Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

DF118 Tablets 30mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance	Per Tablet
Dihydrocodeine Hydrogen Tartrate	30 mg

Excipients: also contains lactose monohydrate, 127.2 mg per tablet

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet
Biconvex round white uncoated tablet marked with ‘DF’ running horizontally and ‘118’ running vertically in a cross formation 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

For oral administration.

Adult Dosage:

The usual dose is one tablet every four to six hours or as directed by the physician.

DF118 is not recommended for administration to children.

DF118 is best administered with or after food.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Respiratory depression; obstructive airways disease.

4.4 Special warnings and precautions for use

Prolonged use of high dosage may induce dependence with a withdrawal syndrome on discontinuation. Use with caution in patients with a previous history of opioid abuse. See section 4.5 for additional information.

Repeated use may result in the development of tolerance.

As dihydrocodeine may bring about histamine release, DF118 should not be given during an attack of asthma and it should be administered with due care to persons liable to such attacks.

Dosage should be reduced in the elderly, in hypothyroidism, chronic hepatic disease and renal insufficiency.

Alcohol should be avoided whilst under treatment with DF118. Use with caution in patients taking concomitant CNS depressive medications.

Use with caution in patients with biliary tract disorders, pancreatitis, severe cor pulmonale, obstructive inflammatory bowel conditions or prostatic hypertrophy.

Observe caution in patients with depressed consciousness, head injury or raised intracranial pressure.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Dihydrocodeine should only be used with caution in patients who are currently receiving, or have within the previous two weeks received monoamine oxidase inhibitors.

Potential interaction with sildenafil (prolonged priapism reported).

Co-administration of dihydrocodeine in users of opiates/opioids, in particular with heroin/diamorphine, methadone and benzodiazepines, may increase the risk of accidental fatal overdose.

4.6 Fertility, pregnancy and lactation

All the narcotic analgesics are able to traverse the placenta and are also excreted in the 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

Side-effects include constipation, nausea, vomiting, headache and vertigo. Drowsiness, urinary retention, abdominal pain, paralytic ileus, dizziness, confusion, mood changes, hallucinations, paraesthesia, tolerance, dependence, respiratory depression and urticaria may occur.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

The effects seen with overdose will be potentiated by simultaneous ingestion of alcohol or psychotropic drugs.

Deaths due to multiple drug intoxication may occur at blood dihydrocodeine concentrations below 1000ng/ml, whereas most fatal cases involving dihydrocodeine alone have dihydrocodeine concentrations higher than 1000ng/ml with the exception of naïve users who have no tolerance to dihydrocodeine.

Co-administration of dihydrocodeine in users of opiates/opiods, in particular with heroin/diamorphine, methadone and

benzodiazepines may increase the risk of accidental fatal overdose.

Symptoms of Dihydrocodeine Overdose

Nausea and vomiting are common, and pupils may be pinpoint on eye examination. Central nervous system depression, including respiratory depression, may develop, but is unlikely to be severe unless the overdose is very large or other sedative agents have been co-ingested, including alcohol. Hypotension and tachycardia may occur in some cases.

Management of Dihydrocodeine Overdose

This should include general symptomatic and supportive measures including maintaining a clear airway and monitoring of vital signs until stable.

The specific opioid antagonist naloxone hydrochloride should be used to treat severe respiratory depression at a dosage of 0.4 - 2.0 mg subcutaneously or intravenously, repeated as required at 2-3 minute intervals or it may be given as a continuous intravenous infusion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Analgesics - Natural opium alkaloids
ATC code: NO2A AO8

Dihydrocodeine hydrogen tartrate is an opioid analgesic related to codeine. It is used for the relief of moderate to severe pain.

5.2 Pharmacokinetic properties

The pharmacokinetics of dihydrocodeine are similar to those of codeine. Absorption after oral administration may vary because of substantial first pass metabolism in the liver. Peak plasma concentrations are achieved in approximately 2 hours. The elimination half-life varies between 3 and 5 hours. Excretion occurs almost entirely via the kidney as conjugates with glucuronic acid.

5.3 Preclinical safety data

Dihydrocodeine hydrogen tartrate has been used for many years and thus it is not considered necessary to provide information under this section.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Microcrystalline Cellulose
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package in order to protect from light.

6.5 Nature and contents of container

DF118 tablets are packed in polypropylene securitainers and are available in packs of 100 and 500.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1329/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4 April 1984

Date of last renewal: 15 February 2010

10 DATE OF REVISION OF THE TEXT

July 2015