

PACKAGE LEAFLET: INFORMATION FOR THE USER

Welldorm 707mg Tablets

Cloral Betaine

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 Tablets. 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 find that you are experiencing unpleasant side effects you should consult your doctor.

In this leaflet:

1. What Welldorm Tablets are and what they are used for
2. Before you take Welldorm Tablets
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1. What Welldorm Tablets are and what they are used for

Welldorm Tablets contain cloral betaine, which is one of a group of medicines called hypnotics ('sleeping tablets'). Cloral betaine rapidly breaks down in the stomach to form chloral hydrate. Welldorm tablets are 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 used in adolescents under the supervision of a medical specialist.

2. Before you take Welldorm Tablets

Do not take Welldorm Tablets 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 12 years of age.

Speak to your doctor before taking Welldorm Tablets if you:

- are allergic to chloral hydrate or any of the other ingredients in Welldorm Tablets
- 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 Tablets with food and drink

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

Welldorm Tablets should be taken with water or milk.

Pregnancy and breast feeding

Welldorm Tablets 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 Tablets.

Important information about some of the ingredients of Welldorm Tablets

Welldorm Tablets contain azorubine carmoisine (E122) which may cause an allergic reaction.

Welldorm Tablets also contain sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

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 Tablets

Always take Welldorm Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Welldorm Tablets 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:

1 - 2 tablets. In the frail elderly or patients with liver problems a smaller dose may be required.

Do not take more than 4 tablets per day.

Children 2 - 11 years :

An oral solution of Welldorm is available.

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

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

If you take more Welldorm Tablets 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 Tablets

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

Store below 25°C. Do not refrigerate. Store in the original package.

Keep out of the reach and sight of children.

The expiry date is printed on the end panel of the carton and on the tablet blisters.

Do not use your medicine after this date.

If your doctor decides to stop treatment, return any left over tablets 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 Tablets contain

The active substance in Welldorm Tablets is Cloral Betaine. Each tablet contains 707mg of cloral betaine (equivalent to 414mg chloral hydrate).

In addition to cloral betaine, Welldorm Tablets contain povidone, maize starch, sodium citrate, purified talc, magnesium stearate, hypromellose (E464), hydroxypropylcellulose (E463), macrogol 400, macrogol 8000, disodium edetate, azorubine carmoisine (E122), brilliant blue FCF aluminium lake (E133), titanium dioxide, (E171), sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217).

What Welldorm Tablets look like and contents of the pack

They are bluish-purple film coated oval tablets. A pack size of 30 tablets is available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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