

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DHC Continus Prolonged-release Tablets 60 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dihydrocodeine Tartrate 60mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Prolonged-release tablets.

White capsule-shaped tablets with 'DHC 60' on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an analgesic in the relief of moderate to severe pain.

4.2 Posology and method of administration

Adults only

One tablet 12 hourly.

Elderly

Reduced dosage or increased intervals between doses may be required.

Route of Administration

Oral.

4.3 Contraindications

DHC CONTINUS tablets should not be used in patients hypersensitive to the active ingredient or any of the other constituents of the product or in patients with respiratory depression or obstructive airways disease, paralytic ileus, head injury, raised intracranial pressure or acute alcoholism. As dihydrocodeine may cause the release of histamine it should not be given during an attack of asthma. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. DHC CONTINUS tablets should not be used in children under 12 years of age.

4.4 Special warnings and precautions for use

DHC CONTINUS tablets should be used with great caution in patients with a history of asthma.

Reduced dosage or increased intervals between doses may be required in patients with hypothyroidism and in those with renal or hepatic dysfunction.

Dihydrocodeine should be administered with caution to patients with a history of opioid abuse, biliary tract disorders, prostatic hypertrophy, pancreatitis, constipation, obstructive bowel disorders and severe cor pulmonale.

Dihydrocodeine has a recognised abuse and addiction profile similar to other opioids. Prolonged use of high dosage may induce dependence with a withdrawal syndrome on discontinuation. Tolerance to analgesic effects may develop upon repeated administration.

DHC Continus tablets must be swallowed whole, and not broken, chewed or crushed. The administration of broken, chewed or crushed tablets may lead to a rapid release and absorption of a potential overdose of dihydrocodeine (see Section 4.9)

4.5 Interaction with other medicinal products and other forms of interaction

Dihydrocodeine should be used with caution in patients who are currently receiving, or have within the previous two weeks received, monoamine oxidase inhibitors.

Other central nervous system depressants, including sedatives or hypnotics, phenothiazines, other tranquillisers and alcohol, may result in respiratory depression or sedation.

4.6 Pregnancy and lactation

All the narcotic analgesics are able to traverse the placenta and are also excreted in milk. They should not be used during pregnancy or lactation unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

This product may induce drowsiness. Patients receiving it should not drive or operate machinery unless it has been shown not to affect physical or mental ability.

4.8 Undesirable effects

Common adverse drug reactions seen during therapy are constipation, nausea, vomiting, headache, somnolence, pruritus and rash. Uncommon adverse reactions are urinary retention, ureteric or biliary spasm, dry mouth, mood changes, blurred vision, sweating, decreased libido, flushing, abdominal pain, hypotension, paraesthesia, confusion, dizziness, hallucinations, urticaria, paralytic ileus and respiratory depression. Tolerance and dependence may occur.

4.9 Overdose

Acute overdosage with dihydrocodeine can be manifested by somnolence progressing to stupor or coma, miotic pupils, bradycardia, hypotension and respiratory depression or apnoea.

A patent airway must be administered. Administer naloxone 0.8mg intravenously. Repeat at 2 - 3 minute intervals as necessary, or by an infusion of 2mg in 500ml of normal saline or 5% dextrose (0.004 mg/ml). The infusion should be run at a rate related to the previous bolus doses administered and should be in accordance with the patient's response. Empty the stomach. Assist respiration if necessary. Maintain fluid and electrolyte levels.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Natural opium alkaloids
ATC code: N02A A08

Dihydrocodeine is a semisynthetic narcotic analgesic with a potency between morphine and codeine.

It acts on opioid receptors in the brain to reduce the patient's perception of pain and improve the psychological reaction to pain by reducing the associated anxiety.

5.2 Pharmacokinetic properties

Dihydrocodeine is well absorbed from the gastrointestinal tract following administration of DHC CONTINUS tablets and plasma levels are maintained throughout the twelve hour dosing interval.

Like other phenanthrene derivatives, dihydrocodeine is mainly metabolised in the liver with the resultant metabolites being excreted mainly in the urine. Metabolism of dihydrocodeine includes O-demethylation, N-demethylation and 6-keto reduction.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose anhydrous
Hydroxyethylcellulose
Cetostearyl alcohol
Magnesium stearate
Purified talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Polypropylene containers with polyethylene lids, containing 8, 56, or 250 tablets.
PVdC coated PVC blisters with aluminium backing foil containing 8 or 56 tablets.
Polyethylene contains with polypropylene lids, containing 56 tablets.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 913/8/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 March 1987

Date of last renewal: 19 April 2005

10 DATE OF REVISION OF THE TEXT

March 2006