

## Package Leaflet: Information for the User Chlordiazepoxide 5mg & 10mg film-coated Tablets

Read all of this leaflet carefully before you start taking this medicine:

- 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. **Do not pass it on to others.** It may harm them even if their symptoms are the same as yours.

### In this leaflet:

1. What Chlordiazepoxide film-coated Tablets are and what they are used for
2. Before you take Chlordiazepoxide film-coated Tablets
3. How to take Chlordiazepoxide film-coated Tablets
4. Possible side effects
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## 1. What Chlordiazepoxide film-coated Tablets are and what they are used for

The active ingredient (which makes the tablets work) is chlordiazepoxide hydrochloride. It belongs to a group of drugs known as benzodiazepines and has a calming effect. Chlordiazepoxide film-coated Tablets are used for the short-term relief (2-4 weeks only) of **severe or disabling anxiety** occurring alone or along with sleeping problems, **muscle spasm of varied causes** and for the **relief of symptoms of sudden alcohol withdrawal**.

## 2. Before you take Chlordiazepoxide film-coated Tablets

**Do not take Chlordiazepoxide Tablets** if you:

- have had any **unusual or allergic reactions** to chlordiazepoxide, other benzodiazepine medicines or to any of the other ingredients in the tablets (see Section 6).
- have a disorder known as **myasthenia gravis** a condition where muscles become easily tired and weak leading to difficulty breathing
- have **severe liver disease**
- suffer from lung disease or **breathing difficulties**
- have a condition called **sleep apnoea** where you have difficulty breathing while asleep
- suffer from **phobias or obsessive behaviour**
- are **pregnant, planning a pregnancy or breast-feeding**

**Children:** Chlordiazepoxide Tablets are not to be used in anyone under 18 years of age.

**Check with your doctor before taking Chlordiazepoxide Tablets** if you have:

- a history of **alcohol or drug abuse**
- suffered from **depression** or **recently suffered the death of a close friend or relative** (because there is a risk of suicide in such patients)
- suffered from **mental illness**
- an **intolerance to sugars**, as these tablets contain a type of sugar called lactose.

### Dependence

There is a risk of becoming reliant on this type of medicine (dependence) which increases with high doses, duration of treatment and in patients with a history of alcoholism and drug abuse. If dependence has developed, withdrawal symptoms will occur if you suddenly stop treatment. Treatment should therefore be gradually withdrawn. See Section 3, '**If you stop taking Chlordiazepoxide Tablets**'.

### Tolerance

Chlordiazepoxide may not work as well in promoting sleep after repeated use for a few weeks. If after a few weeks you notice that the tablets are not working as well as when you first started treatment, you should speak to your doctor.

### Memory problems

Chlordiazepoxide can cause partial loss of memory (anterograde amnesia). This happens most often several hours after taking this product. To reduce the risk, you should ensure that you will be able to have an uninterrupted sleep of 7-8 hours.

### Sleep problems

Chlordiazepoxide Tablets may make you feel sleepy or forgetful. If you are taking Chlordiazepoxide Tablets for sleep problems you should take your medicine at bedtime to allow 7 to 8 hours of uninterrupted sleep.

### Taking other medicines

Some medicines can increase the sedative effects or other side effects of Chlordiazepoxide Tablets. **Tell your doctor if you are taking any other medicines**, especially:

- drugs for mental disturbances such as chlorpromazine
- tranquillisers (to relieve anxiety) and antidepressants (for depression)
- medicines for sleep
- pain relieving medicines and drugs for allergies
- sedative antihistamines (for allergies) such as promethazine
- barbiturates (for anxiety and difficulty sleeping)
- drugs for epilepsy (eg phenytoin and phenobarbital)
- medicines for high blood pressure
- disulfiram (used to treat alcoholism)
- cisapride (for stomach disorders)
- baclofen and tizanidine (muscle relaxants)
- lofexidine (for opiate drug withdrawal)
- nabilone (for nausea and vomiting after chemotherapy)
- cimetidine (to treat ulcers)
- anaesthetics (to remove sensation or cause unconsciousness for surgical procedures)
- sodium oxybate (to treat sudden muscular weakness in people who have a sleep disorder known as narcolepsy).

If you go to a doctor, dentist or hospital for any reason, tell them you are taking Chlordiazepoxide film-coated Tablets.

### Alcohol

**Do not take alcohol** with this medicine. Alcohol is likely to increase the effects of chlordiazepoxide and this can be dangerous. If you have a history of alcohol or drug abuse, you must tell your doctor before taking this medicine.

### Pregnancy and breast-feeding

Do not take this medicine if you are pregnant, might become pregnant, or are breast-feeding. If for medical reasons you are prescribed Chlordiazepoxide Tablets during late pregnancy or during labour, your baby may have a low body temperature, floppiness, and breathing and feeding difficulties and may be at risk of developing withdrawal symptoms in the first few days.

