

Package leaflet: Information for the user

# Chloral hydrate 200 mg/5ml Oral Solution

Chloral hydrate

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. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your product is Chloral hydrate 200 mg/5ml Oral Solution but it will be referred to as Chloral hydrate Oral Solution throughout this leaflet.

## What is in this leaflet

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

### 1. What Chloral hydrate Oral Solution is and what it is used for

Chloral hydrate Oral Solution contains chloral hydrate, which is one of a group of medicines called hypnotics (sleep inducing drugs).

Adults

Chloral hydrate Oral Solution is 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. Chloral hydrate Oral Solution should be used in addition to non-drug therapies.

Children and adolescents aged 2 years and above

Chloral hydrate Oral Solution is 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 disorder). It is only used when the sleeplessness interferes with normal daily life and other therapies (non-drug therapies and other drugs) have failed. Chloral hydrate Oral Solution should be used in addition to behavioural therapy and sleep hygiene management. The use of Chloral hydrate Oral Solution in children and 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 Chloral hydrate Oral Solution

**Do not take Chloral hydrate Oral Solution if you:**

- are allergic to chloral hydrate or any of the other ingredients of this medicine (see section 6)
  - have severe liver problems
  - have severe 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 to a child under 2 years of age.

## Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Chloral hydrate Oral Solution if you:

- are elderly or frail (weak),
- have mild or moderate kidney impairment,
- have mild or moderate liver impairment,
- suffer from alcoholism or drug addiction problems,
- have dependency to sleep medications,
- 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,
- 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 Chloral hydrate Oral Solution

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 tranquillisers (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).

## Taking Chloral hydrate Oral Solution with food and drink and alcohol

Alcohol can increase the sedative effect of chloral hydrate. Alcohol should therefore be avoided whilst taking this medicine.

Chloral hydrate Oral Solution should be taken with water or milk.

## Pregnancy and breast-feeding

Chloral hydrate Oral Solution 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 Chloral hydrate Oral Solution. Ask your doctor whether you may drive or operate machines.

## Chloral hydrate Oral Solution contains sodium benzoate.

This medicine contains 0.5 mg sodium benzoate in each ml. This medicine contains less than 1 mmol sodium (23 mg) per 20 ml dose, that is to say essentially 'sodium-free'.

## Laboratory Tests

If you are having blood tests for your thyroid, tell your doctor or nurse that you are taking this medicine, as chloral hydrate may interfere with these tests.

### 3. How to take Chloral hydrate Oral Solution

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For Chloral hydrate Oral Solution to work successfully, your doctor will need to identify the most appropriate dose for treating your sleeplessness. Chloral hydrate Oral Solution is available in three strengths (143 mg/5 ml, 200 mg/5 ml and 500 mg/5 ml). Your doctor will help you to select the most appropriate strength and dose.

Chloral hydrate Oral Solution should be administered as a single daily dose, 15-30 minutes before bedtime.

The usual recommended doses for Chloral hydrate 200 mg/5 ml Oral Solution are:

#### Adults and Children aged 12 years and over and the Elderly

The usual starting dose is 430 – 860 mg (10.75-21.5 ml of the 200 mg/5 ml strength).

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

Not more than 50 ml of the 200 mg/5 ml strength Chloral hydrate Oral Solution (equivalent to 2 g of Chloral Hydrate) should be taken in any one day.

For doses more than 20 ml of the 200 mg/5 ml strength, Chloral hydrate 500 mg/5 ml should be used.

#### Children 2-11 years

The use of Chloral hydrate Oral Solution in children and adolescents is not generally recommended and if used should be under the supervision of a medical specialist. The dose will be calculated by your doctor or pharmacist based on the weight of the child. You should follow their instructions. Not more than 25 ml of the 200 mg/5 ml strength Chloral hydrate Oral Solution (equivalent to 1 g of Chloral Hydrate) should be taken in any one day.

For doses more than 20 ml of the 200 mg/5 ml strength, Chloral hydrate 500 mg/5 ml should be used.

For doses below 1 ml of the 200 mg/5 ml strength, Chloral hydrate 143 mg/5 ml should be used.

