

PACKAGE LEAFLET

Package leaflet: Information for the user

Clomethiazole 192 mg Capsules

clomethiazole

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 Clomethiazole Capsules are and what they are used for
2. What you need to know before you take Clomethiazole Capsules
3. How to take Clomethiazole Capsules
4. Possible side effects
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1. What Clomethiazole Capsules are and what they are used for

Clomethiazole Capsules contain a medicine called clomethiazole. This belongs to a group of medicines called hypnotics and sedatives. It has a calming (sedative) effect on your nervous system.

Clomethiazole Capsules are used to:

- Treat feelings of restlessness and agitation.
- Help you if you are unable to sleep (short-term treatment).
- Relieve the symptoms of alcohol withdrawal.

2. What you need to know before you take Clomethiazole Capsules

Do not take Clomethiazole Capsules:

- if you are allergic to clomethiazole or any of the other ingredients of this medicine (listed in section 6).
- if you have lung or breathing problems which have recently got worse.

Do not take Clomethiazole Capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Clomethiazole Capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Clomethiazole Capsules:

- if you often have difficulty in breathing.
- if you have a condition called 'sleep apnoea syndrome' (interrupted breathing

when you are asleep).

- if you have ever had liver or kidney problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Clomethiazole Capsules.

Children and adolescents

Clomethiazole Capsules should not be taken by children and adolescents under 18 years of age.

Other medicines and Clomethiazole Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Clomethiazole Capsules can affect the way some medicines work and some medicines can have an effect on Clomethiazole Capsules.

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

- Propranolol (for high blood pressure).
- Diazoxide (for high blood pressure or low blood sugar).
- Cimetidine (for stomach ulcers or heartburn).
- Carbamazepine (for anxiety, epilepsy, mood swings or a painful condition of the face called 'trigeminal neuralgia').
- Other medicines used to treat epilepsy.
- Sedatives (to help you relax or sleep).
- Painkillers.
- Antidepressants (to treat depression or prevent it recurring).
- Antibacterials (to treat or prevent an infection).
- Anaesthetics. If you need an operation which requires a general anaesthetic, tell the doctor or dentist before your operation that you are taking Clomethiazole Capsules.

Clomethiazole Capsules with alcohol

Do not drink alcohol while you are taking Clomethiazole Capsules.

If you are taking Clomethiazole Capsules to help with alcohol problems, you must tell your doctor if you have recently had a drink containing alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will decide whether you can take Clomethiazole Capsules during this time.

If you are pregnant or breast-feeding and you are already taking diazoxide (a medicine to treat high blood pressure or low blood sugar), do not take Clomethiazole Capsules.

Driving and using machines

Do not drive or use any tools or machines while taking Clomethiazole Capsules. This is because the medicine can make you feel drowsy (sleepy).

Clomethiazole Capsules contain sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. One Clomethiazole Capsule contains 7 mg of sorbitol. When taken as recommended, each dose contains up to 28 mg of sorbitol.

3. How to take Clomethiazole Capsules

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

- The instructions on the label will remind you of what the doctor said. They will tell you how many capsules to take and how often. Do not take more than you have been told to.
- Swallow the capsule(s) whole with a drink of water. Do not chew, crush or break the capsules.

Use in adults

The usual dose of Clomethiazole Capsules depends on what you are taking them for.

- **To help you to sleep at night**, the usual dose is one or two capsules before bed. Your doctor will give you this medicine for a short period of time.
- **To stop you feeling restless or agitated**, the usual dose is one capsule three times a day.
- **To help you to withdraw from alcohol**, your doctor will start you on a high dose. Your doctor will then gradually reduce the dose. Do not take Clomethiazole Capsules for longer than your doctor has told you to. The maximum amount of time is usually 9 days.

If you have **liver or kidney problems**, the dose depends on how well your kidneys are working. Your doctor may start you on a low dose and gradually increase it.

If you take more Clomethiazole Capsules than you should

If you take too many Clomethiazole Capsules, talk to a doctor or go to a hospital straight away. Take the medicine bottle or carton with you so that it can be identified. The following effects may happen: shallow breathing, low blood pressure (this may make you feel dizzy or faint), low body temperature and coma (being unconscious).

If you forget to take Clomethiazole Capsules

If you forget to take a dose, take it as soon as you remember it.

However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Clomethiazole Capsules

Your doctor may prescribe Clomethiazole Capsules for longer than the usual time period. With longer term use your doctor may need to increase your dose to get the same effect. If you take more than the usual dose for a long period of time, when you stop taking the medicine, you may get withdrawal symptoms such as shaking

(tremors) or fits.

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

4. Possible side effects

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

Severe allergic reactions (these are rare, affecting up to 1 in 1,000 people)

If you have a severe allergic reaction, **stop taking Clomethiazole Capsules and see a doctor straight away**. You may need urgent medical treatment. The signs may include a sudden onset of:

- Rash, itching or hives on the skin.
- Blistering of the skin.
- Swelling of the face, lips, tongue or other parts of the body.
- Shortness of breath, wheezing or trouble breathing.

Other possible side effects:

- Tingling or blocked nose. This can occur within 15 to 20 minutes of taking a dose of Clomethiazole Capsules.
- Sore eyes and headache.
- Runny nose and chest phlegm.
- Stomach upset.
- Changes in how your liver is working (shown by blood tests).
- Feeling over-excited or confused.
- Feeling very sleepy. This is more likely if you are taking a high dose of the medicine or if you are elderly and you are taking the medicine during the day.
- 'Hangover' effects may occur in the elderly.
- Withdrawal symptoms such as shaking (tremors) and fits.

Do not be concerned by this list of side effects. You may not get any of them.

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 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 Clomethiazole Capsules

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

Do not store above 25°C (room temperature). Store your medicine in the original package in order to protect from light and moisture.

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

6. Contents of the pack and other information

What Clomethiazole Capsules contain

- The active substance is clomethiazole. There is 192 mg of clomethiazole in each capsule.
- The other ingredients are medium-chain triglycerides, gelatin, glycerol, titanium dioxide (E171), sorbitol (E420), mannitol, hydrogenated hydrolysed starch and brown iron oxide (E172).

What Clomethiazole Capsules look like and contents of the pack

Clomethiazole Capsules are soft and greyish-brown. They are available in bottles of 60 capsules.

Marketing Authorisation Holder

Neon Healthcare Limited, Mill Studio Business Centre, Crane Mead, Ware, Hertfordshire SG12 9PY, United Kingdom

Manufacturer

CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 23-24, 17489 Greifswald, Germany

For information about this medicine, contact the medical information department on tel.: 0800 145 5034 or email: cheplapharm@redlinepv.co.uk.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK only)

Please be ready to give the following information:

Product name **Clomethiazole Capsules**

Reference number PL 45043/0033

This is a service provided by the Royal National Institute of the Blind.

This leaflet was last revised in October 2020.