### Driving and using machines

Chlordiazepoxide Tablets can cause reduced alertness, drowsiness, blurred vision and dizziness, especially after a change in dose. If you are affected in this way, do not drive, use machines or take part in activities that may put you or others at risk.

## 3. How to take Chlordiazepoxide film-coated Tablets

You will be prescribed the lowest dose needed to control your symptoms. Long term use of Chlordiazepoxide Tablets is not recommended and treatment will be as short as possible. Take the medicine by mouth and only in the doses prescribed.

<b>Anxiety:</b> <b>Adults:</b> Starting dose 5mg daily increased if needed up to 30mg per day. The maximum dose is 100mg per day taken in divided doses throughout the day.	<b>Difficulty sleeping (insomnia) associated with anxiety:</b> <b>Adults:</b> 10mg to 30mg before going to sleep for a maximum of 4 weeks including a 2 week tapering off period.
<b>Muscle spasm:</b> <b>Adults:</b> A total of 10mg to 30mg daily in separate doses.	<b>Relief of symptoms of acute alcohol withdrawal:</b> <b>Adults:</b> 25mg to 100mg, repeated if needed in 2 to 4hrs after initial dose.

If you are **elderly** or **suffer from a lung, liver or kidney condition**, or are **generally unwell**, your doctor will usually prescribe a **lower dose**.

### If you take more than you should

If you accidentally take more tablets than prescribed, you may have difficulty walking and speaking, and you must contact your doctor or nearest hospital casualty department at once. Take any remaining tablets with you, so that they can be identified.

### If you forget to take the tablets

If you miss a dose, skip the missed dose and take the next one when it is due. **Do not take a double dose to make up for a forgotten dose.**

### If you stop taking the tablets

If you stop treatment suddenly, withdrawal symptoms can occur. These include headache, muscle pain, extreme anxiety, tension, difficulty sleeping, restlessness, confusion, irritability and in severe cases mental disturbances, numbness and tingling of the hands and feet, extreme sensitivity to light, noise and touch or fits. To avoid this there will be a tapering off period, during which the dose will be gradually decreased. **Do not stop taking Chlordiazepoxide Tablets without talking to your doctor.** Treatment will not normally last more than 4 weeks. This is because Chlordiazepoxide Tablets may become less effective if you take them for more than four weeks. If you think your medicine is no longer working you should consult your doctor.

## 4. Possible side effects

Like all medicines Chlordiazepoxide can cause side effects. Do not be alarmed by this list of adverse side effects. Most people take Chlordiazepoxide without any problems. **Tell your doctor at once** if you notice any of the following effects:

- **Common:** light-headedness, drowsiness, sleepiness, unsteadiness and walking difficulties. (These effects may persist into the following day and are more likely in the elderly and with higher doses.)
- **Rare:** numbed emotions, reduced alertness, unusual tiredness, headache, dizziness, muscle weakness, vertigo (spinning sensation), low blood pressure, stomach upsets, skin rashes, blurred vision, changes in sexual function, and difficulty passing urine. Rarely different types of anaemia (low levels of haemoglobin, the oxygen carrying pigment in the blood) and jaundice (yellowing of skin and eyeballs) have occurred.
- **Others:** dependence, confusion, restlessness, agitation, irritability, aggressive outbursts, delusions (being suspicious or believing things that are not true), nightmares, hallucinations (seeing or hearing things that are not there), inappropriate behaviour, abnormal production of blood cells causing unexplained bruising or bleeding, depression, amnesia (inability to remember events, names and situations) can result from high dosages.

**If you notice any of the above reactions or side effects**, or any other unusual or worrying effects, **contact your doctor at once.**

## 5. How to store

Keep out of the sight and reach of children. **Do not store above 25°C.** Keep blister in the outer carton. If your doctor tells you to stop the treatment, return any unused tablets to the pharmacist for safe disposal. Do not use after the expiry date stated on the blister and carton.

## 6. Further information

- The active substance (which makes the medicine work) is chlordiazepoxide hydrochloride. Each tablet contains 5mg or 10mg of chlordiazepoxide hydrochloride.
- The other ingredients are: magnesium stearate, lactose monohydrate, pregelatinised maize starch, hydroxypropylmethylcellulose, ethylcellulose, diethyl phthalate, Brilliant Blue (E133), Indigo Carmine (E132).
- The tablets are round, green, film-coated tablets. Available in containers and blister packs of 28, 30, 50, 56, 60, 84, 100, 250, 500, 1000. Not all pack sizes may be marketed.

Marketing Authorisation Holder  
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