

DOXEPIN HCl Capsules

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about DOXEPIN HCl

DOXEPIN HCl for oral use is available as 10 mg and 50 mg capsules containing respectively 10 mg and 50 mg doxepin as doxepin HCl with the following excipients: starch and magnesium stearate.

Doxepin is a dibenzoxepine tricyclic antidepressant. It has moderate antimuscarinic and marked sedative properties and has norepinephrine and serotonin reuptake inhibitor activity.

DOXEPIN HCl is indicated in the following conditions:

- Depression and/or anxiety; the symptoms that respond particularly well to doxepin include anxiety, tension, depression, somatic symptoms and concerns, sleep disturbances, guilt, lack of energy, fear, apprehension and worry.
- Depression and/or anxiety associated with alcoholism (not to be taken concomitantly with alcohol)
- Depression and/or anxiety associated with organic disease
- Psychotic depressive disorders with associated anxiety including involuntal depression and maniac-depressive disorders

DOXEPIN HCl may be used to treat other conditions as well such as certain chronic and neuropathic pain and some types of headache.

DOXEPIN has very potent antihistaminic activity. It has been shown to be an effective oral alternative to conventional antihistamines in the treatment of urticaria.

The way to take DOXEPIN HCl

Take DOXEPIN HCl as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage and duration of treatment are individualized and adjusted according to the condition under treatment and the response obtained.

Usually, the dose may vary between 10 mg and 300 mg.

In the treatment of depression, for most patients with illness of mild to moderate severity, the initial dose is 75 mg daily. Dosage may subsequently be increased or decreased at appropriate intervals according to individual response. The usual optimal dosage range is 75 mg/day to 150 mg/day.

Doses up to 300 mg daily may be required in severely depressed patients.

Patients with very mild symptomatology or emotional symptoms accompanying organic disease may respond to as little as 25 mg to 50 mg daily.

Daily doses up to 150 mg may be given in divided doses or as a single dose at bedtime. If the total daily dose exceeds 150 mg, it should be given in 3 divided doses, although the largest portion, up to a maximum of 150 mg, may be given at bedtime.

A suggested starting dose in the elderly is 10 to 50 mg daily.

In the treatment of urticaria in adults, the dose may vary between 10 mg and 30 mg per day.

Duration of treatment

Duration of treatment is determined according to the disease under treatment. Anti-anxiety effect is apparent before the antidepressant effect. Optimal antidepressant effect may not be evident for 2 to 3 weeks.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

If you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

Contraindications

This drug is contraindicated in the following conditions:

- Hypersensitivity to tricyclic antidepressants or doxepin
- Glaucoma
- Tendency to urinary retention
- Patients with mania
- Severe liver disease
- Lactation
- Recent myocardial infarction

Precautions

- Do not stop taking this medicine without first checking with your doctor. He may want you to reduce gradually the amount you are taking before stopping completely. Doxepin should be withdrawn gradually to reduce the risk of withdrawal symptoms.
- The safety of this drug in pregnancy has not been established.
- Safety and effectiveness of this drug in pediatric patients under 12 years of age have not been established.
- The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy until significant improvement in depression is observed.
- Caution should be exercised when driving a car or operating dangerous machinery since drowsiness may occur.
- This drug must be used with caution in patients with cardiovascular disease including heart block and cardiac arrhythmia, hepatic or renal impairment, history of epilepsy, elderly patients, chronic constipation, prostatic hypertrophy, pheochromocytoma, hyperthyroidism and diabetes.
- If you are having surgery, including dental surgery, tell your doctor or dentist that you are taking doxepin.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug should not be used with sultopride and non selective MAO inhibitors.

Concomitant use of alcohol, clonidine, alpha and beta sympathomimetics (adrenaline, noradrenaline) is not recommended.

Use caution with medications with anticholinergic effects (sedative H1 antihistamines, some drugs for the treatment of Parkinson disease, some antispasmodics, disopyramide, and some neuroleptics), anticonvulsants, valproate, valpromide, carbamazepine, selective serotonin reuptake inhibitors (such as citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), antihypertensive medications, drugs with depressant actions on the central nervous system (narcotic analgesics and cough suppressants, barbiturates, benzodiazepines and other anxiolytics, hypnotics, neuroleptics), antidiabetics, cimetidine, baclofen, guanethidine and sublingual nitrates.

The dose of thyroid hormone medication may need adjustment in case of concomitant use of this drug.

Adverse reactions

The most reported adverse reactions include drowsiness, constipation and dry mouth.

Other adverse reactions include nausea, vomiting, taste disturbances, diarrhea, blurred vision, sweating, weakness, headache, confusion, disorientation, agitation, numbness, tachycardia and postural hypotension.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

DOXEPIN HCl, 10 mg doxepin (as doxepin HCl), pack of 50 capsules

DOXEPIN HCl, 50 mg doxepin (as doxepin HCl), pack of 50 capsules

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