

PACKAGE LEAFLET: INFORMATION FOR THE USER
TRIHEXYPHENIDYL 2 mg TABLETS
TRIHEXYPHENIDYL 5 mg TABLETS

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

WHAT IS IN THIS LEAFLET

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

1. WHAT TRIHXYPHENIDYL IS AND WHAT IT IS USED FOR

TRIHXYPHENIDYL belongs to a group of medicines known as the anti-spasmodics (muscle relaxant) drug. TRIHXYPHENIDYL works by controlling the symptoms of Parkinson's disease. Trihexyphenidyl can also be used to treat movement disorders which may cause by certain drugs.

This medicine helps control shaking (tremor), muscle rigidity, restlessness, muscle spasm, involuntary movements and increased saliva production.

If you are not sure why you have been prescribed these tablets then please ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIHXYPHENIDYL

Do not take TRIHXYPHENIDYL

If you are allergic to TRIHXYPHENIDYL or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or pharmacist **before** taking this medicine if you:

- have high blood pressure or heart problems
- have problems with your liver, kidneys or stomach
- are likely to have increased eyeball pressure (Glaucoma)
- have a prostate problems
- have trouble passing urine
- have a stomach ulcer or suffer from severe heartburn or acid indigestion or any other digestive disorder

- suffer from a condition called muscle weakness (Myasthenia gravis)
- suffer from tardive dyskinesia (unusual movements of the face and tongue)
- have mental health problems
- are elderly.

Children

These tablets are not recommended for use in children.

Other medicines and TRIHXYPHENIDYL

Tell your doctor or pharmacist if you are taking, have recently taken or might take **any** other medicines, even medicines bought without a prescription (like aspirin).

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may affect how TRIHXYPHENIDYL tablets work:

- Monoamine oxidase inhibitors (e.g. Moclobemide, Trancylcypromine) or Tricyclic antidepressant (e.g. Amitriptyline) for the treatment of depression or anxiety
- Medicines called Phenothiazines (e.g. Chlorpromazine, Thioridazine) for the treatment of mental health problems
- Clozapine for schizophrenia
- Parasympathomimetics (e.g. Neostigmine, Bethanechol), Carbachol or Distigmine for difficulty passing urine
- Amantadine for viral infection
- Levodopa to treat Parkinson's disease
- Antihistamines for allergies
- Disopyramide to treat irregular heartbeat
- Nefopam to relieve pain
- Domperidone or Metoclopramide for nausea and vertigo.

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking TRIHXYPHENIDYL.

TRIHXYPHENIDYL with food and drink

If TRIHXYPHENIDYL tablets make you nauseous, take them after meals. If they give you a dry mouth, take them before meals or try chewing gum, peppermints or drinking water.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, 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

TRIHXYPHENIDYL may cause blurred vision or make you less alert. If affected do not drive or operate machinery.

TRIHXYPHENIDYL contains Lactose

If you know you have an intolerance to lactose or other sugars contact your doctor before taking TRIHXYPHENIDYL.

3. HOW TO TAKE TRIHXYPHENIDYL

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

Take this medicine by mouth.

Dosage

Treatment should start at a low dose and be gradually increased until the right dosage has been found.

The recommended dose is:

Adults: Typical doses are 6-10 mg per day for Parkinson's disease and 5-15 mg per day for treating side effects from other drugs. Some patients may need less than this especially if you are also taking other medicines.

Elderly: Patients over 60 years of age will be more sensitive and therefore require smaller doses. Follow your doctor's advice.

Use in Children: Not recommended for children.

If you take more TRIHEXYPHENIDYL than you should

Contact your doctor or pharmacist immediately. Show them the package.

If you forget to take TRIHEXYPHENIDYL

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

If you stop taking TRIHEXYPHENIDYL

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 regularly.

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

4. POSSIBLE SIDE EFFECTS

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

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

- allergic reaction such as swelling of the eyelids, face or lips or skin rash
- 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 any of the side effects become 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme [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

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

Do not store above 25°C. Store in the original package.

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

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What TRIHEXYPHENIDYL contains

The active ingredient is trihexyphenidyl hydrochloride. TRIHEXYPHENIDYL is the new name for Benzhexol. The ingredient itself has not changed.

The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, sodium starch glycolate and magnesium stearate.

What TRIHEXYPHENIDYL looks like and contents of the pack

Trihexyphenidyl 2 mg tablets are round white tablets with the marking MP20 on one side.

Trihexyphenidyl 5 mg tablets are round white tablets with the marking MP21 on one side.

The tablets come in packs containing 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Genethics Europe Limited,
41-43 Klimentos, Klimentos Tower,
Nicosia 1061, Cyprus

Manufacturer

DDSA Pharmaceuticals Limited,
84 Pembroke Road,
London, W8 6NX, UK

For more information about this product, please contact the Marketing Authorisation Holder.

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