

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Welldorm 143.3mg per 5ml Elixir

# Chloral Hydrate

Please read both sides of this leaflet carefully before you start to take your medicine.

It will tell you what you need to know about Welldorm Elixir.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Remember this medicine is only for YOU. Never give it to anybody else, even if their symptoms are the same as yours. If you are experiencing unpleasant side effects you should consult your doctor.

### **In this leaflet:**

1. What Welldorm Elixir is and what it is used for
2. Before you take Welldorm Elixir
3. How to take Welldorm Elixir
4. Possible side effects
5. How to store Welldorm Elixir
6. Further information

### **1. What Welldorm Elixir is and what it is used for**

Welldorm Elixir contains Chloral Hydrate which is one of a group of medicines called hypnotics (sleep inducing drugs). Welldorm Elixir is used for the short-term treatment of severe insomnia (sleeping problems) which is interfering with normal daily life. Welldorm will normally be given in addition to other non drug therapies e.g. counselling.

Welldorm is normally only used in children and adolescents under the supervision of a medical specialist.

### **2. Before you take Welldorm Elixir**

#### **Do not take Welldorm Elixir if you or the patient:**

- have severe liver or kidney problems
- have severe heart problems
- suffer from porphyria (an inherited blood disorder)
- are a child under 2 years of age

#### **Speak to your doctor before taking Welldorm Elixir if you:**

- are allergic to chloral hydrate or any of the other ingredients in Welldorm Elixir
- are suffering from stomach problems (gastritis).

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- medicines to thin your blood (such as Warfarin).
- medicines for depression or nervous disorders.
- medicines intended to reduce muscle spasms.

### **Taking Welldorm Elixir with food and drink**

Alcohol can increase the sedative effect of chloral hydrate. Alcohol should therefore be avoided whilst taking this medicine. Welldorm Elixir should be taken with water or milk.

### **Pregnancy and breast feeding**

Welldorm Elixir should not be taken if you are pregnant or trying to become pregnant or you are breast feeding.

### **Driving and using machines**

Please note, your ability to drive or operate hazardous machinery may be impaired by drowsiness as a result of taking Welldorm Elixir.

### **Important information about some of the ingredients of Welldorm Elixir**

Welldorm Elixir contains the following:

- Sunset Yellow FCF (E110) and Ponceau 4R (E124) which may cause allergic reactions.
- Glycerol which may cause headache, stomach upset and diarrhoea.
- Glucose liquid. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Glucose may also be harmful to the teeth.

### **Laboratory Tests**

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

### **3. How to take Welldorm Elixir**

Always take Welldorm Elixir exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Welldorm Elixir should be taken as a single daily dose usually 15-30 minutes before bedtime.

The usual doses are:

**Adults and Children aged 12 years and over and the Elderly:** 15-30ml. In the frail elderly or patients with liver problems a smaller dose may be required. **Not more than 70ml Welldorm Elixir (equivalent to 2g of Chloral Hydrate) should be taken in any one day.**

**Children 2-11 years:** 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 35ml of Welldorm Elixir (equivalent to 1g of Chloral Hydrate) should be taken in any one day.**

**Children under 2 years** Welldorm Elixir is not suitable for children under 2 years old.

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

Welldorm Elixir is usually prescribed for the short term treatment of sleeping problems, usually for less than 2 weeks. If you take Welldorm Elixir over a long period of time, you may find that the medicine takes longer to work and does not last for as long. This is called "tolerance" to the medicine. If you find you are becoming "tolerant" to Welldorm Elixir do not increase the amount you take. Speak to your doctor.

#### **If you take more Welldorm Elixir 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 stop taking Welldorm Elixir**

Suddenly stopping Welldorm Elixir may cause delirium (severe confusion). Contact your doctor before you stop taking the medicine, he will advise you how to stop.

#### **4. Possible side effects**

This medicine can cause side effects in some people.

Examples of side effects which may occur are:

- Stomach irritation
- Wind
- Allergic skin reactions
- Confusion
- Gut swelling
- Excitement
- Headache
- Lack of co-ordination (ataxia)
- 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.

#### **5. How to store Welldorm Elixir**

Store below 25°C. Store in the original packaging. Keep the bottle in the outer carton.

Keep out of the reach and sight of children.

The expiry date is printed on the carton and on the bottle label. Do not use your medicine after this date.

If your doctor decides to stop treatment, return any left over Elixir to your pharmacist. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **6. Further information**

##### **What Welldorm Elixir contains**

The active substance in Welldorm Elixir is chloral hydrate. Welldorm Elixir also contains glycerol, glucose syrup, sodium benzoate, saccharin sodium, essence of passion fruit (containing natural flavouring, artificial flavouring, propylene glycol (E 1520)), purified water, ponceau 4R (E124) and sunset yellow (E110).

##### **What Welldorm Elixir looks like and contents of the pack**

Welldorm Elixir is a clear, red syrup containing 143.3mg chloral hydrate per 5ml. A Pack size of 150ml is available.

##### **Marketing Authorisation Holder and Manufacturer**

###### **Marketing Authorisation Holder**

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