



## **Benzhexol 2mg and 5mg Tablets**

[trihexyphenidyl hydrochloride]

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

1. What Benzhexol Tablets are and what they are used for
2. What you need to know before you take Benzhexol Tablets
3. How to take Benzhexol Tablets
4. Possible side effects
5. How to store Benzhexol Tablets
6. Contents of the pack and other information

### **1. WHAT BENZHEXOL TABLETS ARE AND WHAT THEY ARE USED FOR**

Benzhexol Tablets contain the active ingredient trihexyphenidyl. This belongs to a group of medicines known as anti-muscarinics which are used in the treatment of Parkinson's disease. This particular medicine is used for treating Parkinson's disease and also to prevent and control side effects which are similar to Parkinson's disease and are caused by certain medicines.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BENZHEXOL TABLETS**

#### **Do not take Benzhexol Tablets:**

- If you are hypersensitive (allergic) to trihexyphenidyl or any of the other ingredients of Benzhexol Tablets.

#### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse before taking Benzhexol Tablets if you:

- Have glaucoma (increased pressure in the eye)
- Suffer from high blood pressure
- Suffer from kidney, heart, liver or prostate problems
- Suffer from stomach or bowel blockage
- Are elderly - these tablets should be used with caution and may cause confusion, delusions and hallucinations
- Suffer from bladder problems or have difficulty passing urine
- Suffer from a condition called myasthenia gravis (a rare muscle weakness disorder)

- Experience unusual movements of the face and tongue as this may be a sign of a serious condition known as tardive dyskinesia
- Have arteriosclerosis (hardening of the arteries).

#### **Other medicines and Benzhexol Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular:

- Other medicines that have an anti-muscarinic effect such as atropine, hyoscine, oxybutynin and tolterodine used to treat bowel or bladder problems
- Monoamine oxidase inhibitors (MAOIs) used to treat depression e.g phenelzine, isocarboxid
- Antihistamines used to treat allergic reactions e.g diphenhydramine
- Disopyramide used to treat an irregular heart beat
- Phenothiazines used to treat mental disorders or nausea and vomiting e.g chlorpromazine, thioridazine and fluphenazine
- Metoclopramide or domperidone used to treat the symptoms of nausea
- Tricyclic antidepressants e.g. amitriptyline
- Nefopam used to treat pain
- Ketoconazole used to treat fungal infections
- Other medicines used in the treatment of Parkinson's disease e.g amantidine and levodopa
- Medicines used to stimulate the nervous system.

If you use nitrate tablets under your tongue to treat angina attacks, you may find that trihexyphenidyl makes your mouth too dry to dissolve them.

#### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice if you are pregnant or planning on becoming pregnant. These tablets should not be used during breast-feeding.

#### **Driving and using machines**

These tablets can cause some people to have blurred vision, feel confused or feel dizzy. If you are affected do not drive or operate machinery.

#### **Benzhexol Tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. HOW TO TAKE BENZHEXOL TABLETS**

Always take Benzhexol Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The tablets are taken orally. The dose should be taken in 3 to 4 divided doses daily, before or with meals.

**Adults:**

The starting dose is 1mg daily. This will be gradually increased until a maintenance dose of 5-15mg daily, in 3-4 divided doses is achieved. The maximum daily dose is 20mg. The dose will be determined for you by your doctor.

**Elderly:**

Patients over 65 years may require a reduced adult dose.

When these tablets are used with other drugs to relieve Parkinson's disease, such as levodopa and amantadine, the dose may need to be reduced.

Your doctor will decide the dose that is best for you. The pharmacist's label will also tell you how many tablets to take and how often.

**If you take more Benzhexol Tablets than you should**

This medicine is to be taken at regular intervals, as determined by the physician. If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Take your tablet pack with you. Symptoms of an overdose include flushing and dryness of the skin, dilated pupils, dry mouth and tongue, irregular heartbeat, increased breathing rate, fever, feeling sick and being sick.

**If you stop taking Benzhexol Tablets**

This medicine is not to be stopped abruptly, keep taking your medicine until your doctor tells you how to reduce the dose slowly.

**If you forget to take Benzhexol Tablets**

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and continue with the regular dosing schedule.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Allergic reactions may occur rarely, with symptoms such as rash, itching, swelling of the face, wheeziness, shortness of breath, tightness in the chest, fever, low blood pressure and feeling dizzy particularly when standing up. **If any of these occur STOP taking the medicine and contact a doctor immediately.**

**Other side effects that may occur:-**

- Dry mouth, difficulty swallowing
- Constipation, feeling sick and being sick
- Large pupils, lack of near vision, eye discomfort, increased sensitivity to light and painful increased pressure in the eye
- Agitation
- Confusion
- Hallucinations
- Feeling optimistic
- Inability to sleep or restlessness
- Forgetfulness
- Paranoid delusions (being worried that something bad is happening without any reason)

- Redness and dryness of the skin or skin rashes
- Difficulty passing urine or unable to pass urine
- Thirst
- Fever
- Faster heartbeat
- Worsening of myasthenia gravis (very tired or weak muscles).



These side effects are more likely to occur in patients receiving higher than the recommended dose.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE BENZHEXOL TABLETS**

Check the expiry date printed on the label or side of the box. Do not use after the expiry date stated on the label.

Store in the original package.

In case of any visible signs of deterioration, you should discard the package.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

**Keep out of the sight and reach of children.**

**6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Benzhexol Tablets contain:**

Benzhexol 2mg and 5mg Tablets contain 2mg and 5mg of the active ingredient trihexyphenidyl hydrochloride respectively.

The other ingredients are: magnesium stearate, maize starch, pregelatinised maize starch and lactose.

**What Benzhexol Tablets look like and contents of the pack**

Benzhexol Tablets are white, flat bevel edged tablets with a breakline.

Pack sizes for 2mg and 5mg tablets are 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1000 in plastic containers.

Blister packs in cartons contain 28, 30, 42, 56, 60, 84, 90 and 112 tablets.

**Marketing Authorisation Holder**

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