SOUTH AFRICAN PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S6

PROPRIETARY NAME AND DOSAGE FORM

DF 118 TABLETS

DF 118 INJECTION (solution for injection)

COMPOSITION

Each tablet of DF 118 TABLETS contains 30 mg of dihydrocodeine tartrate

Excipients:

Lactose monohydrate, magnesium stearate, maize starch, pregelatinised maize starch.

Contains sugar: Lactose monohydrate 133,00 mg

Each 1 ml of DF 118 INJECTION contains 50 mg of dihydrocodeine tartrate.

Excipients:

Sodium metabisulphite, water for injection

Preservative:

Sodium metabisulphite 0,1 % *m/v*

Sugar free

CATEGORY AND CLASS

A 2.9 Other analgesics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The action of dihydrocodeine tartrate is almost purely analgesic - it is virtually free from sedative or hypnotic effects. 30 mg given parenterally has been shown to have an analgesic potency equivalent to that of 10 mg of morphine. In a study of oral analgesics for the relief of chronic pain, the same dose was found to be equivalent to 100 mg of pethidine. In both these trials dihydrocodeine was found to have a lower incidence of side effects than either morphine or pethidine.

It is fully active when administered orally and at the recommended doses, causes little or no respiratory depression; in addition to being a potent analgesic the compound also exhibits well-defined antitussive activity.

In patients already habituated to a medicine such as pethidine the substitution of dihydrocodeine in equi-analgesic doses has led to the appearance of abstinence symptoms.

This suggests that dihydrocodeine despite its effectiveness as an analgesic has a very low addiction potential and can be safely administered more frequently than the more potent narcotic medicines and for longer periods.

INDICATIONS

DF 118 is indicated in all painful conditions where an alert patient is desired viz. sciatica, osteoarthritis, chronic rheumatoid arthritis, arthritis of the spine, peripheral vascular disease, post-herpetic neuralgia, Paget’s disease, malignant disease, post-operative pain. Because

DF 118, 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.

CONTRAINDICATIONS

See SIDE EFFECTS and WARNINGS AND SPECIAL PRECAUTIONS.

WARNINGS AND SPECIAL PRECAUTIONS

As dihydrocodeine may bring about histamine-release, DF 118 should not be given during an attack of asthma and it should be administered with due care to persons liable to such attacks.

DF 118 should be administered with caution if there is marked impairment of liver function.

Excipients

DF 118 TABLETS contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take DF 118 TABLETS.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Notice should be taken of current views that any medicine should be prescribed with caution during pregnancy.

DOSAGE AND DIRECTIONS FOR USE

General information: As DF 118 is fully active when administered orally this route is to be preferred whenever possible. The analgesic effect of DF 118 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.

DF 118 TABLETS is best administered with or after food.

It is not recommended for administration to children.

DF 118 TABLETS:

Adult dosage: 1 tablet (30 mg) every four to six hours or as directed by the physician.

DF 118 INJECTION:

Patients who, for one reason or another, are unable to be treated with the tablets may be given up to 50 mg by intramuscular or deep subcutaneous injection.

SIDE EFFECTS

Relative to its effects as an analgesic, the side effects of DF 118 are mild. If constipation occurs it can be treated with a gentle laxative. Nausea and giddiness occur in some sensitive patients; these effects are dose related and usually disappear when the dose is reduced.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Gross overdosage may cause death through respiratory depression.

Treatment

In the case of tablets, gastric lavage should be carried out if indicated. Close supervision of respiration is essential and oxygen administration and artificial ventilation must promptly be instituted when indicated. This should either be done by means of mouth to mouth respiration or by ventilation through a closely fitting mask or an endotracheal tube. Respiratory depression can be counteracted with naloxone hydrochloride administered intravenously, intramuscularly or subcutaneously at a dosage level of 0,4 mg in adults and repeated as required at two to three minute intervals until the desired effect has been obtained. The dose for neonates and children is 5 µg to 10 µg/kg bodymass administered intravenously, intramuscularly or subcutaneously and repeated as required at two to three minute intervals until the desired effect has been obtained. An adequate airway should be established in the apnoeic infant before naloxone is administered.

In the unconscious patient a clear air passage must at all times be maintained by introducing an airway, placing the patient in the tonsil position and elevating the chin. The introduction of an endotracheal tube must also be considered.

Early correction of acid-base imbalance subsequent to prolonged respiratory depression is essential.

IDENTIFICATION

DF 118 TABLETS: A white, circular, biconvex tablet embossed DF 118 on one side.

DF 118 INJECTION: A clear, colourless solution practically free from extraneous matter.

PRESENTATION

DF 118 TABLETS: 100 tablets are packed in a white polypropylene container with a white high density polyethylene, tamper evident cap with a leaflet in a cardboard carton..

DF 118 INJECTION: 1 x 1 ml clear Type I glass snap neck ampoules. 10 ampoules are packed in a polyvinyl chloride blister tray together with a leaflet in a cardboard carton.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from light.

Do not remove DF 118 INJECTION ampoules from the carton until required for use.

Keep DF 118 TABLETS container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

DF 118 TABLETS: B726 (Act 101/1965)

DF 118 INJECTION: B730 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT

PHARMACARE LIMITED

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DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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