

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Chloral Hydrate 500mg/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, 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 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 (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 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),
- 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 Chloral Hydrate Oral Solution**

Tell your doctor or pharmacist if you are taking or 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).

### **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 Glycerol, Glucose, Sodium Benzoate and Propylene Glycol**

- Glycerol may cause headache, stomach upset and diarrhoea.
- Liquid Glucose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.  
The medicine contains 1.655 g glucose per dose. This should be taken into account in patients with diabetes mellitus.  
Glucose may also be harmful to the teeth.
- This medicine contains 6.3 mg of sodium benzoate in each 5 ml, which is equivalent to 1.26 mg/ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Propylene glycol: This medicine contains 18.39 mg propylene glycol in each 5 ml which is equivalent to 3.678 mg/ml. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, which is to say that it is 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 Chloral Hydrate Oral Solution exactly as your doctor has told you. You should 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 two strengths (500mg/5ml and 143mg/5ml). Your doctor will help you to select the most appropriate strength and dose.

Chloral Hydrate Oral Solution should be taken as a single daily dose, 15-30 minutes before bedtime, with water or milk.

### **The usual recommended doses for Chloral Hydrate 500mg/5ml Oral Solution are:**

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

The usual starting dose is 430-860 mg (4.3-8.6 ml of the 500mg/5ml strength).

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

**Not more than 20 ml of the 500mg/5ml strength Chloral Hydrate Oral Solution (equivalent to 2 g of chloral hydrate) should be taken in any one day.**

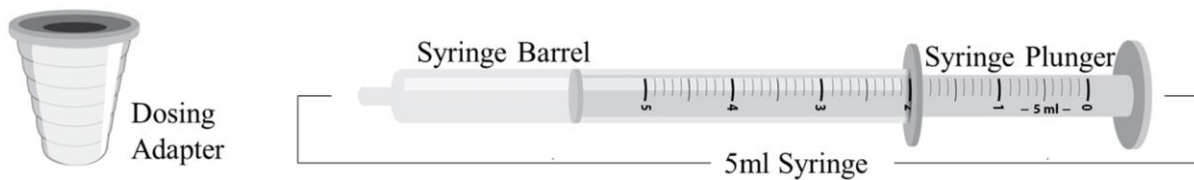
**Children 2-11 years:**

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 10 ml of the 500mg/5ml strength Chloral Hydrate Oral Solution (equivalent to 1 g of chloral hydrate) should be taken in any one day.**

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

**Method of administration**

The box containing this medicine will contain a 5 ml dosing syringe and a dosing adapter, which should be used only for Chloral Hydrate 500mg/5ml Oral Solution.

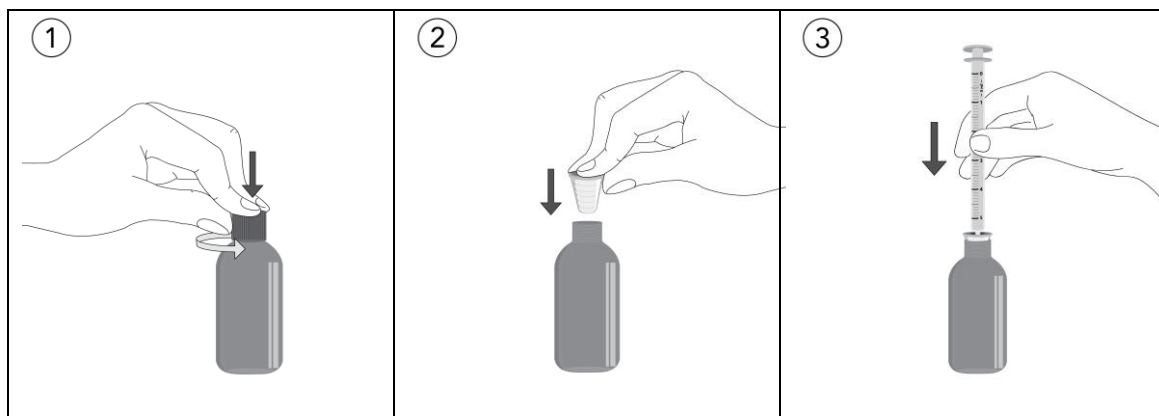


Instructions are provided below for using the dosing syringe.

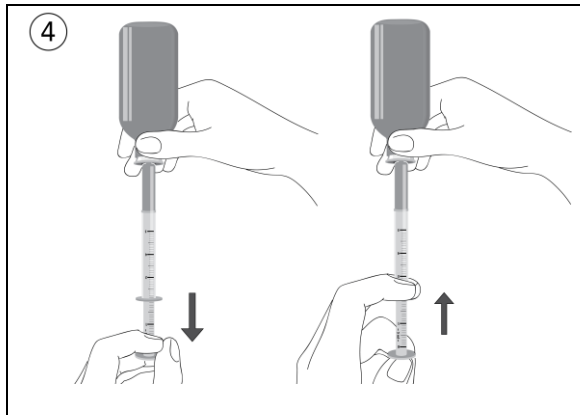
If you have any questions about how to use the syringe, you should ask your doctor, pharmacist or nurse.

