

# CHLORAL HYDRATE MIXTURE

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Chloral Hydrate Mixture?

Chloral Hydrate Mixture contains the active ingredient chloral hydrate. It is used short term to treat insomnia, a condition where people have difficulty sleeping. Chloral Hydrate Mixture is also used to calm patients down and make them sleepy before surgery.

For more information, see Section [1. Why am I using Chloral Hydrate Mixture?](#) in the full CMI.

### 2. What should I know before I use Chloral Hydrate Mixture?

Do not use if you have ever had an allergic reaction to chloral hydrate or any of the ingredients listed at the end of this leaflet.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Chloral Hydrate Mixture?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Chloral Hydrate Mixture and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Chloral Hydrate Mixture?

Follow your doctor's instructions about how to take Chloral Hydrate Mixture.

More instructions can be found in Section [4. How do I use Chloral Hydrate Mixture?](#) in the full CMI.

### 5. What should I know while using Chloral Hydrate Mixture?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell any doctor, dentist or pharmacist you visit that you are using Chloral Hydrate Mixture.</li><li>• Tell your doctor immediately if you become pregnant while taking Chloral Hydrate Mixture.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take Chloral Hydrate Mixture for a longer time than your doctor has prescribed.</li><li>• Do not suddenly stop taking Chloral Hydrate Mixture or lower the dose without first checking with your doctor.</li><li>• Do not let yourself run out of medicine over the weekend or on holidays.</li><li>• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Chloral Hydrate Mixture affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while taking Chloral Hydrate Mixture.</li><li>• Combining Chloral Hydrate Mixture and alcohol can make you more sleepy, dizzy or lightheaded.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Chloral Hydrate Mixture should be stored below 25°C and kept away from light.</li><li>• Store it in a cool dry place away from moisture, heat or sunlight.</li></ul>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# CHLORAL HYDRATE MIXTURE

Active ingredient(s): *Chloral Hydrate Mixture 1g/10mL*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Chloral Hydrate Mixture. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Chloral Hydrate Mixture.**

Where to find information in this leaflet:

- [1. Why am I using Chloral Hydrate Mixture?](#)
- [2. What should I know before I use Chloral Hydrate Mixture?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Chloral Hydrate Mixture?](#)
- [5. What should I know while using Chloral Hydrate Mixture?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Chloral Hydrate Mixture?

**Chloral Hydrate Mixture contains the active ingredient chloral hydrate.** Chloral hydrate belongs to a group of medicines called sedatives and hypnotics. It is used short term to treat insomnia, a condition where people have difficulty sleeping.

In patients with insomnia, Chloral Hydrate Mixture decreases the time it takes to fall asleep and increases the length of time spent sleeping. Chloral Hydrate Mixture is also used to calm patients down and make them sleepy before surgery.

If your child is to be given chloral hydrate before a dental or medical procedure, it should only be administered at the health care facility where the procedure is to be done. This will allow the health care professional to monitor your child.

Chloral Hydrate mixture remains active in the body for many hours and may cause drowsiness the next day.

Your doctor may have prescribed Chloral Hydrate Mixture for another use. Ask your doctor if you have any questions about why Chloral Hydrate Mixture has been prescribed for you.

In general, sedatives and hypnotics such as Chloral Hydrate Mixture should be taken for short periods only (no more than 2 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of Chloral Hydrate Mixture may lead to dependence on the medicine.

## 2. What should I know before I use Chloral Hydrate Mixture?

### Warnings

**Do not use Chloral Hydrate Mixture if:**

- **you are allergic to chloral hydrate, or any of the ingredients listed at the end of this leaflet.**
- Always check the ingredients to make sure you can use this medicine.
- **You must not take Chloral Hydrate Mixture if you have had any of the following medical conditions:**
  - severe liver disease
  - severe kidney disease
  - severe heart disease
  - gastritis (inflammation of the stomach)
  - oesophagitis (inflammation of the oesophagus)
  - stomach ulcers
  - inherited blood diseases known as porphyria
- Do not give this medication to children unless advised by the child's doctor.
- Do not give Chloral Hydrate Mixture to children who experience sleep apnoea, a condition which leads to temporary stops in breathing during sleep.
- Do not take Chloral Hydrate Mixture if the bottle is damaged or shows signs of tampering.
- Do not take Chloral Hydrate Mixture which has not been properly stored.

**You must tell your doctor if:**

- you have had an allergic reaction to any other medicines, foods, dyes or preservatives
- you have a history of or have a current drug or alcohol addiction
- you have any other medical conditions, especially the following:
  - kidney problems
  - liver diseases
  - stomach ulcers
  - breathing difficulties (e.g. asthma)
  - sleep apnoea in children, a condition which leads to temporary stops in breathing during sleep
- you drink alcohol. Alcohol may increase the effects of Chloral Hydrate Mixture.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.** Your doctor will discuss with you the possible risks and benefits of using Chloral Hydrate Mixture during pregnancy.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** This medicine may pass into the breast milk and there is a possibility that your baby may be affected. Your doctor will discuss with you the possible risks and benefits of using Chloral Hydrate Mixture during breastfeeding.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with Chloral Hydrate Mixture and affect how it works.**

Your doctor or pharmacist will be able to tell you which medicines, vitamins or supplements are safe to take with Chloral Hydrate Mixture.

In particular, tell your doctor if you are taking any of the following:

- Any medicines used to prevent clotting of the blood (e.g. Coumadin®, Marevan®)
- Benzodiazepines and other medicines used to treat anxiety or to help you sleep
- Strong pain killers e.g. morphine
- Medicines used to control depression or mood swings
- Antipsychotic medicines, used to treat mental illnesses
- Medicines used to treat hay fever, coughs and colds
- Alcohol
- Frusemide, a medicine to treat high blood pressure and other heart conditions

This list is not exhaustive. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Chloral Hydrate Mixture.