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

## Duration of treatment and stopping treatment

Chloral hydrate Oral Solution is usually prescribed for the short-term treatment of sleeping problems when other non-medication treatments (e.g. behavioural therapy and sleep hygiene) have failed, for a maximum treatment period of 2 weeks.

Repeat courses of Chloral hydrate Oral Solution 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 Chloral hydrate Oral Solution over a long period of time, you may find that the medicine takes longer to work and the effect does not last for as long. This is called "tolerance" to the chloral hydrate ingredient. If you find you are becoming "tolerant" to Chloral hydrate Oral Solution, do not increase the amount you take. Speak to your doctor.

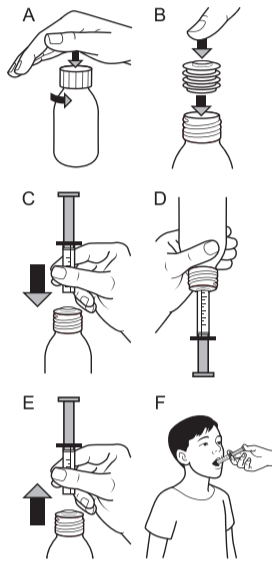
Following prolonged treatment with Chloral hydrate Oral Solution the dose should be slowly reduced before discontinuation, because there is a risk of withdrawal symptoms. Suddenly stopping Chloral hydrate Oral Solution may cause delirium (severe confusion). Contact your doctor before you stop taking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

#### Method of administration

Chloral hydrate Oral Solution is for oral use only and should be administered with water or milk.

A 10 ml graduated oral syringe with intermediate graduations of 0.5 ml and a "Press-In" Bottle Adapter (PIBA) are provided with the product.

1. Open the bottle and at first use insert the "Press-In" Bottle Adapter (PIBA) (see pictures A-B).
2. Insert the syringe into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).
3. Remove the filled syringe from the bottle in the upright position (see picture E).
4. Discharge the syringe contents into the mouth. Repeat steps 2 to 4 as needed to achieve the required dose (see picture F).
5. Replace the cap on the bottle (PIBA remains in place).
6. To clean the oral syringe:
  - Remove plunger from barrel.
  - Wash the disassembled pieces by rinsing them with room temperature (between 20 and 25°C) tap water.
  - Dry the disassembled pieces by exposure to air (atmospheric condition) for at minimum 2 hours.
  - Reassemble the syringe.
  - Do this after each time that you use the syringe.



#### Alternative method of administration (with feeding tubes)

This medicine can also be administered via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. If you want to know more, there is information in the Summary of Product Characteristics (SmPC). Ask your doctor, pharmacist or nurse about this.

#### Administering this medicine via NG or PEG tubes

1. Ensure the tube is clear before administering the medicine.
2. Flush the tube with 10ml of boiled cooled water.
3. Administer the medicine into the tube with a suitable measuring device.
4. Immediately, flush the tube again, twice, with 10ml of boiled cooled water.

#### If you take more Chloral hydrate Oral Solution 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 Chloral hydrate Oral Solution

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:

Not known (frequency cannot be estimated from the available data)

- 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:

Not known (frequency cannot be estimated from the available data)

- 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) detected by tests as advised 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.

In new-borns and children <2 years of age, there is an increased risk of side effects. Do not give to a child under 2 years of age.

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, 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](http://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 Chloral hydrate Oral Solution

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 carton and label after EXP. The expiry date refers to the last day of that month.

Store below 25 °C.

After first opening use within 1 month.

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 Chloral hydrate Oral Solution contains

- The active substance is chloral hydrate.
- Each 5ml of Chloral hydrate Oral Solution contains 200 mg of chloral hydrate.
- The other ingredients are: sodium benzoate (E211), sucralose, hydrochloric acid, concentrated (for pH adjustment) and purified water.

#### What Chloral hydrate Oral Solution looks like and contents of the pack

Chloral hydrate Oral Solution is a clear, colourless solution. It is supplied in amber, type III glass bottles, safely closed with a child-resistant, screw cap with tamper evident closure. Each bottle contains 100 ml or 150 ml or 200 ml of this medicine. Not all pack sizes may be marketed.

A CE marked 10 ml oral syringe of 0.5 ml graduations along with a press-in bottle adaptor are also provided.

#### Marketing Authorisation Holder

Atnahs Pharma UK Limited  
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#### Manufacturer

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