 08854-3714