SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dihydrocodeine 30mg Tablets BP.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains dihydrocodeine tartrate 30 mg

Also contains Lactose monohydrate 155 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet
White, flat, circular, bevel edged plain tablet with breakline.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dihydrocodeine 30mg Tablets BP (as an analgesic) are indicated for the relief of moderate to severe pain. Dihydrocodeine 30mg Tablets BP are indicated in all painful conditions where an alert patient is desired, e.g. sciatica, osteo-arthritis, chronic rheumatoid arthritis, arthritis of the spine, peripheral vascular disease, post-herpetic neuralgia, Paget's disease, malignant disease, post-operative pain.

Because Dihydrocodeine, in the recommended doses, causes little or no respiratory depression, its use in the treatment of post-operative pain may reduce the risk of chest complications.

4.2 Posology and method of administration

Posology:

The analgesic effect is not materially enhanced by increasing the dose above that recommended below; in severe cases the interval between doses should be reduced to obtain the requisite analgesic cover.

Adults and children over 12 years: One tablet (30 mg) every 4 – 6 hours or at the discretion of the practitioner. Maximum dose in 24 hours 180mg (6 tablets)

Paediatric population: A more suitable dosage form is recommended for children under 12 years (e.g. elixir)

Elderly: Dosage should be reduced in the elderly

Method of administration:

For oral use.
It is recommended that this product should be taken during or after food.

4.3 Contraindications

- Hypersensitivity to dihydrocodeine or other opioid analgesics or to any of the excipients listed in section 6.1.
- Respiratory depression
- Obstructive airways disease
- Acute alcoholism.
- Risk of paralytic ileus.

Head injuries or conditions in which intracranial pressure is raised

4.4 Special warnings and precautions for use

Dihydrocodeine should be given in reduced doses or with caution to patients with asthma and decreased respiratory reserve. Avoid use during an acute asthma attack.

Dihydrocodeine should be avoided, or the dose reduced in patients with hepatic or renal impairment

Dihydrocodeine should be given in reduced doses or with caution to;
debilitated patients, adrenocortical insufficiency, prostatic hyperplasia, urethral stricture, hypotension, shock, inflammatory or obstructive bowel disorders, hypothyroidism or convulsive disorders However, these conditions should not necessarily be a deterrent to use in palliative care.
Use with caution in patients with a history of drug abuse

Alcohol should be avoided while under treatment with these tablets.

The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

These tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

The risk and benefit of continued use should be assessed regularly by the doctor.

Risk from concomitant use of sedative medicines such as benzodiazepines or related drugs:
Concomitant use of dihydrocodeine and sedative medicines such as benzodiazepines or related drugs may result in sedation, respiratory depression, coma and death. Because of these risks, concomitant prescribing with these sedative medicines should be reserved for patients for whom alternative treatment options are not possible. If a decision is made to prescribe dihydrocodeine concomitantly with sedative medicines, the lowest effective dose should be used, and the duration of treatment should be as short as possible.
The patients should be followed closely for signs and symptoms of respiratory depression and sedation. In this respect, it is strongly recommended to inform patients and their caregivers to be aware of these symptoms (see section 4.5).

The leaflet will state in a prominent position in the 'before taking' section:

- Do not take for longer than directed by your doctor
- Taking dihydrocodeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
- Taking a painkiller for headaches too often or for too long can make them worse.

The label will state (To be displayed prominently on outer pack-not boxed):

- Do not take for longer than directed by your doctor as taking dihydrocodeine regularly for a long time can lead to addiction

4.5 Interaction with other medicinal products and other forms of interaction

Dihydrocodeine may cause the release of histamine; hence this product should not be administered during an asthmatic attack and should be administered with caution in patients with allergic disorders.

The depressant effects of opioid analgesics (Dihydrocodeine) are enhanced by other central nervous system (CNS) depressants such as;

- Alcohol-enhanced hypotensive, sedative effect and respiratory depression
- Anaesthetics- may increase anaesthetic and sedative effect.
- Sedating antihistamines-may enhance the CNS depressive effects when taken with opioids.
- Anxiolytics or Hypnotics-may enhance CNS depressive effects when taken with opioids
- Tricyclic antidepressants-may enhance CNS depressive effects when taken with opioids
- Antipsychotics- enhanced hypotensive, sedative effect.

MAOIs taken with pethidine have been associated with severe CNS excitation or depression. Although this has not been documented with dihydrocodeine, it is possible that a similar interaction may occur with other opioid analgesics. Therefore, the use of dihydrocodeine should be avoided while the patient is taking MAOIs and for 2 weeks after MAOI discontinuation.

