PACKAGE LEAFLET: INFORMATION FOR THE USER

TRIHEXYPHENIDYL HYDROCHLORIDE 2mg TABLETS

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others.
 It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is TRIHEXYPHENIDYL HYDROCHLORIDE 2mg TABLETS but will be referred to as Trihexyphenidyl Tablets or Trihexyphenidyl throughout this leaflet.

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1. WHAT TRIHEXYPHENIDYL TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Trihexyphenidyl Tablets. Trihexyphenidyl is an antispasmodic (muscle relaxing) drug. Trihexyphenidyl is used to treat Parkinson's disease. Trihexyphenidyl helps patients with Parkinson's disease by improving muscle control and reducing stiffness so that they can move more naturally. Trihexyphenidyl can also be used to treat movement disorders (extreme restlessness, involuntary movements or muscle spasms) which may be caused by certain drugs.

2. BEFORE YOU TAKE TRIHEXYPHENIDYL TABLETS Do not take Trihexyphenidyl Tablets if you:

 are allergic (hypersensitive) to trihexyphenidyl or any other ingredient in the tablets (see section 6–'Further information for details')

Take special care with Trihexyphenidyl Tablets if you:

- have glaucoma
- have heart, liver or kidney disease or suffer from high blood pressure
- have prostate problems
- have trouble passing urine
- have a stomach ulcer or suffer from severe heartburn or acid indigestion or any other digestive disorders
- suffer from a condition called myasthenia gravis
- suffer from tardive dyskinesia (unusual movements of the face and tongue)
- are elderly or under the age of 21

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (like aspirin).

Take special care if you are taking any of the following:

- monoamine oxidase inhibitors (e.g. moclobemide, tranylcypromine) or tricyclic antidepressants (e.g.amitriptyline) for the treatment of depression
- phenothiazines (e.g. chlorpromazine, thioridazine) or clozapine for the treatment of mental illness
- antihistamines for the treatment of allergies
- disopyramide for the treatment of an irregular heart beat
- levodopa for the treatment of Parkinson's disease
- · amantadine for viral infections
- nefopam, a painkiller
- metoclopramide or domperidone
- parasympathomimetics (e.g. neostigmine, bethanechol) for the treatment of urinary retention

Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, planning to become pregnant, or breast-feeding without consulting your doctor first.

Driving and using machines

Trihexyphenidyl can cause blurred vision or dizziness. Do not drive or operate machinery if this happens to you.

Important Information about the ingredients of Trihexyphenidyl Tablets

This medicine contains starch. This is suitable for people with coelic disease. Patients with wheat allergy (different from coelic disease) should not take this medicine.

3. HOW TO TAKE TRIHEXYPHENIDYL TABLETS

Always take Trihexyphenidyl Tablets exactly as your doctor has told you to. The label on your medicine should also tell you. You should check with your doctor or pharmacist if you are not sure.

The dose of trihexyphenidyl varies from person to person depending on the symptoms. You will normally start on a low dose and this may be increased gradually by your doctor. The usual dose is between 5 – 15mg per day (each tablet contains 2mg). Some people may need less, especially if they are also taking other medicines. Also, if you are over 65 years of age, you may need less than the usual dose.

Trihexyphenidyl Tablets should be taken at meal times (just before or just after a meal). If you are not sure how many tablets to take or when to take them, ask your pharmacist. Trihexyphenidyl Tablets should be swallowed whole with a glass of water.

If you take more Trihexyphenidyl Tablets than you should

If you have taken an overdose of Trihexyphenidyl Tablets (that is more than the doctor has told you to) get medical help immediately, either by calling your doctor or going to the nearest hospital casualty department. Remember to take the labelled medicine bottle with you, whether there are any Trihexyphenidyl Tablets left or not.

If you forget to take Trihexyphenidyl Tablets

If you forget to take a tablet you should take it as soon as you remember. However, if this is within 2 hours of your next dose you should skip the missed tablet and carry on taking the rest of your tablets as usual. Do not take a double dose to make up for the forgotten tablet.

If you stop taking Trihexyphenidyl Tablets

Do not stop taking this medicine suddenly as your symptoms may get worse. If your dose needs to be lowered, your doctor will reduce the amount you should take gradually.

4. POSSIBLE SIDE EFFECTS

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

If you experience any of the following very rare side effects, you should tell your doctor or go to your nearest casualty department immediately:

- allergic reactions such as swelling of the eyelids, face or lips, skin rash
- difficulty breathing or tightness in the chest
- difficulty swallowing

If you experience any of the following rare 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 or weak muscles)
- large pupils and lack of near vision

- · eye discomfort and increased sensitivity to light
- painful increased pressure in the eye
- faster heart beat
- 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 common side effects are severe or become troublesome

- dryness of mouth (this can be approved by sucking pastilles)
- constipation
- blurring of vision or dizziness
- feeling sick or nervous

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRIHEXYPHENIDYL HYDROCHLORIDE 2mg TABLETS

- Keep your tablets in the original container until you need to take one.
 This protects the tablets from moisture which may spoil them.
- Do not use after the expiry date printed on the carton, or tablet blister strip. The expiry date refers to the last day of the month.
- Keep your tablets in a safe, dry place where children cannot reach them.
- Your tablets should be kept at room temperature (15-30°C).
- If your doctor decides to stop your medicine you should return any tablets that are left to your pharmacist (chemist) for disposal.
 Medicines should not be put down the sink, the toilet or in the waste bin.
- If you have any queries please ask your pharmacist (chemist).
- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Trihexyphenidyl Tablets contain?

Trihexyphenidyl hydrochloride Tablets contain 2mg of the active ingredient Trihexyphenidyl hydrochloride.

The other ingredients in Trihexyphenidyl Tablets are calcium hydrogen phosphate (used to bind the ingredients of the tablet together), maize starch (used to add bulk to the tablet) and magnesium stearate.

What Trihexyphenidyl Tablets looks like and contents of the pack

Trihexyphenidyl hydrochloride in a white, round tablet marked with a breakline on one side.

TrihexyphenidylTablets are available in packs of 100 Tablets.

Manufacturer by: Teopharma S.r.l., Via F.lli Cervi, 8 – 27010 Valle Salimbene (PV), Italy.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

TRIHEXYPHENIDYL HYDROCHLORIDE 2mg TABLET; PL 18799/2752

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