SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Mypaid 120mg SR Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 120mg dihydrocodeine tartrate.

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Prolonged-release tablets.
Round, flat, white to off-white tablets, half scored on one side.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of severe pain in cancer and other chronic conditions.

4.2. Posology and method of administration

Oral
The tablets should not be chewed.

Adults and children older than 12 years: 60 mg - 120 mg every 12 hours.

Elderly: Dosage should be reduced.

Children up to 12 years: Not recommended.

4.3. Contraindications

Hypersensitivity to dihydrocodeine or any of the excipients.
Respiratory depression, obstructive airways disease.
As dihydrocodeine may cause the release of histamine, it should not be given during an asthma attack.
Avoid in acute alcoholism and where there is a risk of paralytic ileus.
Opioid analgesics should not be administered to patients with increased intracranial pressure and head injury.
Avoid concomitant use with and for 2 weeks after stopping MAOIs

4.4. Special warnings and precautions for use

Caution should be exercised in hypotension, hypothyroidism, asthma (see 4.3), decreased respiratory reserve, prostatic hypertrophy and convulsive disorders. Severe withdrawal symptoms may occur in dependent patients if treatment is withdrawn abruptly.

The dose should be reduced in elderly and debilitated patients. Reduce dose or avoid in hepatic or renal function impairment.

4.5. Interactions with other medicinal products and other forms of interaction

Opioid analgesics may interact wth the following:
Alcohol - enhanced hypotensive and sedative effects
Antidepressants, Tricyclic - sedative effects possibly increased
Antipsychotics - enhanced hypotensive and sedative effects
Anxiolytics and Hypnotics - increased sedative effect
Cimetidine - metabolism of opioid analgesics inhibited by cimetidine (increased plasma concentration)
Ciprofloxacin - avoid premedication with opioid analgesics (reduced plasma concentration of ciprofloxacin) when ciprofloxacin used for surgical prophylaxis.
Domperidone - opioid analgesics antagonise effects of domperidone on gastro-intestinal activity
MAOIs - possible CNS excitation or depression (hypertension or hypotension) when opioid analgesics given with MAOIs —avoid concomitant use and for 2 weeks after stopping MAOIs
Metoclopramide - opioid analgesics antagonise effects of metoclopramide on gastro-intestinal activity.
Mexiletine - opioid analgesics delay absorption of mexiletine
Moclobemide - possible CNS excitation or depression (hypertension or hypotension)

Ritonavir - plasma concentration of opioid analgesics (except methadone) possibly increased by ritonavir

There is an increased risk of toxicity with myelosuppressive drugs

4.6. Pregnancy and lactation

Dihydrocodeine has been taken in pregnancy, although there is very little published about its safety.

Third trimester: Depression of neonatal respiration; withdrawal effects in neonates of dependent mothers; gastric stasis and risk of inhalation pneumonia in mother during labour.

Dihydrocodeine has not been reported to be excreted in breast milk. However, it is advisable that dihydrocodeine only be administered to breast-feeding mothers if considered essential.

4.7. Effects on ability to drive and use machines

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

4.8. Undesirable effects

Nausea and vomiting (particularly in initial stages), constipation, and drowsiness; larger doses may produce respiratory depression and hypotension. Other side-effects include abdominal pain, difficulty with micturition, urinary retention, ureteric or biliary spasm, dry mouth, sweating, paraesthesia, headache, facial flushing, vertigo, bradycardia, tachycardia, palpitations, postural hypotension, hypothermia, confusion, hallucinations, dysphoria, mood changes, dependence, miosis, decreased libido or potency, rashes, urticaria and pruritus.

4.9. Overdose

Opioid analgesics cause varying degrees of coma, respiratory depression, and pinpoint pupils. The specific antidote naloxone is indicated if there is coma or bradypnoea.

Since naloxone has a shorter duration of action than many opioids, close monitoring and repeated injections are necessary according to the respiratory rate and depth of coma. Where repeated administration of naloxone is required, it may be given by continuous intravenous infusion and the rate of infusion adjusted according to vital signs.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic Group: Analgesics, Natural Opium Alkaloids – Dihydrocodeine

ATC code: NO2A AO8

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 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

Glyceryl behenate
Calcium sulphate dihydrate
Copovidone VA 64
Sodium stearyl fumarate

6.2. Incompatibilities

Not applicable

6.3. Shelf life

3 years

6.4. Special precautions for storage

Store below 25^{o}C

6.5. Nature and contents of container

PVC/PVDC/Aluminium foil blister
Packs containing 56 or 60 tablets. Not all pack sizes may be marketed.

6.6. Instruction for use and handling

Not applicable

7 MARKETING AUTHORISATION HOLDER

Sandoz Limited
Frimley Business Park,
Frimley,
Camberley,
Surrey,
GU16 7SR,
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

PL 04416/0582

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

02/05/2006

10 DATE OF REVISION OF THE TEXT

08/02/2011