

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cloral Betaine 707 mg Film-coated Tablets Cloral Betaine

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Cloral Betaine Tablets are and what they are used for

Cloral Betaine Tablets contain cloral betaine, which is one of a group of medicines called hypnotics (sleep inducing drugs).

Adults:

Cloral betaine tablets are used for the short-term (maximum 2 weeks) treatment of severe sleeplessness (insomnia) which is interfering with normal daily life and where non-drug therapies (such as behavioural therapy and sleep hygiene) and other drugs have failed. Cloral betaine tablets should be used in addition to non-drug therapies.

Adolescents aged 12 years and above:

Cloral betaine tablets are used for the short-term (maximum 2 weeks) treatment of severe sleeplessness (insomnia) in children and adolescents with suspected or definite disorders that affect the development of the neurological system and brain (neurodevelopmental disorders). It is only used when the sleeplessness interferes with normal daily life and other therapies (non-drug therapies and other drugs) have failed. Cloral betaine tablets should be used in addition to behavioural therapy and sleep hygiene management. The use of cloral betaine tablets in adolescents is not generally recommended and if used should be under the supervision of a medical specialist.

2. What you need to know before you take Cloral Betaine Tablets

Do not take Cloral Betaine Tablets if you

- are allergic to cloral betaine or any of the other ingredients (listed in section 6)
- have severe liver or kidney problems
- have severe heart problems
- suffer from porphyria (an inherited blood disorder)
- have active inflammation of the stomach or gullet (gastritis or oesophagitis), a stomach or gut ulcer or perforation of the stomach or gut wall
- are pregnant or breast feeding

Do not give Cloral Betaine Tablets to children under 12 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cloral Betaine Tablets:

- if you are elderly or frail (weak)
- if you have mild or moderate kidney impairment
- if you have mild or moderate liver impairment,
- if you suffer from alcoholism or drug addiction problems
- if you have dependency to sleep medications
- if you have had inflammation of the stomach or gullet (gastritis or oesophagitis), an ulcer in the stomach or the gut (gastric or duodenal ulcer) or perforation of the stomach or gut wall in the past,
- if you have heart disease or heart rhythm abnormalities (including so called QT prolongation seen with ECG monitoring)
- if you have low potassium or magnesium levels

Other medicines and Cloral Betaine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is important to tell your doctor if you are taking any of the following:

- sleep medication and tranquilisers (sedatives, hypnotics).
- medicines to thin your blood (such as Warfarin).
- medicines for depression or nervous disorders.
- medicines intended to reduce muscle spasms.
- medicines that affect the heart rhythm, such as medicines for heart rhythm abnormalities, medicines against malaria, some medicines against allergies (antihistamines), medicines to treat certain mental health disorders (antipsychotics) and medicines that lower potassium or magnesium levels (diuretics).

Cloral Betaine Tablets with food, drink and alcohol

Alcohol can increase the sedative effect of chloral hydrate. Alcohol should therefore be avoided whilst taking this medicine. Cloral Betaine Tablets should be administered as a single daily dose, 15-30 minutes before bedtime, with water or milk.

Pregnancy and breast feeding

Cloral Betaine Tablets **should not be taken** if you are pregnant or trying to become pregnant or you are breast feeding.

Driving and using machines

Please note that your ability to drive or operate hazardous machinery may be impaired by drowsiness as a result of taking Cloral Betaine Tablets. Ask your doctor whether you may drive or operate machines.

Important information about some of the ingredients of Cloral Betaine Tablets

Cloral Betaine Tablets contain azorubine carmoisine (E122) which may cause an allergic reaction. Cloral Betaine Tablets also contain sodium methyl parahydroxybenzoate (E219) and sodium propylparahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

Laboratory Tests

If you are having blood tests for your thyroid, tell your doctor or nurse as cloral betaine may interfere with these tests.

3. How to take Cloral Betaine Tablets

Always take Cloral Betaine Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For Cloral Betaine Tablets to work successfully, your doctor will need to identify the most appropriate dose for treating your sleeplessness. Your doctor will help you to select the most appropriate strength and dose.

Cloral Betaine Tablets should be taken as a single daily dose, 15-30 minutes before bedtime, with water or milk.

The usual recommended doses for Cloral Betaine Tablets are:

Adults and Children aged 12 years, adolescents and the Elderly:

The usual starting dose is 1 - 2 tablets.

In the frail elderly or patients with liver problems a smaller dose may be required.

No more than 4 tablets should be taken in any one day.

Cloral Betaine Tablets are not suitable for use in children under 12 years of age.