**Instructions for use:**

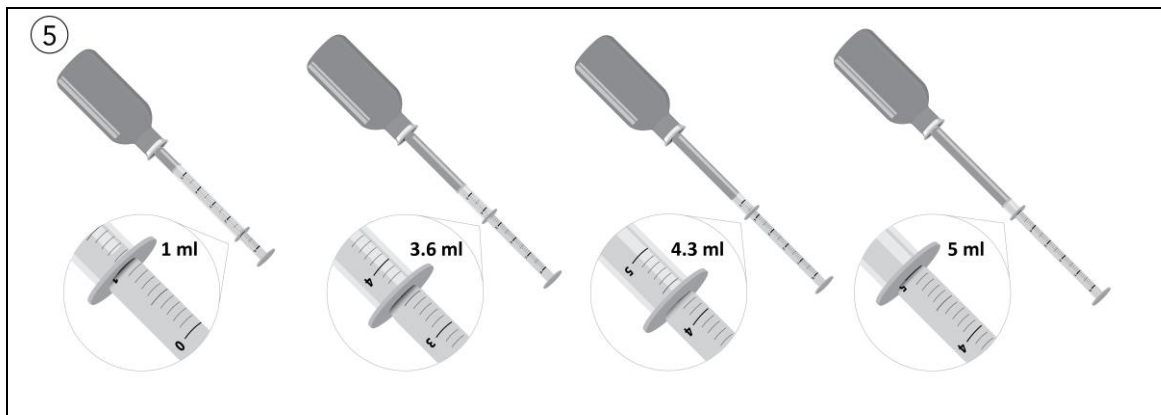
- Open the bottle: press the cap and turn it anticlockwise (see figure 1).
- Holding the bottle, take the plastic syringe adapter from the box and insert the adapter firmly into the bottle neck (see figure 2).
- Take the syringe and put it in the adapter opening (see figure 3).



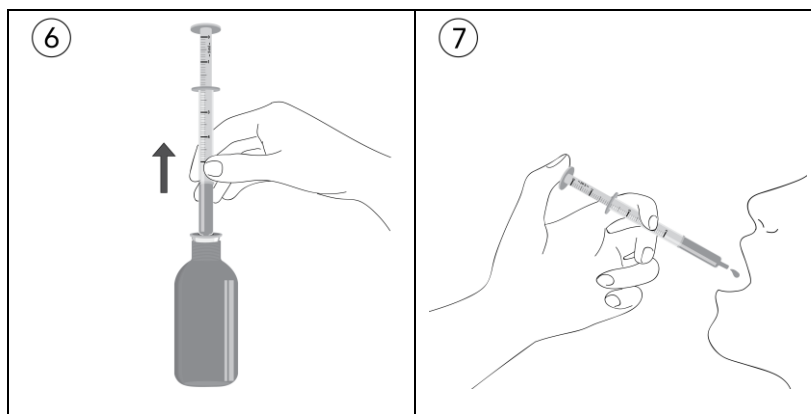
- Turn the bottle upside down and fill the syringe with a small amount of solution by pulling the plunger down (see figure 4), then push the plunger upward in order to remove any possible bubbles.



- Pull the plunger down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (see figure 5 which represents examples of measuring dose of 1 ml, 3.6 ml, 4.3 ml and 5 ml).



- Turn the bottle the right way up. Remove the syringe from the adapter (see figure 6).
- Administer the contents of the syringe into the mouth by pushing the plunger to the bottom of the syringe (see figure 7) and ensure that the medicine is swallowed.



## **After use**

Remove the adapter from the bottle and close the bottle with the plastic screw cap. Wash the adapter and syringe with warm water. Dry and replace them into the box with your medicine.

## **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.

## **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, pinpoint 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:**

- 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) 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 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](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**

Store below 25°C. Keep the bottle upright in the outer carton in order to protect from light. Use within 28 days of opening.

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

Do not use Chloral Hydrate Oral Solution after the expiry date which is stated on the bottle label and carton after “EXP”.

The expiry date refers to the last day of that 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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Chloral Hydrate Oral Solution contains**

The active substance in Chloral Hydrate Oral Solution is chloral hydrate.

The other ingredients are glycerol (E 422), liquid glucose, sodium benzoate (E 211), sodium citrate (E 331), citric acid (E 330), saccharin sodium (E 954), essence of passion fruit (containing natural flavouring, artificial flavouring, propylene glycol (E1520)) and purified water.

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

Chloral Hydrate Oral Solution is a clear colourless solution containing 500 mg chloral hydrate per 5 ml.

A pack size of 150 ml is available.

Each pack also contains a 5 ml oral syringe (polypropylene body, HDPE plunger) with intermediate graduations of 0.1 ml, and syringe adapter (LDPE).

### **Marketing Authorisation Holder**

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

### **Manufacturer**

Waymade PLC  
Sovereign House  
Basildon, Essex, SS14 3FR  
United Kingdom

Waymade PLC  
Josselin Road,  
Burnt Mills Industrial Estate,  
Basildon,  
SS13 1QF  
United Kingdom.

Laboratorium Sanitatis, S.L.  
Parque Tecnológico de Álava  
Leonardo da Vinci, 11  
01510 Miñano, Álava  
Spain

The Product Licence number is PL 23138/0021.

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

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