RICHYGOLD INTERNATIONAL LIMITED (Pharmaceutical Formulations)

Product Name= RICHDOL SYRUP
Generic Name= PARACETAMOL B.P 125mg/5ml

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

RICHDOL SYRUP (Paracetamol B.P 125mg/5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Paracetamol B.P…….125mg
Excipients…….Q.S

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A reddish colored oral liquid syrup with raspberry flavor in 60ml Amber Bottle.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol is a medicine used to treat mild to moderate pain. Paracetamol can also be used to treat fever (high temperature). It's dangerous to take more than the recommended dose of paracetamol. Paracetamol overdose can damage your liver and cause death.

4.2 Posology and method of administration

Posology

For oral use only.

- **Infants (2–3 months):** Not typically recommended unless prescribed by a doctor. Consult a healthcare provider.
- **Children (3 months–6 years):**
  - Dosage is usually based on weight: **10–15 mg/kg per dose**, given every 4–6 hours, up to a maximum of 4 doses in 24 hours.
  - Example: For a 10 kg child, the dose is 100–150 mg (4–6 ml) per dose.
- **Children (6–12 years):**
  - Typically, 5–10 ml per dose, every 4–6 hours, up to a maximum of 4 doses in 24 hours.

- **Maximum daily dose:** Should not exceed **60 mg/kg/day** for children or as advised by a doctor.

4.3 Method of administration

- Give with or Without Food: Paracetamol syrup can be given with or without food. If the child has an upset stomach, giving it with food may help.

- . Gastrointestinal upset can sometimes occur if taken on an empty stomach. This can be alleviated by taking paracetamol after eating or along with a meal.

4.4 Contraindications

Paracetamol is not suitable for some people. To make sure it's safe for you, tell your doctor or pharmacist if you:

- have ever had an allergic reaction to paracetamol or any other medicine
- have liver or kidney problems
- regularly drink more than the maximum amount of alcohol recommended (14 units a week)

If you weigh less than 50kg (8 stone), check with your doctor or pharmacist. You may need to take a lower dose.

4.5 Special warnings and precautions for use

Paracetamol is intended to be used as prescribed by the doctor. Inform the doctor if you are allergic to the medicine or any ingredient present in the medicine. If you have liver disease or drink alcohol on a daily basis, then the medication should also be avoided. The following are some diseases that must be disclosed to the doctor before taking medication. Here they are:

- Liver diseases
- Kidney disorder
- Myasthenia Gravis
- Heartbeat disorder
- Low levels of potassium in the blood

4.6 Use in pregnancy

- Category A: Paracetamol has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Lactation

- Paracetamol is excreted in small amounts (< 0.2%) in breast milk. Maternal ingestion of paracetamol in usual analgesic doses does not appear to present a risk to the breastfed infants.

4.7 Interaction with other medicinal products and other forms of interaction

The following interactions with paracetamol have been noted:

- Anticoagulant drugs (warfarin) - dosage may require reduction if paracetamol and anticoagulants are taken for a prolonged period of time
- Paracetamol absorption is increased by substances that increase gastric emptying, e.g., metoclopramide
- Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g., propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- Paracetamol may increase chloramphenicol concentrations
- The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- Paracetamol excretion may be affected and plasma concentrations altered when given with probenecid
- Cholestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

4.8 Undesirable effects

Side effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Skin rashes and hypersensitivity reactions occur occasionally. Overdosage with paracetamol if left untreated can result in severe, sometimes fatal liver damage and rarely, acute renal tubular necrosis.

4.9 Overdose; Symptoms include abdominal pain, nausea, vomiting, liver problems and seizures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is a p-aminophenol derivative that exhibits analgesic and antipyretic activity. It does not possess anti-inflammatory activity. Paracetamol is thought to produce analgesia through a central inhibition of prostaglandin synthesis.

5.2 Pharmacokinetics Properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses but increases with increasing doses. The elimination half-life varies from about 1 to 3 hours.

Paracetamol is metabolised extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulphate conjugates. Less than 5% is excreted unchanged. The metabolites of paracetamol include a minor hydroxylated intermediate which has hepatotoxic activity. This intermediate metabolite is detoxified by conjugation with glutathione; however, it can accumulate following paracetamol overdosage (more than 150mg/kg or 10g total paracetamol ingested) and if left untreated can cause irreversible liver damage.

Paracetamol is metabolised differently by premature infants, newborns, infants and young children compared to adults, the sulphate conjugate being predominant.

5.3 Preclinical Safety Data: None other than what is stated in the SmPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch
Starch(paste)
PVPK-30
Sodium Starch Glycollate
Microcrystalline cellulose
Methyl Paraben
Propyl Paraben
Purified Talc
Magnesium Stearate
Colloidal Anhydrous Silica

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Keep this medicine out of the sight and reach of children.
Do not store above 30°C, protect from light.

6.5 Nature and contents of container

60ml in Pet Amber bottle

6.6 Special precautions for disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

7. MARKETING AUTHORISATION HOLDER

Richygold International Limited (Pharmaceutical formulations)
103C Amuwo-Odofin Industrial Scheme Off Oshodi Apapa Express Way, Lagos Nigeria

8. DATE OF FIRST AUTHORISATION

31st JANUARY 2019

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