

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DHC Continus Prolonged-release Tablets 120 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dihydrocodeine Tartrate 120 mg

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Prolonged release tablet.

White to off-white, capsule-shaped, biconvex tablet with DHC 120 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. 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.

4.4 Special warnings and special precautions for use

Prolonged use of high dosage may induce dependence with a withdrawal syndrome on discontinuation. Repeated use may result in the development of tolerance. DHC CONTINUS tablets should be used with great caution in patients with a history of asthma. Opioid analgesics should be avoided in patients with raised intracranial pressure or head

injury.

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

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 alcohol, will accentuate the sedative effects of this product.

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

The most common adverse drug reactions seen during therapy are constipation, nausea, vomiting, headache and vertigo. Occasional adverse reactions are urinary retention, abdominal pain, hypotension, paraesthesia, confusion, hallucinations and rash with or without pruritus. Tolerance and dependence may occur.

4.9 Overdose

Administer naloxone 0.8 mg intravenously. Repeat at 2 - 3 minute intervals as necessary, or by an infusion of 2 mg in 500 ml 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 patients' 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

- 1) 20µm hard tempered aluminium foil backed PVdC/PVC blister packs (56 tablets).
- 2) Polypropylene containers with polyethylene lids (56 tablets).

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 913/8/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 19th April 2005

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May 2005

