Heminevrin® 192 mg Capsules/Clomethiazole 192 mg Capsules (clomethiazole)

Your medicine is available using any of the above names but will be referred to as Heminevrin Capsules throughout this leaflet.

Patient Information Leaflet

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 Heminevrin Capsules are and what they are used for
2) What you need to know before you take Heminevrin Capsules
3) How to take Heminevrin Capsules
4) Possible side effects
5) How to store Heminevrin Capsules
6) Contents of the pack and other information.

1) What Heminevrin Capsules are and what they are used for
Heminevrin 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.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Heminevrin 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 Heminevrin Capsules.

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

Other medicines and Heminevrin 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 Heminevrin Capsules can affect the way some medicines work and some medicines can have an effect on Heminevrin 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 Heminevrin Capsules.

Heminevrin Capsules with alcohol
Do not drink alcohol while you are taking Heminevrin Capsules.
If you are taking Heminevrin 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 Heminevrin 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 Heminevrin Capsules.

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

Heminevrin 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 Heminevrin Capsule contains 7 mg of sorbitol. When taken as recommended, each dose contains up to 28 mg of sorbitol.

3) How to take Heminevrin 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 Heminevrin 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 Heminevrin 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 Heminevrin Capsules than you should
If you take too many Heminevrin 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 Heminevrin 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 Heminevrin Capsules
Your doctor may prescribe Heminevrin 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 less than 1 in 1,000 people) If you have a severe allergic reaction, **stop taking Heminevrin 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 Heminevrin 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 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 Heminevrin Capsules
- Do not use after the expiry date printed on the bottle label
- Do not store above 25°C. Store in the original container in order to protect from light and moisture.
- Keep all medicines out of the sight and reach of children.
- If your doctor tells you to stop taking the capsules, please take them back to the pharmacist for safe disposal. Only keep the capsules if your doctor tells you to.
- If the capsules become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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 Heminevrin Capsule contains**
Each soft capsule contains 192mg clomethiazole.

Heminevrin Capsules themselves are made of the following: Medium-chain triglycerides, gelatin, glycerol (85%), sorbitol, D-Mannitol, oligosaccharides, titanium dioxide (E171) and brown iron oxide (E172).

**What Heminevrin Capsule looks like and the contents of the pack**
The unmarked, soft capsules are greyish-brown coloured.

Heminevrin Capsules are available as 30 capsules in amber glass bottles.

PL 10383/2047 Heminevrin 192mg Capsules

**Who makes and repackages your medicine:**
Your medicine is manufactured by Cheplapharm Arzneimittel GmbH, Bahnhofstrasse 1a, Mesekehenagen, D-17498 Germany. Procured from within the EU and repackaged by the Product Licence holder: Primecrown Ltd., 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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**Blind or partially sighted?**
Is this leaflet hard to see or read?
Call 020 8839 3000 to obtain the leaflet in a format suitable for you.