IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0678/039/004
Case No: 2051498

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

GlaxoSmithKline Consumer Healthcare (Ireland) LTD

Stonemasons Way, **Rathfarnham**, **Dublin 16**, **Ireland**

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

Panadol Cold and Flu Citrus 500mg Soluble Tablets

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 **30/05/2008** until **10/06/2008**.

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

Panadol Cold and Flu Citrus 500mg Soluble Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg of Paracetamol.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Soluble tablet
Round white tablets with bevelled edges.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a mild analgesic and antipyretic. The tablets are recommended for use in the short-term management of the symptoms of headache, toothache, menstrual pain, musculoskeletal disorders and for symptoms of common colds and ‘flue including sore throat, headache, muscle ache and fever. Panadol may also be used in the symptomatic relief of mild to moderate pain associated with osteoarthritis, as diagnosed by a doctor.

4.2 Posology and method of administration

Panadol Cold & Flu Citrus Soluble is for oral administration.

Adults:
2 tablets dissolved in water 3-4 times daily. A maximum dose of 8 tablets daily should not be exceeded.

Children (6-12 years):
½ to 1 tablet dissolved in water 3-4 times daily. A maximum dose of 4 tablets daily should not be exceeded.

Children under 6 years:
Use of this product is not recommended.

Doses should not be more frequent than every 4 hours. Not more than 4 doses should be taken in any 24 hour period.

4.3 Contraindications

Known hypersensitivity to paracetamol or any of the other ingredients.
Use in children under 6 years of age.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.
Patients should be advised not to take other paracetamol-containing products concurrently.
If symptoms persist, consult your doctor.

Prolonged use except under medical supervision may be harmful.
This product should only be used when clearly necessary.

Each Panadol Soluble Tablet contains 427 mg (18.5 mmol) of sodium, and should only be used with caution in patients with hypertension, oedema or renal insufficiency because of the sodium content.

If you have been diagnosed with liver or kidney impairment, seek medical advice before taking this medication.

Each tablet contains aspartame (E951)-contains a source of phenylalanine (equivalent to 26.38mg/tablet). May be harmful for people with phenylketonuria.

Each tablet contains Sorbitol powder (E420) at 62.50 mg per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no effect.

4.6 Pregnancy and lactation

There is epidemiological evidence of the safety of paracetamol in human pregnancy. Paracetamol is the mild analgesic of choice during pregnancy. However as with all drugs, caution should be exercised in its use during the first trimester. Paracetamol is excreted in breast milk. However the level of paracetamol present is not considered to be harmful.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse effects from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labeled dose and considered attributable are tabulated below by System Organ Class.

Skin and subcutaneous tissue disorders
Dermatitis allergic* very rare (<1/10,0000).

* Hypersensitivity reactions including skin rashes and angioedema have been reported very rarely 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 12g paracetamol (24 standard 500mg tablets) or more than 150mg paracetamol per kg bodyweight (9g paracetamol in a 60kg 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 12g or 150mg/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 induce 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 has analgesic and antipyretic actions.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Concentration in plasma reaches a peak in 30-60 minutes. Plasma half-life is 1-4 hours. Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma protein binding is variable. Excretion is almost exclusively renal, in the form of conjugated 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

Citric Acid (anhydrous)
Sorbitol Powder (E420)
Sodium Bicarbonate
Sodium laurilsulfate
Anhydrous Sodium Carbonate
Aspartame (E951)
Acesulfame Potassium (E950)
Povidone
Dimeticone
Ascorbic Acid (E300)
Orange flavour 567124 AP0454

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

Do not store above 25°C. Keep in original package.

6.5 Nature and contents of container

The tablets are packed into PPFP laminate sachets or lacquer PPFP or PPF surlyn laminate sachets. The strips are then enclosed in cardboard cartons to give pack sizes of 12, 24 or 60 tablets.

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 precautions required.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA 678/39/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11 June 1993

Date of last renewal: 11 June 2003

10 DATE OF REVISION OF THE TEXT

July 2005