ARTWORK FOR SUBMISSION
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CDP 5mg x 100 Capsules
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WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE
The name of your medicine is Chlordiazepoxide 5mg Capsules or Chlordiazepoxide 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

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR
Chlordiazepoxide 5mg is used to help with symptoms of withdrawal from alcohol or other medicines called benzodiazepine anxiolytics. Your medicine is provided under the National Health Service and is normally used in situations where other medicines are not suitable.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE YOUR MEDICINE
DO NOT TAKE this 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 (obsessive disorders)
• 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 cranial ataxia

Warnings and precautions
Talk to your doctor or pharmacist or nurse before taking Chlordiazepoxide capsules if:
• 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 may lead to 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 take 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 or their dosage is not prescribed.
Tell your doctor or pharmacist if you are taking any of the following medicines:
• Anti-depressants, tranquillisers (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
• anasthetic 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)

3. HOW TO TAKE YOUR MEDICINE
Always take this medicine exactly as your doctor or pharmacist has told you. The label on your medicine container or blister pack 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 the expiry date. 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 make changes to the prescribed dose yourself. If you think that the effect of your medicine is too weak or too strong to be used by you, please consult your doctor.
Your doctor will decide the correct dosage for your condition.
Swallow the capsules whole with a glass of water.

Adults
• Dosage: The usual dose is 5mg every 4 hours for those with impaired renal function or elderly patients; the daily dose is 20mg in divided doses.

4. POSSIBLE SIDE EFFECTS
This medicine may make you feel drowsy or affect your speech or coordination. Patients should be advised that sedation, amnesia (forgetfulness), impaired concentration, dizziness, blurred vision and impaired visual performance may occur and that, if affected, you should not drive or operate machinery or carry out any activity in which you may need extra concentration, where this would put themselves or others at risk 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
• restlessness
• anxiety
• sedation and dizziness - symptoms include drowsiness and light-headedness the next day
• hallucinations
• confusion
• headaches and muscle pain

In severe cases the following symptoms may occur:
• changes in mood or behaviour or the way you think
• feeling of unreality or being separated from the body
• hallucinations
• (fevers and convulsions)
• If you are woken up soon after taking the medicine your memory may be temporarily affected.

The number of Chlordiazepoxide capsules that you take may affect your sleep and may have to be reduced slowly before stopping them. Treatment should not be continued at the full dose beyond 4 weeks. Long-term use of this medicine above this dosage is not recommended.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

5. HOW TO STORE YOUR MEDICINE
Keep this medicine out of the sight and reach of children.
Do not take this 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 25ºC.

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 gelatin, Povidone, E472 (Vegetable gum) and E171 (Titanium dioxide).

What Chlordiazepoxide looks like and how to identify it
The 5mg capsules have a yellow body and transparent cap and are marked “CDP” in white. The 10mg capsules have a green body and black cap and are marked “CDP” in white. The capsules are available in pots containing 28, 30, 60, 90, 100 and 500 capsules and blister packs containing 28, 30 and 90 capsules, only on prescription from your doctor. Not all pack types or sizes may be manufactured.

Marketing Authorisation Holder Athlone Laboratories Limited, Ballymurry, Co. Kildare, Ireland.
Company responsible for release of this medicine
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