In future, before you start to take any other medicines, tell your doctor or pharmacist that you are taking Chloral Hydrate Mixture.

## 4. How do I use Chloral Hydrate Mixture?

Follow your doctor's instructions about how to take Chloral Hydrate Mixture.

Read the directions label of your Chloral Hydrate Mixture carefully. If you have any concerns about how to take Chloral Hydrate Mixture, talk to your doctor or pharmacist.

### How much to take / use

The usual adult dose is 5 – 10 mL taken 15 – 30 minutes before bedtime.

**You should not take more than 20mL a day.**

If you have kidney or liver disease, or are elderly, your doctor may start you on a lower dose to prevent untoward side effects.

Your doctor or pharmacist will tell you how much Chloral Hydrate Mixture you will need to take each day.

Smaller doses are used in children. If Chloral Hydrate Mixture has been prescribed for a child, your doctor or pharmacist will tell you what the dose for your child is. It is important that you give your child the correct dose.

### How to take /use it

Shake the bottle well and accurately measure the dose with a medicine measure.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

Mix the dose with water, ginger ale, or fruit juice before you take it. Mixing with a drink can help reduce the risk of stomach upset.

### How long to take / use it for

Do not take Chloral Hydrate Mixture for longer than your doctor says.

Usually, Chloral Hydrate Mixture should be taken for short periods only (no more than 2 weeks). Continuous long term use is not recommended unless advised by your doctor.

The use of Chloral Hydrate Mixture may lead to dependence on the medicine within two weeks of use.

If you are concerned that you may be dependent talk to your doctor.

Continue to take Chloral Hydrate Mixture until your doctor tells you to stop.

### If you forget to use Chloral Hydrate Mixture

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not try and make up for the dose that you missed by taking more than one dose at a time. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### **If you use too much Chloral Hydrate Mixture**

If you think that you have used too much Chloral Hydrate Mixture, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

#### **You should do this even if there are no signs of discomfort or poisoning.**

Signs of overdose include feeling dizzy or feeling faint, drowsiness, confusion, breathing difficulties, irregular heartbeats and coma.

## **5. What should I know while using Chloral Hydrate Mixture?**

### **Things you should do**

- Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

- Tell your doctor if you feel the mixture is not helping your condition.
- Tell your doctor immediately if you become pregnant while taking Chloral Hydrate Mixture.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Chloral Hydrate Mixture.

If you are about to be started on any new medicines, remind your doctor, dentist or pharmacist that you are taking Chloral Hydrate Mixture.

- Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking Chloral Hydrate Mixture.

- If you have diabetes and use urine test strips to test your sugar levels, speak to your doctor or pharmacist about which test strips to use.

Chloral Hydrate Mixture may interfere with urine test strips which use copper sulphate. This may lead to false results with some urine test strips.

### **Things you should not do**

- Do not take Chloral Hydrate Mixture for a longer time than your doctor has prescribed.

Chloral Hydrate Mixture should only be taken for short periods (no more than 2 weeks) unless otherwise advised by your doctor.

- Do not suddenly stop taking Chloral Hydrate Mixture or lower the dose without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted side effects. Your doctor will explain how you should slowly reduce your dose of Chloral Hydrate Mixture before you can stop taking it completely.

- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use Chloral Hydrate Mixture to treat any other complaints unless your doctor says to.

### **Driving or using machines**

#### **Be careful before you drive or use any machines or tools until you know how Chloral Hydrate Mixture affects you.**

As with other sedatives and hypnotic medicines, Chloral Hydrate Mixture may cause drowsiness in some people.

### **Drinking alcohol**

#### **Tell your doctor if you drink alcohol.**

Be careful when drinking alcohol while taking Chloral Hydrate Mixture.

Combining Chloral Hydrate Mixture and alcohol can make you more sleepy, dizzy or lightheaded.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking Chloral Hydrate Mixture.

### **Looking after your medicine**

#### **Chloral Hydrate Mixture should be stored in a safe place where children cannot reach it**

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Keep your Chloral Hydrate Mixture in its bottle until it is time to take it.

#### **Chloral Hydrate Mixture should be stored below 25°C and kept away from light.**

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• nausea, vomiting</li> <li>• diarrhoea, flatulence</li> <li>• unpleasant taste in the mouth</li> <li>• drowsiness, tiredness (sometimes lasting the next morning)</li> <li>• dizziness, light-headedness</li> <li>• unsteadiness</li> <li>• headache, hangover feeling</li> <li>• unpleasant dreams</li> <li>• sweet smelling urine</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• sudden signs of allergy such as a rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; wheezing or troubled breathing</li> <li>• breathing difficulty</li> <li>• excitement</li> <li>• confusion, lack of concentration</li> <li>• hallucinations or delusions</li> <li>• paranoid behaviour</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Chloral Hydrate Mixture contains

Active ingredient	Chloral hydrate
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(main ingredient)	
Other ingredients (inactive ingredients)	Sucrose Citric acid Sodium citrate Saccharin sodium Glycerol Methyl hydroxybenzoate Ethanol Propylene glycol Natural Peppermint Flavour 7-7686 Water – purified

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Chloral Hydrate Mixture looks like

Chloral Hydrate Mixture 1g/10mL is a clear, colourless syrupy liquid. It comes in 200mL bottles.

Australian Registration Number: AUST R 42850.

### Who distributes Chloral Hydrate Mixture

Orion Laboratories Pty Ltd T/A Evaris Pharma  
 25-29 Delawney Street  
 Balcatta WA 6021  
[www.evarispharma.com](http://www.evarispharma.com)

This leaflet was prepared in September 2003.

Date of last amendment: November 2025.