

CHLORDIAZEPOXIDE

5 mg & 10 mg 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.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

THIS LEAFLET CONTAINS

1. What Chlordiazepoxide is for
2. Before you take Chlordiazepoxide
3. How to take Chlordiazepoxide
4. Possible side effects
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6. Further information

1. WHAT CHLORDIAZEPOXIDE IS FOR

Chlordiazepoxide belongs to a group of medicines called benzodiazepines. It can be used in the **short-term** (2-4 weeks only) treatment of:

In adults:

- severe anxiety, occurring alone or in association with insomnia (difficulty in sleeping), stress or a loss of control with reality (psychosis)
- muscle spasms
- the symptoms of alcohol withdrawal.

Chlordiazepoxide tablets are **not for use in children**.

If you are not sure why you have been prescribed this medicine then please ask your doctor.

2. BEFORE YOU TAKE CHLORDIAZEPOXIDE

Do not take Chlordiazepoxide and tell your doctor if you:

- are allergic to Chlordiazepoxide, any of the other ingredients in the tablets (listed in section 6 of this leaflet) or to other benzodiazepines
- have severe liver, lung or breathing problems
- have muscle weakness sometimes causing difficulty breathing (myasthenia gravis)
- suffer from breathing problems whilst asleep (sleep apnoea)
- suffer from depression, mental health problems, irrational fears (phobias) or obsessions
- are pregnant, planning to become pregnant or are breast-feeding, (see 'Pregnancy and breast-feeding' below)

Take special care with Chlordiazepoxide

Tell your doctor **before** you take this medicine if you:

- have a history of alcohol or drug abuse
- suffer from a personality disorder
- have recently suffered a loss or bereavement
- are elderly or have problems with your liver or lungs

Medicines such as Chlordiazepoxide may lead to:

- **addiction.** You may become dependent on these capsules. Any risk is more likely with high doses, prolonged treatment or if you have a history of alcohol or drug abuse.
- **tolerance.** Chlordiazepoxide tablets may become less effective after a few weeks. If you think that the tablets are not working as well as they did, you should consult your doctor.
- **withdrawal.** You may experience withdrawal effects if your treatment is stopped suddenly. Withdrawal symptoms can occur with Chlordiazepoxide tablets even when normal doses are given for short periods of time, (see section 3; 'If you suddenly stop taking Chlordiazepoxide').

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken **any** other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they may **affect** how Chlordiazepoxide tablets work:

- Medicines to treat depression such as Fluvoxamine or Mirtazapine
- Medicines to treat mental health problems such as Olanzapine or Prochlorperazine
- Medicines to calm you down or to help you sleep
- Sodium oxybate to reduce daytime sleepiness or sudden loss of muscle strength
- Disulfiram or Lofexidine for drug dependence
- Strong pain killers or general anaesthetics
- Nabilone to treat sickness caused by chemotherapy
- Medicines to treat epilepsy such as Phenytoin or barbiturates
- Levodopa to treat Parkinson's disease
- Medicines to treat high blood pressure such as Captopril, Enalapril (ACE inhibitors), Doxazosin, Prazosin (alpha-blockers), Candesartan, Losartan (angiotensin-II receptor antagonists), Guanethidine, Hydralazine, Minoxidil, Moxonidine or Sodium nitroprusside
- Medicines to treat high blood pressure or chest pain such as Propranolol, Atenolol (beta-blockers), Amlodipine, Felodipine (calcium-channel blockers), Glycerol trinitrate, Isosorbide mononitrate (nitrates)
- Medicines to increase urine production such as Diuretics
- Muscle relaxants such as Baclofen or Tizanidine
- Rifampicin to treat bacterial infections
- Cimetidine to treat ulcers
- Antihistamines for allergies

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Chlordiazepoxide.

Taking Chlordiazepoxide with food and drink

Alcohol may increase the sedative effects of Chlordiazepoxide and make you feel very sleepy. **Do not drink alcohol** whilst taking Chlordiazepoxide.

Grapefruit juice contains one or more components that alter how the body uses some medicinal products, including benzodiazepines. **Do not drink grapefruit juice** whilst taking Chlordiazepoxide.

Pregnancy and breast-feeding

Do not take Chlordiazepoxide if you are pregnant, planning to become pregnant or you are breast-feeding, unless your doctor has told you to.

If you take this medicine late in your pregnancy or during labour your baby might have an irregular heart rate, a low body temperature, floppiness, and breathing and feeding difficulties.

If you take this medicine regularly during late pregnancy, your baby may become dependent on Chlordiazepoxide and may develop withdrawal symptoms after birth.

Make sure you follow your doctor's advice.

Driving and using machines

Chlordiazepoxide may make you feel sleepy, cause loss of concentration or memory or muscle weakness. Do not drive or operate machinery if you are affected in this way. 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.

Important information about some of the ingredients of Chlordiazepoxide

Chlordiazepoxide 5 mg and 10 mg tablets contain **lactose** (a type of sugar). If you know you have an intolerance to some sugars contact your doctor before taking this medicine.

