

Package leaflet: Information for the user

Clomethiazole 31.5 mg/ml Syrup

clomethiazole

(as clomethiazole edisilate)

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 Syrup is and what it is used for
2. What you need to know before you take Clomethiazole Syrup
3. How to take Clomethiazole Syrup
4. Possible side effects
5. How to store Clomethiazole Syrup
6. Contents of the pack and other information

1. What Clomethiazole Syrup is and what it is used for

Clomethiazole Syrup contains 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 Syrup is 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 Syrup

Do not take Clomethiazole Syrup:

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

Warning and precautions

Talk to your doctor or pharmacist before taking Clomethiazole Syrup:

- 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 Syrup.

Children and adolescents

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

Other medicines and Clomethiazole Syrup

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 Syrup can affect the way some medicines work and some medicines can have an effect on Clomethiazole Syrup.

In particular, 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 Syrup.

Clomethiazole Syrup with alcohol

Do not drink alcohol while you are taking Clomethiazole Syrup.

If you are taking Clomethiazole Syrup 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 or pharmacist for advice before taking this medicine. Your doctor will decide whether you can take Clomethiazole Syrup 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 Syrup.

Driving and using machines

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

Clomethiazole Syrup contains sorbitol, ethanol and sodium

- **Sorbitol:** This medicine contains 350 mg sorbitol in each ml. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- **Ethanol:** This medicinal product contains small amounts of ethanol (alcohol). It contains less than 100 mg per dose.
- **Sodium:** This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Clomethiazole Syrup

Always take this medicine exactly as your doctor or pharmacist 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 much syrup to take and how often. Do not take more than you have been told to.

The syrup should be diluted with water or juice before use, then taken immediately. It must not be kept for later administration. Try to take your medicine without it coming into contact with anything plastic. If this is not possible, keep the contact time as short as possible.

Use in adults

The usual dose of Clomethiazole Syrup depends on what you are taking it for.

- **To help you to sleep at night**, the usual dose is one to two 5 ml spoonfuls 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 5 ml spoonful 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 Syrup 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 Syrup than you should

If you take too much Clomethiazole Syrup, 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 Syrup

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 Syrup

Your doctor may prescribe Clomethiazole Syrup 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 Syrup 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 Syrup.
- 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 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 Clomethiazole Syrup

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

Store between 2 and 8°C in the fridge in the original packaging. Clomethiazole Syrup must not be stored in plastic containers (see section 3). Do not freeze.

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

After first opening of the container Clomethiazole Syrup is stable for 120 days.

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 Syrup contains

- The active substance is clomethiazole (as clomethiazole edisilate). There is 31.5 mg of clomethiazole in each millilitre (ml) of syrup.
- The other ingredients are purified water, liquid sorbitol (non-crystallising) (E420), ethanol, cineole, sodium hydroxide and levomenthol.

What Clomethiazole Syrup looks like and contents of the pack

Clomethiazole Syrup is a clear, colourless solution. It is available in 300 ml bottles.

Marketing Authorisation Holder

Neon Healthcare Ltd., 8 Chase Road, John Tate Road,
Hertford, SG13 7NN, United Kingdom

Manufacturer

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

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 Syrup

Reference number PL 45043/0034

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

This leaflet was last revised in May 2023.