IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0004/026/001
Case No: 2032173

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

The Boots Company Plc

1 Thane Road, **Nottingham NG2 3AA**, **United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Day Cold Comfort

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **07/02/2007** until **12/04/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Day Cold Comfort

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol	600mg/30ml
Pseudoephedrine hydrochloride	40mg/30ml
Pholcodine	10mg/30ml

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Oral solution
A clear, orange slightly viscous solution with a menthol and mixed fruit flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of the symptoms of colds and influenza.

4.2 Posology and method of administration

For oral administration.

Adults and children over 12 years: 30ml

Children 6 to 12 years: 15ml

Doses may be repeated every 4 hours, up to a maximum of 4 doses in 24 hours if needed.

Children under 6 years: Not to be given to children under 6 years of age.

4.3 Contraindications

1. Use in patients with a known hypersensitivity to any of the ingredients.
2. Use in patients who are receiving monoamine oxidase inhibitors, or within fourteen days of stopping such treatment.
3. Use in patients who are currently receiving other sympathomimetic drugs.

4.4 Special warnings and precautions for use

1. The product should be used with great care in patients suffering from cardiovascular disease or hyperthyroidism.
2. Use with caution in diabetic patients as this product may cause an increase in blood sugar level.

4.5 Interaction with other medicinal products and other forms of interaction

1. Caution should be exercised in its use with anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents as they may provoke or worsen ventricular arrhythmias.
2. This product should be used with caution in patients receiving digitalis, β- adrenergic blockers, methyldopa or other antihypertensive agents, and tricyclic antidepressants.

4.6 Pregnancy and lactation

This product should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

May cause nausea, vomiting, diarrhoea or constipation, epigastric pain, headache, blurred vision, tinnitus, irritability, nightmares, anorexia, difficulty in micturition, tachycardia, tremors, skin rashes, sputum retention and sweating.

4.9 Overdose

Symptoms of overdosage may include drowsiness, headache, nausea, vomiting, tachycardia, urinary retention, hallucinations, coma, hyperreflexia, tremor, excitement, hypertension and arrhythmias. Hepatic and renal impairment may occur after 3-5 days, together with hypoprothrombinaemia, metabolic acidosis, hypoglycaemia or hyperglycaemia. Treatment consists of emesis or gastric lavage, if indicated. Plasma paracetamol levels should be checked. If patient presents less than 16 hours after ingestion, 2.5g methionine should be given orally every four hours for four doses. Alternatively, or if the patient is vomiting or unconscious, acetylcysteine should be given intravenously, 150mg/kg over 15 minutes, followed by an infusion of 50mg/kg in 500ml of 5% dextrose over 4 hours and then 100mg/kg in a litre of 5% dextrose over the next 16 hours. In addition, symptomatic and supportive therapy may be necessary including the administration of a beta-blocker if supraventricular tachycardia supervenes and the administration of the specific narcotic antagonist naloxone.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions. Pseudoephedrine is a sympathomimetic agent with both direct and indirect effects on adrenergic receptors. Pholcodine is a cough suppressant.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10-60 minutes after oral administration. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations. Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half life varies from about 1 to 3 hours.

Pseudoephedrine is absorbed from the gastrointestinal tract. It is resistant to metabolism and is excreted largely unchanged in the urine. It has a half life of several hours but elimination is enhanced and half life shortened in acid urine.

Pholcodine is rapidly absorbed after oral administration and maximum plasma concentrations are attained in about 4-8 hours. The elimination half life ranges from 32 to 43 hours. The drug has a large volume of distribution and is only

23.5% protein bound.

Pholcodine is metabolised in the liver but undergoes little conjugation with glucuronide and sulphate.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Propylene glycol
Glycerol
Citric acid
Sodium citrate
Sodium benzoate (E211)
Peach flavour
Pear drop flavour
Lime flavour
Levomenthol
Riboflavine 5 phosphate sodium
Liquid sugar demin or Sucrose
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Keep the container tightly closed. Store in the original package.

6.5 Nature and contents of container

Either a clear glass bottle with pilfer proof aluminium screw cap or a clear PET bottle with child resistant cap.
Each contains 210 ml of liquid.

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

The Boots Company Plc.
1 Thane Road West
Nottingham NG2 3AA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 4/26/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 April 1983

Date of last renewal: 13 April 2003

10 DATE OF REVISION OF THE TEXT

April 2003