Chlordiazepoxide 5 mg and 10 mg tablets also contain **sunset yellow** (E110), which may cause allergic reactions.

3. HOW TO TAKE CHLORDIAZEPOXIDE

Always take Chlordiazepoxide tablets exactly as your doctor has told you. Swallow the tablets whole.

When taking this medicine try to make sure you sleep well for 7-8 hours per night.

Dosage

You will be prescribed the lowest effective dose for the shortest time necessary to treat your symptoms. This will reduce the risk of addiction.

Adults:

Anxiety:

The usual dose is 30 mg a day in divided doses. This can be increased to a maximum of 100 mg a day in divided doses.

Insomnia in association with anxiety:

The usual dose is 10-30 mg at bedtime.

Muscle spasms:

The usual dose is 10-30 mg a day in divided doses.

Alcohol withdrawal symptoms:

The usual dose is 25-100 mg, which may be repeated after two to four hours if necessary.

Elderly or debilitated (those that are weak or feeble): Usually require half the adult dose, as you are likely to be more sensitive to the effects of Chlordiazepoxide. Follow your doctor's advice.

If you have kidney or mild liver problems you may also be given a lower dose, this should not be more than half the usual adult dose.

Children: Not recommended.

If you take more Chlordiazepoxide than you should

Contact your doctor or go to a hospital immediately. Show them the package or container. Symptoms of an overdose may include drowsiness, confusion, tiredness, breathing problems, difficulty in controlling movements, low blood pressure or falling into a coma.

If you forget to take Chlordiazepoxide

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you have missed.

If you suddenly stop taking Chlordiazepoxide

The risk of withdrawal symptoms is greater. Your doctor will gradually reduce your dose to reduce the possibility of withdrawal effects.

Withdrawal symptoms may include headache, sweating, diarrhoea, muscle pain, tension, extreme anxiety, mood changes, sleep disturbances, depression or irritability and occasionally hallucinations, fits, unusual behaviour, numbness and tingling of the hands and feet or sensitivity to light, noise or touch.

Treatment should be gradually withdrawn otherwise the symptoms you are being treated for may return more intensely than before (rebound sleeplessness and anxiety). The risk of this happening is greater when you stop taking Chlordiazepoxide suddenly.

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

4. POSSIBLE SIDE EFFECTS

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

If you get any of the following side effects, STOP TAKING this medicine and see your doctor at once:

- feeling restless, agitated irritated or depressed
- nightmares or hallucinations (feeling or seeing things that are not there)
- aggressive outbursts or rages
- unusual behaviour or false beliefs (delusions).

Other side effects include:

The most common side effects are:

- feeling sleepy, light-headed
- unsteadiness
- clumsiness and loss of co-ordination.

You could notice the above common side effects even after a single dose and they may continue for more than 24 hours. If you are elderly you are more likely to suffer from side effects, especially confusion.

Side effects that occur less often are:

- loss of memory
- headache
- dizziness or a feeling of spinning (vertigo)
- reduced alertness and tiredness
- low blood pressure
- stomach upsets
- skin rashes
- muscle weakness
- problems with your vision
- changes in sex drive
- difficulty passing urine
- numbed emotions

Other side effects are:

- dependence (addiction)
- shaking (tremor)
- difficulty in speaking
- making more saliva than usual
- loss of control of your bladder or bowels (incontinence)

A few cases of unusual bleeding or bruising of the skin, feeling feverish or yellowing of the skin and whites of the eyes (jaundice) have been known to occur.

If any of the side effects become 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 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CHLORDIAZEPOXIDE

Keep out of the sight and reach of children.

Store below 25°C and away from light. Store in the original package or container and keep the container tightly closed.

Do not use the tablets after the expiry date, which is stated on the package or container. The expiry date refers to the day, month and year.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Chlordiazepoxide contains

The active ingredient in Chlordiazepoxide 5 mg and 10 mg tablets is chlordiazepoxide hydrochloride.

The other ingredients are lactose, maize starch, pregelatinised starch, magnesium stearate, hypromellose, ethylcellulose, diethyl phthalate, hydroxypropyl cellulose, quinoline yellow (E104), titanium dioxide (E171), sunset yellow (E110) and patent blue V (E131).

What Chlordiazepoxide looks like and contents of the pack

Chlordiazepoxide 5 mg tablets are round green film-coated tablets with the marking MP3 on one side.

Chlordiazepoxide 10 mg tablets are round green film-coated tablets with the marking MP4 on one side.

The tablets come in blister packs and containers of 28, 30, 50, 56, 60, 84, 100, 250, 500 and 1000.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Genethics Europe Limited,
41 – 43 Klimentos, Klimentos Tower,
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Manufacturer

Custom Pharmaceuticals Limited,
Conway Street, Hove,
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For more information about this product, please contact the Marketing Authorisation Holder.

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