When dihydrocodeine is taken concomitantly with antipsychotics there may be an increased sedative and hypotensive effect. Concomitant use of dihydrocodeine and ritonavir should be avoided due to the risk of toxicity.

Motility stimulants- Dihydrocodeine may antagonise the gastrointestinal effects metoclopramide and domperidone.

Cyclizine may counteract the haemodynamic benefits of opioids.

Mexiletine- Dihydrocodeine may delay absorption of mexiletine.

Cimetidine- may inhibit the metabolism of opioids

Sedative medicines such as benzodiazepines or related drugs: The concomitant use of opioids with sedative medicines such as benzodiazepines or related drugs increases the risk of sedation, respiratory depression, coma and death because of additive CNS depressant effect. The dose and duration of concomitant use should be limited (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

Whilst there is no adequate evidence of safety in human pregnancy, dihydrocodeine has been widely used without apparent ill-effect for many years and studies in animals have not yet demonstrated any hazard. The administration of opioid analgesics during labour may cause respiratory depression in the new-born infant, therefore administration should be avoided during the later stages of pregnancy. Babies born to opioid-dependant mothers may suffer withdrawal symptoms.

Breast-feeding

Dihydrocodeine passes into breast milk in very small amounts which are probably insignificant, however, it is recommended that administration should be avoided if the mother is breast feeding.

4.7 Effects on ability to drive and use machines

Dihydrocodeine may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery.

Effects such as paraesthesia, dizziness, vertigo, muscle rigidity, visual disturbances, drowsiness, confusion, syncope and hallucinations may occur. Do not drive or operate machinery if affected.

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

Skin disorders; rash, urticaria, pruritius, sweating.

Central and peripheral nervous system disorders; paraesthesia, dizziness, headache, vertigo, respiratory depression. Muscle rigidity has been reported after high doses.
Vision disorders; visual disturbances, miosis.
Psychiatric disorders; drowsiness, changes of mood, confusion, sexual dysfunction, hallucinations, euphoria.
Gastro-intestinal system disorders; dry mouth, nausea, vomiting, abdominal pain, constipation.
Liver and biliary system disorders; biliary spasm which may be associated with alterations in liver enzyme values.
Cardiovascular disorders general; hypotension, syncope.
Heart rate and rhythm disorders; bradycardia, tachycardia, palpitations.
Vascular (extracardiac) disorders; facial flushing.
Urinary systems disorders; Micturition may be difficult and there may be ureteric spasm.
Body as a whole, general; oedema.

- Regular prolonged use of dihydrocodeine is known to lead to addiction and tolerance. Symptoms of restlessness and irritability may result when treatment is then stopped.
- Prolonged use of a painkiller for headaches can make them worse.

Reporting of Suspected Adverse Reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

The effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms
Central nervous system depression, including respiratory depression, may develop but is unlikely to be severe unless other sedative agents have been co-ingested, including alcohol, or the overdose is very large. The pupils may be pin-point in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely.

Management
This should include general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Consider activated charcoal if an adult presents within one hour of ingestion of more than 350 mg or a child more than 5 mg/kg.

Give naloxone if coma or respiratory depression is present. Naloxone is a competitive antagonist and has a short half-life so large and repeated doses may be required in a seriously poisoned patient. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics, Natural Opium Alkaloids,
ATC code: N02A A08

Dihydrocodeine is an analgesic of the opioid class. Dihydrocodeine tartrate is an analgesic with uses similar to those of morphine but it is much less potent as an analgesic and has only mild sedative effects.

5.2 Pharmacokinetic properties

Absorption

Dihydrocodeine is well absorbed after oral administration.

Peak plasma levels occur 1.6 - 1.8 hours after ingestion.

Plasma half-life has been reported to be 34 hours after oral ingestion.
Dihydrocodeine is metabolised in the liver by 0- and N- demethylation.
Biotransformation
After oral administration the bioavailability of the drug is approximately 20%, indicating that the pre-systemic metabolism plays a substantial role in reducing the bioavailability of dihydrocodeine.
Elimination

Dihydrocodeine is excreted in the urine as unchanged drug and metabolites. The mean elimination half life ranges between 3.5 – 5 hours.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Lactose Monohydrate
Povidone
Sodium Starch Glycollate (Type A)
Magnesium Stearate
Colloidal Anhydrous Silica

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Container: Do not store above 25° C. Keep the container tightly closed. Store in the original container.

Blister packs: Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

HDPE tablet container with LDPP cap of 25, 50, 100, 250, 500, 1000 tablets.

AL/PVC blisters
Pack size: 14, 28, 30, 56, 60, 84 and 100 tablets

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 17907/0010

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10 DATE OF REVISION OF THE TEXT

09/05/2019