



Trihexyphenidyl Hydrochloride 5mg/5ml Syrup

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

1. What Trihexyphenidyl Syrup is and what it is used for

Trihexyphenidyl Syrup belongs to a group of medicines called antimuscarinics.

Trihexyphenidyl Syrup is used to treat some of the symptoms of Parkinson's disease such as shakiness or stiffness of the muscles which can cause difficulty moving.

Some medicines can cause side effects which are like the symptoms of Parkinson's disease and it is also used to reduce these side effects.

2. What you need to know before you take Trihexyphenidyl Syrup

Do not take Trihexyphenidyl Syrup:

- if you are allergic to trihexyphenidyl hydrochloride or any of the other ingredients of this medicine (listed in section 6) or to similar medicines such as orphenadrine hydrochloride or procyclidine hydrochloride.

Do not give Trihexyphenidyl Syrup to children.

Warnings and precautions

Talk to your doctor before taking Trihexyphenidyl Syrup if:

- you have glaucoma (increased pressure in the eye)
- you suffer from high blood pressure
- you suffer from kidney, heart, liver, bowel or prostate problems
- you suffer from digestive system or stomach problems
- you suffer from bladder problems or have difficulty passing urine
- you suffer from a condition called myasthenia gravis (a rare muscle weakness disorder)
- you experience unusual movements of the face and tongue as this may be a sign of a serious condition known as tardive dyskinesia
- you are elderly - this medicine should be used with caution and may cause confusion, delusions and hallucinations.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you take Trihexyphenidyl Syrup.

Other medicines and Trihexyphenidyl Syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. Tell your doctor or pharmacist if you are taking or have taken any of the following medicines as they may interfere with Trihexyphenidyl Syrup:

- 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, for example isocarboxazid, moclobemide or phenelzine
- antihistamines used to treat allergies, for example diphenhydramine
- disopyramide used to treat irregular heartbeat
- phenothiazines used to treat psychoses or nausea and vomiting, for example chlorpromazine or thioridazine
- tricyclic antidepressants used to treat depression for example amitriptyline
- metoclopramide or domperidone used to treat the symptoms of nausea
- nefopam used to treat pain
- other medicines used in the treatment of Parkinson's disease for example amantadine and levodopa
- clozapine used to treat schizophrenia
- parasympathomimetic medicines used for the treatment of urine retention, for example neostigmine or bethanechol.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Trihexyphenidyl Syrup.

Pregnancy, breast-feeding and fertility

Do not take Trihexyphenidyl Syrup if you are breast-feeding.

Tell your doctor if you are pregnant, trying to become pregnant or are breast-feeding.

Driving and using machines

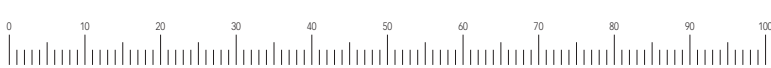
Taking Trihexyphenidyl Syrup may make your vision blurred or make you feel less alert than usual. If you are affected you should not drive or use machines until the effect has worn off.

Trihexyphenidyl Syrup contains sucrose, ethanol, propylene glycol and sodium benzoate

- sucrose - there is 2.6g of sucrose in every 5ml of syrup. The maximum dose of Trihexyphenidyl Syrup supplies 10.4g sucrose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- ethanol - this medicine contains 0.817 mg of alcohol (ethanol) in each 5 mL, which is equivalent to 0.1634 mg/ml. The amount in 5mL of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- propylene glycol - this medicine contains 19.27mg propylene glycol per 5ml of syrup. If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine
- sodium benzoate - this medicine contains 5.9 mg sodium benzoate in each 5ml, which is equivalent to 1.18 mg/ml.
- sodium - this medicine contains less than 1mmol sodium (23 mg) per 5mL, that is to say essentially 'sodium-free'.

E1V74RBJ3

Continued overleaf



ARTWORK VERSION: **2**

PREFLIGHT VERSION: -

Date: 09/11/22

Operator: Steve

JOB INFORMATION	
Product Name:	Trihexyphenidyl Hydrochloride 5mg/5ml Syrup
Strength:	5mg/5ml
Pack Size:	200ml
Bottle Size:	200ml
Design Icon:	N/A
New Item Code:	E1V74RBJ3
Previous Item Code:	E1V74RBJ2
Supplier Code:	N/A
Change Control No.:	CR-00591

JOB SPECIFICATION	
Keyline Ref:	UKL413
Dimensions:	150 x 500mm
Folded Size:	150 x 33mm
Tabbed:	NO
Pharmacode:	759
EAN Code:	N/A
No. of Colours:	1
Page Number:	1 of 2
MAIN BODY TEXT	
Font Type:	Univers Roman
Font Size:	10pt
Univers Bold	
COLOURS	
Print Colours:	BLACK
Non-print Colours:	KEYLINE

APPROVALS	
Third Party Approval Required	TICK APPLICABLE BOX YES <input type="checkbox"/> NO <input type="checkbox"/>
Name:	_____
Signature:	_____
Date:	___/___/___
Authority Approval Supplied	TICK APPLICABLE BOX YES <input type="checkbox"/> N/A <input type="checkbox"/>
Regulatory Sign-off	
Name:	_____
Signature:	_____
Date:	___/___/___

3. How to take Trihexyphenidyl Syrup

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

The usual dose starts with 2mg (2ml) per day. This may be increased by your doctor gradually to a maximum of 20mg (four 5ml spoonfuls) a day.

If you take more Trihexyphenidyl Syrup than you should

If you accidentally take too much syrup, or someone else takes any of your medicine, you should tell your doctor at once or contact the nearest casualty department. Show any left-over medicines or the empty container to the doctor.

If you forget to take Trihexyphenidyl Syrup

Do not worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose (within 1-2 hours). DO NOT take a double dose. Then go on as before.

If you stop taking Trihexyphenidyl Syrup

Do not stop taking this medicine suddenly as your symptoms may get worse.

If you want to stop taking Trihexyphenidyl Syrup ask your doctor who will tell you how to reduce the dose gradually.

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

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.**

Trihexyphenidyl Syrup sometimes causes the following side effects in some people:

- dry mouth, difficulty swallowing
- constipation, feeling or being sick
- blurred vision, large pupils, lack of near vision, eye discomfort, increased sensitivity to light and painful increased pressure in the eye
- feeling agitated or nervous
- 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
- feeling thirsty
- fever (raised body temperature)
- faster heartbeat
- worsening of myasthenia gravis (very tired or weak muscles).

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 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 Syrup

- Keep Trihexyphenidyl Syrup out of the sight and reach of children.
- Do not store above 25°C. Do not refrigerate or freeze. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label (exp: month, year). 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 protect the environment.

6. Contents of the pack and other information

What Trihexyphenidyl Syrup contains

The active substance is trihexyphenidyl hydrochloride.

Each 5ml of Trihexyphenidyl Syrup contains 5mg trihexyphenidyl hydrochloride. The other ingredients are citric acid, sodium benzoate, propylene glycol, glycerol, ethanol, blackcurrant flavour, sucrose and water.

See Section 2 'Trihexyphenidyl Syrup contains sucrose, ethanol, propylene glycol and sodium benzoate'

What Trihexyphenidyl Syrup looks like and contents of the pack

Trihexyphenidyl Syrup is a colourless syrup available in bottles of 200ml.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Rosemont House, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in: October 2022