

PATIENT INFORMATION LEAFLET

TROPIUM Capsules 5 mg
TROPIUM Capsules 10 mg
TROPIUM Tablets 5 mg
TROPIUM Tablets 10 mg
(Chlordiazepoxide Hydrochloride)

**PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE.
KEEP THIS LEAFLET UNTIL YOU HAVE FINISHED ALL THE PRESCRIBED COURSE OF TROPIUM.
IF YOU HAVE ANY QUESTIONS CONCERNING YOUR MEDICINE ASK YOUR DOCTOR OR PHARMACIST FOR MORE INFORMATION.**

What is in TROPIUM Capsules and Tablets?

The active ingredient of TROPIUM is chlordiazepoxide hydrochloride BP.

TROPIUM capsules 5 mg contain chlordiazepoxide hydrochloride BP 5 mg.
TROPIUM capsules 10 mg contain chlordiazepoxide hydrochloride BP 10 mg.
TROPIUM tablets 5 mg contain chlordiazepoxide base as the hydrochloride BP 5.60 mg.
TROPIUM tablets 10 mg contain chlordiazepoxide base as the hydrochloride BP 11.20 mg.

TROPIUM capsules 5 mg are yellow and black and marked TROPIUM in white.
TROPIUM capsules 10 mg are green and white and marked TROPIUM in black.
TROPIUM tablets 5 mg are round green film-coated tablets.
TROPIUM tablets 10 mg are round green film-coated tablets.

The capsules contain the following inactive ingredients: lactose, maize starch, sodium starch glycollate, magnesium stearate, erythrosine (E127), quinoline yellow (E104), titanium dioxide (E171), gelatin, black iron oxide (E172), indigotine (E132).

The tablets contain the following inactive ingredients: maize starch, magnesium stearate, lactose, pregelatinised maize starch, hydroxypropylmethylcellulose, ethylcellulose, diethyl phthalate, titanium dioxide, hydroxypropyl cellulose, colours E104, E131 and E110.

Both strengths of TROPIUM capsules and tablets are available in containers and blister packs of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000.

The active ingredient in TROPIUM capsules and tablets, chlordiazepoxide, belongs to a group of drugs known as benzodiazepines and has tranquillising properties.

The name and address of the Product Licence holder is:
Chelonia Healthcare Limited, 11 Boumpoulinas, 3rd Floor, 1060 Nicosia, Cyprus

TROPIUM is manufactured by either:
DDSA Pharmaceuticals Ltd., Chatfield Road, off York Road, London SW11 3SE or Meridian Healthcare (UK) Ltd., 208-214 York Road, London SW11 3SE.

Why have you been prescribed TROPIUM?

TROPIUM is used for the short-term relief of severe or disabling anxiety occurring alone, or coupled with sleeping problems.

Before taking your medicine

Before taking this medicine, tell your doctor if any of the following apply:

- If you have ever had any unusual or allergic reactions to TROPIUM or any of the other ingredients contained in the medicine.
- If you have experienced unusual or allergic reactions in the past to other drugs belonging to the same benzodiazepine group as this medicine.
- If you are pregnant or planning a pregnancy.
- If you are breast-feeding.
- If you have a history of depression.
- If you have had problems breathing.
- If you have severe liver disease.
- If you have a disorder known as 'myasthenia gravis' characterised by muscle weakness sometimes leading to difficulty breathing.
- If you have a condition called 'sleep apnoea' where you have difficulty breathing while asleep.
- If you are allergic to any foods, preservatives or dyes.
- If you are taking other medicines. Some medicines will affect the actions of TROPIUM e.g. neuroleptics (such as chlorpromazine), tranquillisers, antidepressants, hypnotics (medicines for sleep), analgesics and anaesthetics and sedative antihistamines, all of which will increase the sedative effects of TROPIUM. Alcohol will also increase the effects of TROPIUM by depressing the central nervous system, and should therefore be avoided. Barbiturates and anti-epileptic drugs will increase the side effects of TROPIUM.

Also tell your doctor if you are taking the following drugs:

- Cisapride
- Lofexadine
- Nabilone
- Baclofen
- Tizanidine
- Cimetidine

If you go to a doctor, dentist or hospital for any reason, tell them you are taking TROPIUM.

