

CHLORAL HYDRATE MIXTURE

Chloral Hydrate Mixture 1g/10mL

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Chloral Hydrate Mixture.

This leaflet answers some common questions about Chloral Hydrate Mixture. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Chloral Hydrate Mixture against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is Chloral Hydrate Mixture used for?

The brand name of your medicine is Chloral Hydrate Mixture. The active ingredient in Chloral Hydrate Mixture is called 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.

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

Before you take Chloral Hydrate Mixture

Do not take if:

You must not take Chloral Hydrate Mixture if you have an allergy to:

- Chloral hydrate

➤ Any of the ingredients listed at the end of this leaflet (See "Ingredients")

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 after the expiry date (EXP) printed on the bottle.

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.

If the bottle of Chloral Hydrate Mixture has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Chloral Hydrate Mixture, talk to your doctor or pharmacist.

Tell your doctor if:

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 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
- you are breast feeding, or wish 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
- 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

Taking other medicines:

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

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 hayfever, coughs and colds
- Alcohol
- Frusemide, a medicine to treat high blood pressure and other heart conditions

Some medicines may affect the way other medicines work. They may also react with Chloral Hydrate Mixture resulting in untoward or sometimes dangerous side effects. Your doctor or pharmacist will be able to tell you which medicines are safe to take with Chloral Hydrate Mixture.

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.

How do I take 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:

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

You should not take more than 20 mL 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 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 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

(Continued)

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 take it:

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.

**What do I do if I take too much?
(Overdose)**

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Chloral Hydrate Mixture. Do this, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

Keep telephone numbers for these places handy.

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

While you are taking Chloral Hydrate Mixture

Things you must 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 you 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.

Things you must 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

(Continued)

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 his or her symptoms seem similar to yours.

Do not use Chloral Hydrate Mixture to treat any other complaints unless your doctor says to.

Things to be careful of:

Be careful driving or operating machinery 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. Make sure you know how you react to Chloral Hydrate Mixture before you drive a car, operate machinery, or do anything else that could be dangerous.

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.

What are the side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Chloral Hydrate Mixture, even if the problem is not listed below.

Like other medicines, Chloral Hydrate Mixture can sometimes cause unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you get any unwanted side effects, tell your doctor or pharmacist.

Tell your doctor if you notice any of the following that are troublesome or ongoing, and they worry you:

- nausea, vomiting
- diarrhoea, flatulence
- unpleasant taste in the mouth
- drowsiness, tiredness (sometimes lasting the next morning)
- dizziness, light-headedness
- unsteadiness
- headache, hangover feeling
- unpleasant dreams
- sweet smelling urine

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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
- breathing difficulty
- excitement
- confusion, lack of concentration
- hallucinations or delusions
- paranoid behaviour

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Your doctor or pharmacist will have more information. Your doctor or pharmacist should discuss the possible side effects of Chloral Hydrate Mixture with you.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

How do I store Chloral Hydrate Mixture?

Storage:

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.

Do not leave Chloral Hydrate Mixture in the car or on windowsills. Do not store medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Disposal:

If your doctor tells you to stop taking Chloral Hydrate Mixture, ask your pharmacist what to do

(Continued)
with any mixture that is left over.

Product Description

What it looks like:

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

Ingredients:

Active Ingredient: Chloral Hydrate 100mg per mL

Inactive Ingredients:

- Sucrose
- Citric acid – anhydrous
- Sodium citrate
- Saccharin sodium
- Glycerol
- Methyl hydroxybenzoate
- Ethanol
- Propylene glycol
- Peppermint oil
- Water – purified

What other information should I know?

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.

Speak to your doctor or pharmacist if you are not sure which test to use.

Where to go to for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Sponsor

Chloral Hydrate Mixture is supplied in Australia by:

ORION Laboratories Pty Ltd
25-29 Delawney Street
Balcatta WA 6021

*Australian Registration
Number: AUST R 42850*

This leaflet was prepared in
September 2003

*Date of last amendment:
14th June 2006*

Code: CHL01218_2_CMI