

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0678/106/003

Case No: 2054166

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

GlaxoSmithKline Consumer Healthcare (Ireland) Limited

Stonemasons Way, Rathfarnham, Dublin 16, Ireland

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

Beechams Cold & Flu Hot Lemon with Honey 600mg/40mg powder for oral solution.

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 **11/09/2008** until **19/10/2011**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Beechams Cold & Flu Hot Lemon with Honey 600mg/40mg powder for oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	mg / 6 g powder sachet
Paracetamol	600.00
Ascorbic Acid	40.00

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution.

Sachets containing an off white free flowing powder for oral solution with an odour of lemon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The relief of symptoms of influenza, feverishness, chills and feverish colds including headache, and aches and pains. It is also indicated for the alleviation of menstrual pain, toothache and musculoskeletal disorders.

4.2 Posology and method of administration

Directions for use

Empty the contents of one sachet into a cup or mug. Half fill with very hot water. Stir well. Add cold water as necessary and sugar if desired.

Recommended Dose and Dosage Schedule

Adults (including elderly) and children aged 12 years and over:

One sachet to be taken every four hours, if necessary, up to a maximum of six sachets in any 24 hours.

Not to be given to children under 12 years of age except on medical advice

4.3 Contraindications

This product is contraindicated in patients with hypersensitivity to any of the ingredients, and in patients with severe hepatic or renal impairment.

4.4 Special warnings and precautions for use

Caution is advised in the administration of paracetamol to patients with impaired renal and hepatic function or if they are taking other drugs that affect the liver.

Keep out of the reach of children.

Do not take other medicines containing paracetamol while using this product.

Contains paracetamol.

Do not exceed the stated dose.

If symptoms persist consult your doctor

Prolonged use of this product, except under medical supervision, may be harmful

This product should only be used when clearly necessary.

Patients with rare hereditary problems of fructose intolerance, glucose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol is reported to increase the half-life of chloramphenicol. Large doses of paracetamol may potentiate the effect of coumarin anticoagulants. The hepatotoxicity of paracetamol may be potentiated by other drugs that affect the liver.

4.6 Pregnancy and lactation

Use during pregnancy and lactation is not contraindicated. However caution should be exercised and use during pregnancy should be on the advice of a doctor.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Skin rashes and other allergic reactions occur occasionally with paracetamol.

4.9 Overdose

Immediate medical attention (in-hospital, if possible) is required in the event of overdose, even if there are no significant early symptoms. There may be no early symptoms following a life-threatening overdose. Ingestion of more than 12 g paracetamol (24 standard 500 mg tablets) or more than 150 mg paracetamol per kg bodyweight (9 g paracetamol in a 60 kg individual), whichever is the smaller, can cause severe liver damage. Liver damage (as demonstrated by a rise in plasma transaminase levels) may be apparent between 8 and 36 hours following overdose. Biochemical evidence of maximal damage, however, may not be attained until 72-96 hours after ingestion of the overdose.

Intravenous N-acetylcysteine (NAC) is effective when initiated within 8 hours of the overdose. Efficacy declines progressively after this time, but NAC may provide some benefit up to and possibly beyond 24 hours. Oral methionine is also effective provided that it is given within 10 to 12 hours of the overdose. Activated charcoal should be considered if the dose of paracetamol ingested exceeds 12 g or 150 mg/kg, whichever is the smaller, and the procedure can be undertaken within 1 hour of the overdose. There is little evidence that undertaking gastric lavage will be of benefit to a patient in whom paracetamol is known to have been the only substance ingested.

Symptoms of paracetamol overdose in the first 24 hours may include pallor, nausea, vomiting, anorexia, and abdominal pain. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Liver damage results when excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol: Provides the analgesic and antipyretic actions.

Ascorbic acid is commonly included in combination cold products to compensate for vitamin C losses that may occur in the initial stages of acute viral infections, including the common cold.

5.2 Pharmacokinetic properties

Paracetamol - is readily absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine, mainly as glucuronide and sulphate conjugates.

Ascorbic acid - Is readily absorbed from the GI tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic acid in excess of the body's needs is eliminated in the urine as metabolites.

5.3 Preclinical safety data

There are no pertinent data not already described elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sodium citrate
Citric acid anhydrous
Maize Starch (dried)
Sodium cyclamate
Saccharin sodium
Lemon Flavour
Honey
Caramel (E150)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The product is packed in laminate sachets comprising paper / polythene / aluminium foil / polythene. Five or ten sachets may be contained in a box.

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

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
Stonemasons Way
Rathfarnham
Dublin 16

8 MARKETING AUTHORISATION NUMBER

PA 678/106/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 20th October 2006

10 DATE OF REVISION OF THE TEXT

January 2007