IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0979/008/002
Case No: 2033335

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

Reckitt Benckiser Ireland Ltd

7 Riverwalk, **Citywest Business Campus**, **Dublin 24**, **Ireland**

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

Disprol Soluble Paracetamol Effervescent Tablets 120mg

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 **19/09/2007**.

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

Disprol Soluble Paracetamol Effervescent Tablets 120mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Paracetamol 120mg.

Excipients: Also includes 5.3 mmol sodium (121.6mg) per typical dose, and sulphur dioxide (E220), trace amounts.

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet
Circular, beveled edge, white, effervescent tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Analgesic/antipyretic. In the management of symptoms of headache, toothache, common cold, influenza and musculo-skeletal pain.

4.2 Posology and method of administration

Children

Three months to under one year: Half to one tablet. Maximum number of tablets in 24 hours - four.

One year to under six years: One to two tablets. Maximum number of tablets in 24 hours - eight.

Six to twelve years: Two to four tablets. Maximum number of tablets in 24 hours - sixteen.

(Under three months - on doctor's advice only).

Doses may be repeated after 4 hours, up to maximum daily dose.

Tablets should be dissolved in water or in a favourite fruit drink, prior to ingestion.

4.3 Contraindications

Hypersensitivity to paracetamol.

4.4 Special warnings and precautions for use

Use with caution in patients with hepatic or renal dysfunction.

Special labelling requirement

1. Dosage should not be continued for more than three days without consulting a doctor.
2. Do not exceed the stated dose.
3. If symptoms persist, consult your doctor.
4. Not to be given to children under three months except on medical advice.
5. Do not give with other medicines containing paracetamol.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

There have been isolated reports of agranulocytosis, methaemoglobinaemia and thrombocytopenic purpura and after overdosage or prolonged administration isolated cases of chronic hepatic necrosis, acute pancreatitis and nephrotoxicity.

4.9 Overdose

Overdosage should be treated promptly by gastric lavage followed by intravenous n-acetylcysteine or oral methionine since liver damage following overdosage does not become apparent for one to six days after ingestion. Initial mild symptoms consist of nausea, vomiting and pallor. Measurement of the blood paracetamol level and the time elapsed since ingestion is important in order to determine whether further therapy with n-acetylcysteine is necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has both analgesic and antipyretic activity which is believed to be mediated principally through its inhibition of prostaglandin synthesis within the central nervous system.

5.2 Pharmacokinetic properties

Paracetamol is absorbed rapidly and completely mainly from the small intestine producing peak plasma levels after 15-20 minutes following oral dosing. The systemic availability is subject to first-pass metabolism and varies with dose between 70% and 90%. The drug is rapidly and widely distributed throughout the body and is eliminated from plasma with a T½ of approximately 2 hours. The major metabolites are glucuronide and sulphate conjugates (>80%) which are excreted in urine.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate
Anhydrous Sodium carbonate
Saccharin sodium
Anhydrous Citric acid
Maltodextrin
Fantasy lime flavour (contains sulphur dioxide (E220))
Magnesium stearate
Povidone

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Three years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Tablets contained in strips of soft temper aluminium foil with internal heat-seal lacquer. Foil strips packed in a cardboard outer carton. Each pack will contain 24 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 requirements.

Tablets should be dissolved in water or in a fruit drink, prior to ingestion.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/8/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 November 1986

Date of last renewal: 19 November 2006

10 DATE OF REVISION OF THE TEXT

September 2007