

BENZHEXOL
5 mg tablets

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.

Warning

Indiscriminate use can lead to psychiatric disturbances and overdose.

Information about BENZHEXOL

Each BENZHEXOL tablet contains benzhexol HCl 5 mg.

BENZHEXOL (also named trihexyphenidyl) is an antimuscarinic agent that exerts a direct inhibitory effect upon the parasympathetic nervous system. It also has a relaxing effect on smooth muscle.

- BENZHEXOL is indicated in the symptomatic treatment of all forms of parkinsonism.

BENZHEXOL is often useful as adjunct therapy when treating parkinsonism with levodopa.

- Additionally, BENZHEXOL is indicated for the control of extrapyramidal disorders caused by central nervous system drugs such as the dibenzoxazepines, phenothiazines, thioxanthenes and butyrophenones.

The way to take BENZHEXOL

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

Dosage and duration of treatment are individualized on the basis of the condition under treatment and the response of the patient. The initial dose should be low and then increased gradually, especially in patients over 60 years of age. Whether BENZHEXOL may best be taken before or after meals should be determined by the way the patient reacts. If you are usually more prone to excessive salivation, you may prefer to take it after meals. If the medication tends to dry your mouth excessively, it may be better to take it before meals, unless it causes nausea. BENZHEXOL is given in 2 or 3 divided doses daily.

In Parkinsonism:

BENZHEXOL is started at a low dose and then increased gradually until a total daily dose of 5 to 10 mg/day (half a tablet to one tablet twice daily) according to the response of the patient. For advanced cases, 15 mg or more may be needed daily.

Elderly patients require smaller doses.

In drug-induced Parkinsonism:

The size and frequency of dose are determined by your doctor. The total daily dosage usually ranges between 5 and 15 mg given in 2 or 3 divided doses (half a tablet to one tablet 2 to 3 times daily).

In elderly patients dosage should not exceed 10 mg per day (1 tablet twice daily).

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

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following cases:

- Known hypersensitivity to any of the components
- Angle-closure glaucoma
- Prostatic hypertrophy
- Urinary retention
- Myasthenia gravis

Precautions

- This drug should be used with caution for patients with cardiac, liver, or kidney disorders, hypertension, obstructive disease of the gastrointestinal or genitourinary tracts and in elderly males with possible prostatic hypertrophy.
- This drug should be used with caution in children and geriatric patients.

- 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. It is usual when changing from one drug to another to withdraw the one in small amounts while gradually increasing the dose of the other.
- Intraocular pressure should be closely monitored at regular intervals.
- Use with caution in patients with arteriosclerosis or with a history of idiosyncrasy to other drugs.
- Safety for use during pregnancy has not been established. It is used only when clearly needed. Inform your doctor before using this medication in case of pregnancy.
- Breast feeding is not recommended during treatment with this drug. An inhibitory effect on lactation may occur.
- This drug may cause dizziness or blurred vision; you should observe caution while driving or performing other tasks requiring alertness until the response to the drug is known.

Associations with other medications

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

BENZHEXOL may be given with other drugs used for the relief of parkinsonism, such as other antimuscarinic agents, levodopa and amantadine; reduced dosage may be needed.

Use with caution with alcohol, central nervous system depressants, digoxin, and lisuride.

The concomitant use with other anticholinergic drugs (some antidepressants, antispasmodics, antihistamines H1 or neuroleptics) may increase the incidence of side effects.

Adverse reactions

The most reported side effects include dryness of the mouth, blurred vision, dizziness, mild nausea or nervousness. Such reactions tend to become less pronounced and even to disappear as treatment continues. Before these reactions have remitted spontaneously, they may often be controlled by dosage adjustment.

Other potential side effects include constipation, drowsiness, urinary hesitancy or retention, tachycardia, dilation of the pupil, increased intraocular tension, weakness, mental disturbances, vomiting or headache.

Rarely reported adverse reactions include suppurative parotitis, skin rashes, glaucoma, dilatation of the colon, paralytic ileus or certain psychiatric manifestations.

Elderly patients may develop hallucinations or mental confusion.

Inform your doctor if any of these effects 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

BENZHEXOL, benzhexol HCl 5mg, pack of 100 tablets

Revision date: 03/2006

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