Package leaflet: Information for the user

Trihexyphenidyl 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, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take Trihexyphenidyl Tablets
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1. What Trihexyphenidyl Tablets are and what they are used for

Trihexyphenidyl Tablets contain the active substance trihexyphenidyl hydrochloride. This belongs to a group of medicines known as anticholinergics 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 Trihexyphenidyl Tablets

Do not take Trihexyphenidyl Tablets:
- If you are allergic to trihexyphenidyl hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Trihexyphenidyl Tablets if you:
- Have glaucoma (increased pressure in the eye)
- Have high blood pressure
- Have kidney, heart, liver or prostate problems
- Have stomach or bowel blockage
- Are elderly – these tablets should be used with caution and may cause confusion, delusions and hallucinations
- Have bladder problems or have difficulty passing urine
- Have 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.

Other medicines and Trihexyphenidyl 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, isocarboxazid
- 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
- Other medicines used in the treatment of Parkinson's disease e.g. amantadine and levodopa
- Medicines used to stimulate the nervous system
- Clozapine used to treat schizophrenia
- Parasympathomimetic medicines (e.g. neostigmine, bethanechol) for the treatment of urine retention.

Pregnancy and breast-feeding
Do not take this medicine if you are breast-feeding.

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

Trihexyphenidyl 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 Trihexyphenidyl Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not take more of it and do not take it more often or for a longer time than your doctor ordered.

Common Dosage
This medicine is to be taken by mouth.

Treatment should always be started at a low dose and gradually increased until the right dose for you has been determined.

The recommended dose is:

Adults
The usual dosage for Parkinson's disease is 6 – 10 mg per day, however some patients may need more. This should be given at mealtimes either three or four times a day.

For drug-induced Parkinsonism the normal dose is 5 mg - 15 mg per day. Some patients may be controlled by as little as 1 mg daily.

At the beginning of therapy the dose should be 1 mg on the first day, 2 mg on the second day and thereafter increases of 2 mg per day at 3 - 5 day intervals, continued until the right dose for you is reached.

Use in Children
Trihexyphenidyl Tablets are not recommended for children.

Elderly
If you are over 65 years of age you may require smaller amounts of Trihexyphenidyl Tablets.

In all patients changes in dosage either upward or downwards should only be in small steps over a period of days.

If you take more Trihexyphenidyl 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 overdoses with antimuscarinic agents including flushing and dryness of the skin, dilated pupils, dry mouth and tongue, fast heart rate , rapid respiration, high fever, hypertensions, nausea, vomiting. A rash may appear on the face or upper trunk. Symptoms of CNS stimulation include restlessness, confusion, hallucinations, paranoid and psychotic reactions, incoordination, delirium and occasionally convulsion. In severe overdose, CNS depression may occur with coma, circulatory and respiratory failure and death.

If you forget to take Trihexyphenidyl 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. Do not take a double dose to make up for a forgotten dose.

If you stop taking Trihexyphenidyl Tablets
Do not stop taking this medicine suddenly as your symptoms may get worse. Your doctor will reduce the dose gradually if it needs to be lowered.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

If you experience any of the following side effects, you should stop taking this medicine and contact a doctor immediately:
- Allergic reaction such as swelling of the eyelids, face or lips, skin rash or itching
- Difficulty breathing or tightness in the chest
- Difficulty swallowing.

If you experience any of the following side effects you should tell your doctor as soon as possible:
- Restlessness or agitation
- Feelings of confusion or delusion (loss of the sense of reality)
- Hallucinations
- Difficulty in sleeping
- False sense of well-being
- Immediate or short term memory loss
- Worsening of myasthenia gravis (very tired weak muscles)
- Large pupils and lack of near vision

- Eye discomfort and increased sensitive to light
- Painful increased pressure in the eye
- Faster heartbeat
- Being sick
- Reddening and dryness of skin or skin rashes
- Inability to pass urine or difficulty passing urine
- Thirst
- Fever (raised body temperature).

However you should tell your doctor if any of the following side effects are severe or become troublesome:

- Dryness of mouth (this can be improved by sucking pastilles)
- Constipation
- Blurring vision or dizziness
- Feeling sick or nervous.

If you notice any of the above reactions or side effects, or if you notice other unusual or worrying changes contact your doctor.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Trihexyphenidyl Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

If your medicine comes in a plastic container you should keep the container tightly closed.
If your medicine comes in blister packs you should store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trihexyphenidyl Tablets contain
The active substance is trihexyphenidyl hydrochloride. Each tablet contains either 2mg or 5mg of trihexyphenidyl hydrochloride.

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

What Trihexyphenidyl Tablets look like and contents of the pack
Trihexyphenidyl Tablets are white, flat bevel edged tablets with a breakline.

Trihexyphenidyl Tablets are available in plastic containers or blister packs.

Plastic containers contain 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 or 1,000 tablets.
Blister packs contain 28, 30, 42, 56, 60, 84, 90 or 112 tablets.

Not all pack sizes may be marketed.

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