SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dihydrocodeine Injection BP 50mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains: Dihydrocodeine Tartrate BP 50mg/ml

3. PHARMACEUTICAL FORM

Injection

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

The relief of severe pain.

4.2. Posology and Method of Administration

Route of Administration

By intramuscular or deep subcutaneous injection

Adults

Patients who are unable to be treated with the tablets or elixir may be given up to 50mg by intramuscular or deep subcutaneous injection.

Children

0.5 to 1mg/kg body weight every 4 to 6 hours. Not recommended for children under 4 years.

Elderly

A reduced dose should be given

4.3. Contra-Indications

Respiratory depression, obstructive airways disease, phaeochromocytoma, hypersensitivity to the active ingredients or excipients or acute asthma attack. Dihydrocodeine Injection should be avoided where there is a risk of paralytic ileus.

4.4. Special Warnings and Special Precautions for Use

As dihycirocodeine may bring about histamine release, it should be administered with due care to patients with asthma.

Dosage should be reduced in the elderly, in hypothyroidism, hypotension, in chronic hepatic disease and in renal insufficiency. Opioid analgesics should be avoided in those patients with raised intracranial pressure or head injury.

Dihydrocodeine injection should be avoided in patients with decreased respiratory reserve, prostatic hypertrophy and convulsive disorders.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

Alcohol should be avoided whilst under treatment with dihydrocodeine injection.

Antidepressants: Dihydrocodeine injection should not be administered to patients receiving monoamine oxidase inhibitors, or within two weeks of their withdrawal.

Anxiolytics & Hypnotics: Sedative effects may be enhanced by simultaneous use of dihydrocodeine.

4.6. Pregnancy and Lactation

There is no, or inadequate evidence of safety in human pregnancy but the drug has been used for many years without apparent ill consequence. As with all drugs during pregnancy care should be taken in assessing the risk to benefit ratio. Administration during labour may cause respiratory depression in the new-born infant. It is likely that dihydrocodeine is excreted in breast milk.

4.7. Effects on Ability to Drive and Use Machines

Dihydrocodeine may cause drowsiness. If affected patients should not drive or operate machinery.

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When prescribing this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you
- It is an offence to drive while under the influence of this medicine
- However, you would not be committing an offence (called 'statutory defence') if:
    - The medicine has been prescribed to treat a medical or dental problem and
    - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine and

It was not affecting your ability to drive safely

4.8. Undesirable Effects

Constipation, nausea, vomiting, headache and vertigo occur and are relatively more common when the dose is increased above 30mg. If constipation occurs it can be treated with a gentle laxative. Other undesirable effects include drowsiness, respiratory depression, difficulty with micturition, dry mouth, sweating, headache, miosis, facial flushing, postural hypotension, hallucinations, dysphoria, mood changes, dependence, rashes and pruritus.

4.9. Overdose

Conservative management is recommended: gastric lavage should be carried out. Severe respiratory depression can be treated with naloxone hydrochloride 0.8mg intravenously, repeated as required at 2 or 3 minute intervals.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Dihydrocodeine is a narcotic analgesic which possess pharmacological properties similar to those of morphine. 30mg given parenterally has been shown to have an analgesic potency equivalent to that of 10mg of morphine. In a study of oral analgesics for the relief of chronic pain, the same dose was found to be equivalent to 100mg of pethidine. The duration of action of dihydrocodeine is about 4 - 5 hours, similar to morphine and codeine.

5.2. Pharmacokinetic Properties

Dihydrocodeine injection has been shown to have a satisfactory pharmacokinetic profile by many years of successful clinical experience.

5.3. Pre-clinical 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

Sodium Metabisulphite BP
Sodium Hydroxide BP
Tartaric Acid BP
Water for Injections BP

6.2. Incompatibilities

None known.

6.3. Shelf Life

Three years.

6.4. Special Precautions for Storage

Protect from light.

6.5. Nature and Content of Container

Type I neutral glass 1ml labelled ampoules packed in cartons along with patient leaflets. Carton pack sizes 5 x 1.1ml and 10 x 1.1ml ampoules.

6.6. Instructions for Use, Handling and Disposal

None.

ADMINISTRATIVE DATA

7. MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd
Bampton Road,
Romford,
RM3 8UG
England

8. MARKETING AUTHORISATION NUMBER

PL 0156/0091

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

First Authorised: 14 December 1998

10 DATE OF REVISION OF THE TEXT

28/08/2014