Use while driving or operating machinery

Your ability to perform skilled tasks may be affected when taking TROPIUM, especially after altering the doses you are taking. If you feel drowsy or less alert than normal do not attempt to drive or operate dangerous machinery. Alcohol is likely to increase the drowsiness and sedation caused by this medicine, and should not be taken with this medicine.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - the medicine has been prescribed to treat a medical or dental problem and;
 - you have taken it according to the instructions given by the prescriber or in the information provided with the medicine and;
 - it was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Use in pregnancy and while breast-feeding

Do not take this medicine if you are pregnant, might become pregnant, or are breast-feeding. If your doctor has decided that you should receive this medicine during late pregnancy or during labour, your baby might have a low body temperature, floppiness, and breathing and feeding difficulties. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms and physical dependence on the drug.

Since TROPIUM is found in breast milk, it should not be used while breast-feeding.

When and how to take TROPIUM

This medicine is to be taken by mouth and only in the doses prescribed by your doctor. Do not take more and do not take more often.

Do not stop taking your medicine or change the dose unless your doctor tells you to. Do not take alcohol when taking this medicine. You will be prescribed the lowest dose necessary to control your symptoms for a limited period only. Thereafter there will be a tapering off period, which requires that the dosage will be progressively decreased.

TROPIUM is not recommended for use in children.

Dosages:

Anxiety:

Adults: 5 mg daily increased if necessary to 100 mg daily in divided doses. Long-term chronic use is not recommended.

Elderly and debilitated patients: Half the adult dose.

Insomnia associated with anxiety:

Adults: 10 – 30 mg before going to bed. Treatment will be as short as possible and will normally last from a few days to 2 weeks with a maximum, including the tapering off of 4 weeks. Where extension beyond the maximum treatment period is necessary this will only take place after re-evaluation of the condition of the patient.

Elderly and debilitated patients: Half the adult dose.

Muscle spasm:

Adults: 10 mg to 30 mg daily in divided doses.

Symptomatic relief of acute alcohol withdrawal:

Adults: 25 to 100 mg, repeated if necessary in 2hrs to 4 hrs.

What to do if too many capsules or tablets are taken at the same time

If you accidentally take more capsules or tablets than recommended you may have difficulty walking and speaking, and you must contact your nearest doctor or hospital casualty department at once. Take any remaining capsules/tablets with you and keep in the original container or packaging so that they can be identified.

What if you miss a dose?

If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not take two doses at once. If you feel that this medicine is not working as well after you have taken it for a short time (3-4 days) do not increase the dose, instead check with your doctor.

What side effects can TROPIUM have?

Common side effects include drowsiness, sedation, unsteadiness and walking difficulties. These effects are related to how much of the medicine you take and can often continue into the following day.

The elderly are more susceptible to the above side effects.

Alcohol is likely to increase the drowsiness and sedation caused by this medicine, and should not be taken with this medicine.

Other side effects are rare and include numbed emotions, reduced alertness, unusual tiredness, headache, vertigo (dizziness), muscle weakness, low blood pressure, stomach upsets, skin rashes, blurred vision, changes in sexual function, and difficulty passing urine. Rarely different types of anaemia and jaundice (yellowing of skin and eyeballs) have occurred.

If the medicine is stopped suddenly withdrawal symptoms such as depression, nervousness, difficulty sleeping, irritability, sweating and diarrhoea commonly occur. These withdrawal symptoms will be worse in patients who have in the past experienced dependence on alcohol or other narcotic drugs.

Very rarely convulsions, confusion, aggressive outbursts, severe depression, and excitable behaviour for no apparent reason may result from high dosages, or from abruptly stopping the treatment.

Amnesia (the inability to remember events, names and situations clearly) may occur.

Do not be alarmed by this list of adverse side effects. Most people take TROPIUM without any problems.

Sunset yellow E110 contained in the tablets can cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.

If you notice any of the above reactions or side effects or if you notice other unusual or worrying changes to your health 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 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.

Storing your medicine

You must keep this medicine in a safe place where children cannot get at it. Your medicine could harm them.

Keep your medicine in a dry place, below 25°C. Keep container well closed.

If your doctor tells you to stop the treatment, return any remaining tablets/capsules to the pharmacist.

On the container you will find the words "expiry date" followed by numbers indicating the day, month and year. This is the date after which the medicine is no longer fit for use. Do not use the medicine after this date but return it to your doctor or pharmacist.

A reminder

REMEMBER this medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

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