1.3 **PRESCRIBING INFORMATION**

SUMMARY OF PRODUCT CHARACTERISTICS.

1. **NAME OF THE PRODUCT**
   PARACAFIN CAPSULE.

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
   Each Caplet contains:
   Paracetamol BP---------- 500mg
   Caffiene BP----------30mg

3. **PHARMACEUTICAL FORM**
   Caplet

3.1 Therapeutic Indication.

Paracafin capsule contains specially formulated ingredients to provide additional pain relief.

Paracafin capsule is extra effective against pain, it does not irritate the stomach and is gentle on you. Suitable for: Headache, Backache, Toothache, Rheumatic Pain, Muscle Pain, Period Pain. It is also used to reduce body temperature in feverish condition

4. **CLINICAL PARTICULARS**

4.1 Posology and method of administration

Adults and adolescents aged 12 years and over should take two tablets up to four times a day as needed.

Leave at least four hours between doses. Do not take more than 8 tablets in 24 hours.

4.2 **Contraindications**

- Hypersensitivity to acetaminophen and Children under 12years.
- Paracafin capsule contains caffeine, you should avoid drinking lots of caffeine-containing drinks, eg tea, coffee, cola, while you are taking it. Excessive caffeine consumption can cause insomnia, restlessness, anxiety, irritability, headaches and palpitations.

4.3 **Special warnings and precautions for use**

Where analgesics are used long-term (>3 months) with administration every two days or more frequently, headache may develop or worsen. Headache induced by overuse of analgesics (MOH medication-overuse headache) should not be treated by dose increase. In such cases, the use of analgesics should be discontinued in consultation with the doctor.

Care is advised in the administration of paracetamol to patients with alcohol dependency,

severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

4.2 Interaction with other medicinal products and other forms of interaction

Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.

• Metoclopramide – may increase speed of absorption of paracetamol.

• Domperidone – may increase speed of absorption of paracetamol

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• Colestyramine – may reduce absorption if given within one hour of paracetamol.

• Imatinib - restriction or avoidance of concomitant regular paracetamol use should be taken with imatinib.

4.3 Pregnancy and lactation

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Breast-feeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.4 Effects on ability to drive and use machines

None known.

4.7 Undesirable effect.

Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to Paracetamol

Very rare cases of serious skin reactions have been reported.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics, Anilides

Paracetamol has analgesic and antipyretic properties but it has no useful anti-inflammatory properties.

Paracetamol's effects are thought to be related to inhibition of prostaglandin synthesis.

5.2 Pharmacokinetic properties

Absorption

Paracetamol is readily absorbed from the gastrointestinal tract.

Caffeine is a mild stimulant that helps reduce fatigue. Caffeine is also thought to enhance the painkilling effect of paracetamol.

Distribution

Peak plasma concentrations occur about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

Biotransformation

It is metabolised in the liver. A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol over dosage and cause tissue damage.

Elimination

It is excreted in the urine, mainly as the glucuronide and sulfate conjugates. The elimination half-life varies from about 1 to 4 hours.

5.3 Preclinical safety data

Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties and weak anti-inflammatory activity. It is good for patients in whom NSAIDS and SALICYLATES are contraindicated. Caffeine is a mild CNS stimulant.

Caffeine-induced constriction of cerebral blood vessels, which leads to a decrease in cerebral blood flow and in the oxygen tension of the brain, may contribute to relief of some types of headache.

It has been suggested that the addition of caffeine to acetaminophen may provide a more rapid onset of action and/or enhanced pain relief with lower doses of the analgesic. However, the FDA has determined that studies performed to date have not demonstrated that caffeine is an effective analgesic adjuvant or that it does not interfere with acetaminophen's efficacy as an antipyretic.

6. Pharmaceutical particulars

6.1 List of Excipients:

Paracetamol Crystals

Starch (Dried)

Talcum

Gelatin

PVPK-30

Propyl Paraben

Methyl Paraben

Sodium Lauryl Sulphate

Magnesium stearate

Sodium Starch glycollate

Colloidal silicon dioxide

6.2 Shellf Life:

3 years

6.3 Special Precaution for Storage:

Store in a cool dry place not above 30°C.Protect from light.

6.4 Nature and contents of container: Blister packaging,1 X I0 caplet

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6.5 Special precautions for disposal and other handling:

Keep container in the outer carton to protect from light.

5. MARKETING AUTHORISATION HOLDER

RICHYGOLD INTERNATIONAL LIMITED
103C AMUWO-ODOFIN INDUSTRIAL SCHEME OSHODI APAPA EXPRESS WAY, LAGOS NIGERIA.

6. MARKETING AUTHORISATION NUMBER(S)

None

7. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Not applicable

RICHYGOLD INTERNATIONAL LIMITED

COMMON TECHICAL DOCUMENTS

Product Name= RICHDOL EXTRA CAPLETS
Generic Name= PARACETAMOL 500MG BP, CAFFIENE BP 30MG