If you are unsure about how to take your medicine, ask your doctor or pharmacist.

Duration of treatment and Stopping treatment

Cloral Betaine Tablets are usually prescribed for the short term treatment of sleeping problems when other non-drug therapies (such as behavioural therapy and sleep hygiene) and other drugs have failed, **for a maximum treatment period of 2 weeks.**

Repeat courses of Cloral Betaine Tablets are not recommended and can only be administered following medical specialist re-assessment, because there is a risk of abuse and dependence.

If you take Cloral Betaine Tablets over a long period of time, you may find that the tablets take longer to work and the effect does not last for as long. This is called "tolerance" to the medicine. If you find you are becoming "tolerant" to Cloral Betaine Tablets do not increase the amount you take. Speak to your doctor.

Following prolonged treatment with Cloral Betaine Tablets, the dose should be slowly reduced before discontinuation, because there is a risk of withdrawal symptoms. Suddenly stopping Cloral Betaine Tablets may cause delirium (severe confusion). Contact your doctor before you stop taking the medicine, as they will advise you how to stop.

If you take more Cloral Betaine Tablets than you should

In the event of an accidental overdose, contact your nearest hospital casualty department or tell your doctor immediately. It is advisable to have the medicine in its original packaging available for the doctor or hospital. Signs of an overdose include, vomiting, breathing problems, abnormal heartbeat, abnormally low body temperature, pin point pupils, low blood pressure or coma.

If you forget to take Cloral Betaine Tablets

If you have missed one dose, this dose should be omitted, and the next dose should be taken at the usual time. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

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

Stop taking the medicine and seek urgent medical advice if you have:

- Hypersensitivity and allergic reactions such as itchy skin, skin redness and swelling and skin rash, sudden wheezing, swelling of the face, lips, tongue, throat, or body, rash, fainting or difficulty breathing or swallowing.
- Difficulty in breathing (dyspnoea) or very slow and/or shallow breathing (respiratory depression)
- Heart problems such as slow, fast or irregular heartbeat (which might reflect serious heart problems such as QTc prolongation)
- Sudden or severe confusion (delirium)
- Kidney injury with symptoms such as reduced urine output

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Headache
- Mental side effects such as anxiety, restlessness, excitation or confusion
- Loss of coordination of muscle movements (ataxia)
- Stomach and intestinal problems such as abdominal pain, distension of the abdomen, flatulence, nausea and vomiting (as these might reflect serious problems such as stomach irritation, gastric necrosis, gastric perforation or gut swelling).
- Long-term use of this medication leading to tolerance (usual doses not producing the desired effect),
- Dependence on the medication and its abuse,
- Chronic intoxication with mental symptoms or any other symptoms described here
- Withdrawal symptoms which may be severe and include hallucinations and delirium
- Ketonuria (a condition in which ketone bodies are present in the urine) which can only be detected by tests arranged by your doctor.

If you are elderly you may be more susceptible to confusion and co-ordination problems which may lead to falls and injury.

If you find that you are experiencing unpleasant side effects you should consult your doctor.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to adjust the dose or give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. 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 the side effects you can help provide more information on the safety of this medicine.

5. How to store Cloral Betaine Tablets

Store below 25°C. Do not refrigerate. Store in the original package.

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

Do not use this medicine after the expiry date which is stated on the end panel of the carton and tablet blisters. The expiry date refers to the last day of the month.

If your doctor decides to stop treatment, return any left over tablets to your pharmacist. Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cloral Betaine Tablets contain

The active substance is Cloral Betaine.

Each tablet contains 707mg of cloral betaine (equivalent to 414mg chloral hydrate).

In addition to cloral betaine, Cloral Betaine Tablets contain povidone, maize starch, sodium citrate, purified talc, magnesium stearate, hypromellose (E464), hydroxypropylcellulose (E463), macrogol 400, macrogol 8000, disodium edetate, azorubine carmoisine (E122), brilliant blue FCF aluminium lake (E133), titanium dioxide (E171).

What Cloral Betaine Tablets look like and contents of the pack

Elongated, bluish-purple coloured tablet with a smooth film coat. Very slight odour of chloral.

A pack size of 30 tablets is available.

Marketing Authorisation Holder

Marlborough Pharmaceuticals Ltd, Sovereign House, Miles Gray Road, Basildon, Essex
SS14 3FR, United Kingdom

Manufacturer

Recipharm Limited, Vale of Bardsley, Ashton-under-Lyne, Lancashire, OL7 9RR.

The Product Licence number is PL 23138/0015.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in July 2021.