IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0979/008/001
Case No: 2043497

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 Paracetamol Oral Suspension 120mg/5ml

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 **29/11/2007**.

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 Paracetamol Oral Suspension 120mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol 120mg/5ml.

Excipients: also includes hydrogenated glucose syrup 3.25g per 5ml; methyl hydroxybenzoate (E218) 8.75mg per 5ml and propyl hydroxybenzoate (E216) 3.75mg per 5ml.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
Translucent, pale yellow, viscous suspension with banana-like odour.

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

Route of administration: oral.

Children:	6 years to 12 years:	Two to four 5 ml spoonfuls.
	1 year to 6 years:	One to two 5 ml spoonfuls.
	3 months to 1 year:	Half to one 5 ml spoonfuls.

For babies who develop fever following vaccination at two months, a 2.5 ml dose is suitable. In all other cases, not to be given to children under 3 months without doctor's advice.

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

When prescribed for a baby weighing less than 4.4 kg, dose at 0.5 ml/kg (12 mg/kg) using an oral measuring syringe.

Where dilution is prescribed, the product may be diluted with an equal volume of boiled, then cooled water, to give a suspension of 12 mg/ml (60 mg/5 ml) with a fourteen day shelf-life.

4.3 Contraindications

Hypersensitivity to paracetamol.

4.4 Special warnings and precautions for use

Use with caution in patients with hepatic or renal dysfunction. Each 5 ml of suspension can provide up to 12 Kcal and this should be taken into account when treating diabetic children.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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 3 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; after overdosage or prolonged administration isolated cases of chronic hepatic necrosis, acute pancreatitis and nephrotoxicity.

May cause allergic reactions (possibly delayed).

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

Hydrogenated glucose syrup
Glycerol
Carbomer
Sodium hydroxide
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Anhydrous Citric acid
Saccharin sodium
Banana flavour
Riboflavin sodium phosphate
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Keep the bottle in the outer carton.

6.5 Nature and contents of container

(a) Amber glass bottle with child resistant polythene/polypropylene closure with expanded polythene wad or PVdC faced pulpboard wad and tamper-evident band.

Pack sizes: 50 ml, 60 ml, 100 ml and 140 ml.

(b) Amber polyethylene terephthalate (PET) bottles with tamper evident/CRC cap with expanded polythene wad or PVdC faced pulpboard wad.

Pack sizes: 50 ml, 60 ml, 100 ml and 140 ml.

(c) Four-ply 5 ml laminate sachet composed of paper, polythene, aluminium foil and Surlyn ionomer.

Carton packs of 2, 6, 10 or 12 sachets.

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

Take the required dose in the enclosed spoon. Shake bottle before use.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Limited
7 River Walk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 979/8/1

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

November 2007