



CHLORDIAZEPOXIDE 5mg AND 10mg CAPSULES

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 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take your medicine
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1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Chlordiazepoxide 5mg Capsules or Chlordiazepoxide 10mg Capsules.

Chlordiazepoxide is a member of a group of medicines called benzodiazepine anxiolytics. Your medicine can be used for the short-term relief (2-4 weeks treatment only) of:

- muscle spasm of varied cause
- symptoms of alcohol withdrawal
- anxiety causing distress or insomnia (difficulty sleeping)
- anxiety occurring with mental health problems

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE

DO NOT take your medicine if you:

- are allergic to chlordiazepoxide or any of the other ingredients in chlordiazepoxide capsules. An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- have reduced blood flow to the lungs - symptoms may include coughing and shortness of breath
- have any problems with your breathing
- have anxiety disorders due to unreasonable thoughts and fears (obsessional states)
- have a long-term mental condition causing hallucinations and delusions etc.
- have sleep apnoea (stopping breathing while asleep)
- have a severe liver disorder
- have a muscle weakness disorder known as myasthenia gravis
- suffer from depression that is not being treated
- Chlordiazepoxide capsules are not to be used in anyone under 18 years of age.
- suffer from spinal or cerebral ataxia

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Chlordiazepoxide capsules if you:

- are elderly, have suffered long-term lung, kidney or liver problems (as you may need to take a lower dose)
- have recently suffered a bereavement or loss (your medicine may make it harder to come to terms with your loss) should not be used as a primary treatment or alone
- suffer from psychiatric disorders such as schizophrenia, manic depression, delirium or senile dementia
- have been taking this medication for a long period, as there is a risk of dependence; abrupt termination of treatment results in withdrawal symptoms. These include headache, muscle pain, extreme anxiety, tension, restlessness, nervousness, sweating, confusion and irritability; sleep disturbance, diarrhoea, depression, rebound insomnia and mood changes.
- have a decrease in mental functions you should receive a lower dose
- have a history of drug or alcohol abuse
- Chlordiazepoxide capsules relax the muscles, therefore elderly patients should take extra care when they get up at night as there is a risk of falls and consequently injuries, including hip fractures.

Taking other medicines

Your medicine may interfere with other medicines that you are taking. Please tell your doctor or pharmacist if you are taking, or have recently taken any other medicines even those not prescribed.

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Anti-depressants, tranquilisers (e.g. diazepam), sleeping tablets, neuroleptics, hypnotics and other such medicines which act on the brain and nerves
- drugs used to treat epilepsy (e.g. phenytoin, phenobarbitone) or barbiturates or combinations including them
- anaesthetic drugs (drugs used to put you to sleep during an operation or surgery)
- Medicines that affect the liver e.g. rifampicin, (a drug used in the treatment of tuberculosis)

cimetidine (used to treat acid indigestion & ulcers), omeprazole (used to treat stomach problems) disulfiram and contraceptive agents.

- drugs known as dopaminergics, (e.g. levodopa, used to treat Parkinson's disease)
- baclofen (muscle relaxant), cisparide (prevent constipation), nabilone (anti sickness)
- pain killers (e.g. codeine, morphine) and anaesthetics.
- drugs to treat high blood pressure (antihypertensives) e.g. ACE inhibitors, alpha blockers, angiotensin-II receptor antagonists, calcium channel blockers, adrenergic neurone blockers and moxonidine.
- drugs used to open blood vessels (vasodilators) e.g. nitrates, hydralazine, minoxidil and sodium nitroprusside.
- drugs used to treat heart conditions (cardiac drugs) e.g. digoxin.
- drugs used to thin the blood (anticoagulants) e.g. warfarin
- drugs that increase the loss of salt and water from the body (diuretics) e.g. furosemide.
- sodium oxybate, used in patients with narcolepsy
- theophylline used to make breathing easier
- Antihistamines (used for treating allergies) that cause drowsiness (e.g. chlorphenamine)

Pregnancy, breast-feeding and fertility

DO NOT take this medicine if you are pregnant (especially during the first and last trimester), or might become pregnant without consulting your doctor. Chlordiazepoxide may cause damage to the foetus.

DO NOT take this medicine if you are breast-feeding, as the drug may pass into breast milk. Always ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine may make you feel drowsy or affect your concentration. Patients should be advised that sedation, amnesia (forgetfulness), impaired concentration, dizziness, blurred vision and impaired muscular function may occur and that, if affected, you should not drive or operate machinery or take part in other activities where this would put themselves or others at risk. If insufficient sleep duration occurs, the likelihood of impaired alertness may be increased.

Alcohol

You should avoid drinking any alcohol while you are taking chlordiazepoxide capsules, as you may feel drowsy.

Important information about some of the ingredients of your medicine

Chlordiazepoxide Capsules contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE YOUR MEDICINE

Always take this medicine exactly as your doctor or pharmacist has told you. The label on your medicine should also tell you. Check with your doctor or pharmacist if you are not sure. This medicine is for short-term relief only and should not be used beyond 4 weeks. The dose that your doctor prescribes will depend on the nature of your illness, your reaction to the medicine, your age, and bodyweight. Do not change the prescribed dose yourself. If you think that the effect of your medicine is too weak or too strong, talk to your doctor.

Your doctor will decide the correct dosage for your condition.

Swallow the capsule(s) whole with a glass of water.

Adults

- **Anxiety:** The usual dose is 5mg three times daily and increased if necessary up to 100mg daily in divided doses.
- **Sleeping disorders (insomnia) associated with anxiety:** The usual dose is 10mg to 30mg before going to bed.
- **Relief of symptoms of withdrawal from alcohol:** The usual dose is 25mg to 100mg repeated if necessary 2 to 4 hours after the

initial dose, if necessary.

