

PATIENT INFORMATION LEAFLET

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

This medicine contains Chlordiazepoxide, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly.

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 TROPIUM is and what it is used for
2. What you need to know before you take TROPIUM
3. How to take TROPIUM
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1. What TROPIUM is and what it is used for

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

This medicine has been prescribed for you for the short-term relief of severe or disabling anxiety occurring alone, or coupled with sleeping problems.

It contains the Chlordiazepoxide which belongs to a class of medicines called benzodiazepines.

This medicine has been prescribed to you and should not be given to anyone else.

Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take TROPIUM

Do not take TROPIUM:

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

Warnings and precautions

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Chlordiazepoxide to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months.

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:

- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of benzodiazepines, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Other medicines and TROPIUM

Also tell your doctor or pharmacist if you are taking or might take any other medicines.

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

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

Pregnancy , breast-feeding and fertility

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. 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.

Driving and using machines

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.

Tropium conatins

Tropium 5mg & 10mg capsules and tablets conatins lactose(a type of sugar). If you know you have an intolerance to some sugar contact your doctor before taking this medicine.

3. How to take TROPIUM

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

Your prescriber should have discussed with you how long the course of capsules/tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

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.

If you take use more TROPIUM than you should

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.

If you forget to take TROPIUM

If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not take a double dose to make up for a forgotten dose. 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.

If you stop taking TROPIUM

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as:

- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

4. Possible side effects

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

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.

Unknown frequency: dependence and addiction (see section "How do I know if I am tolerant or addicted?").

Drug Withdrawal

When you stop taking Chlordiazepoxide, you may experience drug withdrawal symptoms, which include:

- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of the sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

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

How do I know if I am tolerant or addicted?

If you notice any of the following signs whilst taking Chlordiazepoxide, it could be a sign that you have become addicted.

- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 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.

How to store TROPIUM

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

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.

Do not use this medicine after the expiry date which is stated on the carton after. 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.

5. Contents of the pack and other information

What *TROPIUM* contains

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.

The other excipients in capsules are: lactose, maize starch, sodium starch glycollate, magnesium stearate, erythrosine (E127), quinoline yellow (E104), titanium dioxide (E171), gelatin, black iron oxide (E172), indigotine (E132).

The other excipient in tablets are: maize starch, magnesium stearate, lactose, pregelatinised maize starch, hydroxypropylmethylcellulose, ethylcellulose, diethyl phthalate, titanium dioxide, hydroxypropyl cellulose, colours E104, E131 and E110.

What *TROPIUM* looks like and contents of the pack

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.

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.

Marketing Authorisation Holder and Manufacturer

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.

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