1 NAME OF THE MEDICINAL PRODUCT

Welldorm Elixir
Chloral Hydrate 143mg per 5ml Elixir

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of Chloral Hydrate Oral Solution contains 143.3mg of Chloral hydrate BP.

3 PHARMACEUTICAL FORM

Oral Solution

4.1 Therapeutic indications

Chloral Hydrate Oral Solution is used for the short-term treatment of severe insomnia which is interfering with normal daily life and where other therapies have failed.

Chloral Hydrate Oral Solution should be used as an adjunct to non-pharmacological therapies.

In children aged 2-11 years treatment should be as an adjunct to behavioural therapy and sleep hygiene management, and usually for duration of less than 2 weeks.

The use of hypnotics in children and adolescents is not generally recommended and if used should be under the supervision of a medical specialist.

4.2 Posology and method of administration

Route of administration: oral. Chloral Hydrate Oral Solution should be administered as a single daily dose, 15-30 minutes before bedtime with water or milk.

Adults and children 12 years and over: The usual dose is 15-30ml (430 – 860 mg). Higher doses should not exceed a maximum of 70ml of elixir (2g chloral hydrate) per dose.

Elderly: Dosage as for adults except for the frail elderly or those with hepatic impairment, where a reduction in dose may be appropriate.

Children (between 2 and 11 years): 1–1.75 ml/kg (30-50mg/kg) of bodyweight. The dose should not exceed 35ml (1g) chloral hydrate.

Children (under 2 years): not recommended.

4.3 Contraindications

Chloral Hydrate Oral Solution should not be used in patients with a marked hepatic or renal impairment, or in patients with severe cardiac disease. Should not be used in patients susceptible to acute attacks of porphyria.
4.4 **Special warnings and precautions for use**
Elderly patients are more likely experience the undesirable effects of hypnotics such as ataxia and confusion which may lead to falls and injury. For use in the frail elderly it is recommended that a lower dose be administered. (See 4.2 Posology and method of administration)

Best avoided in the presence of gastritis and in patients who have previously exhibited an idiosyncrasy or hypersensitivity to chloral hydrate.

4.5 **Interaction with other medicinal products and other forms of interaction**
Alcohol potentiates the sedative effect. Chloral hydrate followed by intravenous frusemide may result in sweating, hot flushes and variable blood pressure including hypertension due to a hypermetabolic state caused by displacement of thyroid hormone from its bound state. Delirium may occur, especially in the elderly, particularly when used in conjunction with psychotropics or anticholinergics. In patients taking anticoagulants, when chloral hydrate is added to or withdrawn from the drug regimen, or its dosage changed, careful monitoring of the prothrombin time is required.

Chloral Hydrate may interfere with laboratory tests of thyroid function

4.6 **Fertility, pregnancy and lactation**
Chloral Hydrate Oral Solution should not be used in pregnancy and lactation.

4.7 **Effects on ability to drive and use machines**
Patients receiving Chloral Hydrate Oral Solution should be warned that their ability to drive or use machinery may be impaired by drowsiness.

4.8 **Undesirable effects**
Gastric irritation, abdominal distension and flatulence may occur. Excitement, tolerance, allergic skin reactions, headache and ketonuria have occasionally been reported. There is a danger of abuse or chronic intoxication and the possibility that habituation may develop. In such patients gastritis and parenchymatous renal injury may develop. After long term use, sudden withdrawal may result in delirium.

Elderly patients are more susceptible to the undesirable effects of hypnotic medications such as Chloral Hydrate Oral Solution and are therefore more susceptible to ataxia, confusion, falls and injuries.

4.9 **Overdose**
The signs and symptoms of overdose involve the cardiovascular, respiratory and central nervous systems. These may include: respiratory depression, arrhythmias,
hypothermia, pin-point pupils, hypotension or coma. Gastric irritation may result in vomiting and even gastric necrosis. If the patient survives, icterus due to hepatic damage and albuminuria from renal damage may appear. Serious problems have arisen with doses as little as 4g and 10g can be fatal. Overdosage should be treated with gastric lavage or inducing vomiting to empty the stomach. Supportive measures must be used. Haemodialysis, and in some cases haemoperfusion, have been reported to be effective in promoting the clearance of trichloroethanol.

5.1 Pharmacodynamic properties

Chloral Hydrate Oral Solution is a chloral hydrate derivative, which leads to a decrease in sleep latency and in the number of awakenings. A near natural sleep is induced and the REM/Non-REM ratio is not altered.

5.2 Pharmacokinetic properties

Chloral hydrate and its metabolite trichloroethanol act as central nervous system depressants. Chloral hydrate is rapidly absorbed from the stomach, and starts to act within 30 minutes. It is widely distributed throughout the body, and is metabolised to trichloroethanol, also an active hypnotic, and trichloroacetic acid in the erythrocytes, liver and other tissues. It is excreted partly in the urine as trichloroethanol and its glucuronide, urochloralic acid, and as trichloroacetic acid. Significant amounts are also excreted in bile. Trichloroethanol has a plasma half life of the order of 8 hours. Trichloroacetic acid has a half-life of several days. In infants the half lives are longer. The value for trichloroethanol is 35 hours whilst for trichloroacetic acid the half life exceeds 6 days, with significant plasma concentrations present at 14 days.

5.3 Preclinical safety data

Chloral hydrate induces liver tumours in male mice, with no tumourigenic effects in rats. The mechanism of tumour induction is not known, but in the absence of clear evidence of mutagenic and clastogenic potential it is unlikely to be relevant in man.

6.1 List of excipients

In addition to the active ingredient, Chloral Hydrate Oral Solution contains:

Glycerol
Liquid glucose
Sodium benzoate
Saccharin sodium
Permitted colours E 124, E 110
Essence of passion fruit
Purified water
6.2 Incompatibilities
None known

6.3 Shelf life
18 months when stored below 25°C

6.4 Special precautions for storage
Store below 25°C. Protect from direct sunlight.

6.5 Nature and contents of container
Amber glass bottle with child-proof plastic screw cap, containing 150ml or 30ml of Chloral Hydrate Oral Solution, presented in a carton.

6.6 Special precautions for disposal
Syrup BP should be used as a diluent.

7 MARKETING AUTHORISATION HOLDER
Marlborough Pharmaceuticals Ltd, 35A High Street, Marlborough, Wiltshire, SN8 1LW

8 MARKETING AUTHORISATION NUMBER(S)
PL 23138/0016

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Marketed since 1957
Date of Renewal: 13th December, 1998
10 DATE OF REVISION OF THE TEXT

19/05/2014