- **Relaxation of muscle spasms:** The usual dose is 10mg to 30mg daily in divided doses throughout the day.

Children

Chlordiazepoxide Capsules are NOT recommended for use in children.

Elderly

The elderly are particularly sensitive to the effects of this medicine and may experience confusion. The usual maximum dose for elderly patients is half the adult dose.

Overdose: If you take more of your medicine than you should

If you take too many capsules tell a doctor or contact your nearest hospital casualty department immediately. Take your medicine with you.

If you forget to take your medicine

If you forget to take a dose of your medicine at the correct time, take it as soon as you remember then carry on as before. **Do not take a double dose to make up for a forgotten dose.**

If you stop taking your medicine

Long term treatment with chlordiazepoxide, especially in high doses, may lead to dependence, with withdrawal symptoms after stopping treatment. Your doctor will advise you on this. Keep taking your medicine until your doctor tells you to stop. Withdrawal effects may occur if the medicine is stopped suddenly. This is less likely if your dose is gradually reduced towards the end of your treatment. Withdrawal symptoms may include:

- difficulty sleeping
- depression
- nervousness
- irritability
- changes in behaviour
- restlessness
- extreme anxiety
- sweating
- diarrhoea
- confusion
- headaches and muscle pain
- tension

In severe cases the following symptoms may occur:

- changes in mood and behaviour or the way you are feeling
- tingling sensations and numbness of the extremities
- over-sensitivity to light, noise and touch
- feeling of unreality or being separated from the body
- hallucinations
- Fits (seizures and convulsions)
- If you are woken up soon after taking the medicine your memory may be temporarily affected.

The number of Chlordiazepoxide Capsules and how often you take them should always be reduced slowly before stopping them. Treatment should not be continued at the full dose beyond 4 weeks. Long term use is not recommended.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Chlordiazepoxide can cause side effects, although not everybody gets them. **Stop taking Chlordiazepoxide Capsules and see a doctor or go to a hospital straight away if you develop any of the following symptoms:** A severe allergic (anaphylaxis) or serious allergic reaction which causes swelling of your face or throat (angioedema), difficulty breathing, thoughts of self harm, yellowing of the skin and eyes (jaundice), abnormality in the blood with symptoms such as weakness, bleeding problems, pale skin, sore throat and frequent infections.

If these behavioural symptoms occur, you must inform your doctor. He/she may want you to stop taking this medicine. Tell your doctor or pharmacist if you develop any of the following side effects:

- **Common side effects** may affect up to 1 in 10 people
 - drowsiness and light-headedness the next day
 - sedation and dizziness - symptoms include slurred speech, lack of co-ordination, tiredness or sometimes blackouts
 - ataxia - symptoms include unsteadiness and clumsiness
 - difficulty controlling movements
 - dependence

Rare side effects may affect up to 1 in 1,000 people

- dizziness
- vertigo
- skin rashes
- changes in sex drive
- difficulty passing urine
- incontinence
- headache

- problems with your eye sight including double vision and blurred vision
- stomach upsets
- numbed emotions
- menstrual disorder
- blood disorders (e.g. blood dyscrasias symptoms include weakness, pale skin and bleeding problems)
- lowering of blood pressure - symptoms include light-headedness, feeling dizzy or faint.

The following side effects have also been reported (Frequency unknown):

- Decreased level of consciousness
- Aggressive outbursts, inappropriate behaviour
- restlessness, agitation, delusion, nightmares, increased liver enzymes, changes in the way you walk and muscle weakness
- Paradoxical reactions (e.g. saliva altered, anxiety, sleep disorders, insomnia, suicide attempt, suicidal ideation)
- tremors, stiffness and slow movement
- hallucinations and nightmares
- Increased appetite

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 or 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 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 YOUR MEDICINE

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

Do not take your medicine after the expiry date, which is stated on the carton or pot label. The expiry date refers to the last day of that month. Store your capsules below 25°C.

Return any unused capsules to your pharmacist. Only keep them if your doctor tells you to.

Do not use this medicine if you notice any visible signs of deterioration or damage.

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 Chlordiazepoxide contains

The capsules contain either 5mg or 10mg of the active substance chlordiazepoxide hydrochloride. The other ingredients are lactose monohydrate, maize starch and magnesium stearate. The capsule shell contains the ingredients Erythrosine (E127) (5mg Capsules only), Iron oxide black (10mg Capsules only), Titanium dioxide, Indigo Carmine (E132), Quinoline Yellow (E104), Gelatin. The printing ink contains the ingredients: Shellac, Dehydrated alcohol, Isopropyl alcohol, Butyl alcohol, Propylene glycol, Strong Ammonia solution, Purified water, Potassium hydroxide and Titanium dioxide.

What Chlordiazepoxide looks like and the contents of the pack

The 5mg capsules have a yellow body and turquoise cap and are marked "CDP 5" in white. The 10mg capsules have a green body and black cap and are marked "CDP 10" in white. The capsules are available in pots containing 28, 30, 56, 60, 100 and 500 capsules and blisters containing 28, 30 and 100 capsules, only on prescription from your doctor. Not all pack types or sizes may be marketed.

Marketing Authorisation Holder

Athlone Laboratories Limited, Ballymurray, Co. Roscommon, Ireland.

Company responsible for release of this medicine


Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.
Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

Distributor

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

PL 06453/0002 and PL 06453/0003

This leaflet was last revised May 2018

Customer: IS	Designer: AWG-MAT	Colours
Product: CDP 5mg x 100 Capsules		
Dimensions: 148mm x 400mm		
Item Code: CP.CDP.JNT.C.IS.V5P1		
Proof No and Date: 1 10/07/2018		
Revision: Update to entire PIL ARTWORK FOR SUBMISSION Supersedes: n/a		