Side Effects:
The following side/ adverse reactions have been selected on the basis of their potential clinical significance (possible cause in parentheses where appropriate-not necessarily inclusive). Those indicating need for medical attention:

- Incidence rare
- Bloody or cloudy urine or
- Difficult or painful urination or
- Frequent urge to urinate or
- Sudden decrease in amount of urine (azotemia renal colic) or Sterile pyuria (with prolonged use of high doses in patients with severe renal function impairment); renal tubular necrosis (in overdosage)
- Skin rash, hives or itching (hypersensitivity)
- Unexplained sore throat and fever or unusual bleeding or brushing (blood dyscrasias)
- Unusual tiredness or weakness (anemia)
- Yellowing of eyes or skin (hepatitis)

Note: Signs of possible liver damage, such as abnormalities in liver function test, pain or tenderness in the liver area, enlargement of the liver or jaundice may occur within 2 to 4 days after ingestion. Maximal changes in liver function tests usually occur 3 to 5 days after ingestion. Overt hepatic disease or failure may occur 4 to 6 days after ingestion. Hepatic encephalopathy (with mental changes, confusion, agitation, or stupor), convulsion, respiratory depression, coma, cerebral edema, coagulation defects, gastrointestinal bleeding, disseminated intravascular coagulation, hypoglycemia, metabolic acid acidosis, renal tubular necrosis, cardiac arrhythmias and cardiovascular collapse may occur.

Symptoms and Treatment of Overdose:
Sign of overdosage may appear shortly after ingestion and they include;-
Diarrhoea, vomiting or nausea, loss of appetite, stomach cramps or pain and unusual increase sweating. If overdosage is suspected seek medical assistance or contact a poison center immediately.

Storage Condition:
Keep container tightly closed. Store in a dry place (below 30°C). Protect from light.

Pack Size:
Plastic bottle containing 60ml,100ml and 120ml.

Products Registration Number:
MAL19910341XZ

Further information can be obtained from your doctor or pharmacist.

ROYCE®

Product Holder/ Manufactured by:
ROYCE PHARMA MFG SDN. BHD. 650435-X
PT 1663, Nilai Industrial Estate,
71800 Nilai, Negeri Sembilan, Malaysia.

Revision date: 161017

ROYCE®

Redon Suspension 250mg/5ml

(Paracetamol - Antipyretic analgesic)

Presentation:
An orange coloured and orange flavoured suspension.

Content:
Each 5ml contains:
Paracetamol 250mg, Sodium Benzoate 0.1% w/v, Methyl Paraben 0.1% w/v and Propyl Paraben 0.01% w/v.

Pharmacological Information:
Analgesic – The mechanism of analgesic action has been fully determined. Acetaminophen may act by inhibiting prostaglandin synthesis in the central nervous system (CNS) and through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of the synthesis of prostaglandin or to inhibition of the synthesis or action of other substances, which sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic – Acetaminophen probably produces antipyretis by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating, and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

Acetaminophen has analgesic and antipyretic effects similar to those of aspirin. However, they have only weak anti-inflammatory effects and do not share the antirheumaric uses of the Salicylates. The pharmacological effects of administered phenacetin are a combination of its inherent effects and those of acetaminophen, its major metabolite. Minor metabolites contribute significantly to the toxic effects of both drugs. The pharmacological properties of acetaminophen and phenacetin have been reviewed by Smith, Randall and Beaver.

Analgesic and Antipyretic, acetaminophen relieve pain of moderate intensify, such as usually occurs in headache and dysmenorrhea, and many muscle joint, and peripheral nerve disorders. Intense pain or that arising from smooth muscle spasm in hollow viscera is not alleviated. Acetaminophen reduces fever by a direct effect on the heat-regulating centers to increase dissipation of body heat.

Acetaminophen reduces fever not by interfering with the release of endogenous pyrogen from leukocytes but by inhibiting the action of endogenous pyrogen on the pyhothalamic heat-regulating centers. The locus of the analgesic effect is uncertain. Laboratory tests have been interpreted to indicate that it is solely a central effect, solely a peripheral effect, or a combination of both. The mechanism of the antipyretic and analgesic effects is also uncertain.

Acetaminophen is more active than aspirin as an inhibitor of prostaglandin synthetase of brain, but it is only a very weak inhibitor of prostaglandin synthesis by a preparation from spleen.

Absorption, distribution, biotransformation and excretion. Acetaminophen and phenacetin are metabolized primary by the hepatic microsomal enzymes.

Acetaminophen is rapidly and practically completely absorbed from the gastrointestinal tract. Plasma concentration reaches a peak in ½ to 1 hour; the plasma half-time is 1 to 3 hours. Acetaminophen is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20% to 50% may be bound at the concentrations encountered during acute intoxication.

About 3% of acetaminophen is excreted unchanged in the urine, and about 80% is excreted in the urine after conjugated in the liver, predominantly with glucuronic acid and to small extent with sulfuric acid. The glucuronide accumulates in plasma before excretion. A conjugate with cysteine and metabolites produced by hydroxylation and deacetylation have also been detected. The hydroxylated metabolites are responsible for methemoglobin formation and hepatotoxicity.

Administration of acetaminophen to patients with impaired renal function results in increased accumulation of conjugated acetaminophen in plasma but only minor changes in the plasma concentrations of phenacetin and free acetaminophen.

Indication:
For the relief of mild to moderate pain and to reduce fever. It provides symptomatic relief only, additional therapy to treat the cause of the pain should be instituted when necessary.

Dosage and Administration:
Children 1 to 6 years: Half to one teaspoonful.
Children 7 to 12 years: One to two teaspoonfuls.
To be taken three or four times a day.

Contraindication:
Medical Problem
Use of this medication should be carefully considered when the following medical problems exist (reasons given where appropriate): Alcoholism or Hepatic disease or viral infection (risk of hepatotoxicity may be increased), Renal function impairment, severe (risk of adverse renal effects may be increased with prolonged use of high doses; Occasional use is acceptable). Caution is also advised in patients with cardiovascular disease or those on a sodium-restricted diet, who should not use buffered acetaminophen effervescent granules without first checking with a physician.

Warning and Precautions:
Precaution to consider.
Note : Chronic toxicity studies in animals have shown that high doses. Acetaminophen cause testicular atrophy and inhibition of spermatogenesis; the relevance of this finding to use in humans is not known.

Cross-sensitivity
Patients hypersensitivity to aspirin may not be hypersensitivity to acetaminophen however, mild bronchospastic reactions with acetaminophen have been reported in some aspirin-sensitive asthmatics (less than 5% of those tested).

Drug interactions and/or related problems Alcohol or Hepatic enzyme-including agents, other
Redon products range should not be combined with other analgesic medications that contain paracetamol. Paracetamol should be given with care to patients with impaired kidney or liver function.

This preparation contains PARACETAMOL. Do not take any other PARACETAMOL-containing-medicines at the same time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash.

These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Interactions with Other Medicaments:
Acetaminophen can induce synthesis of the hepatic microsomal enzymes, but the effect is not seen with usual doses. Similarly, the prothrombinopenic effect of the oral anticoagulant agents may be increased by chronic administration of full doses of acetaminophen, but intermittent doses of the drug have only little such effect.

Pregnancy and Lactation:
For pregnant women and nursing mothers, consult your physician before taking this or any medicine.

Breast-feeding
Problems in humans have not been documented; however, risk-benefit must be considered. Although peak concentration of 10 to 15 mcg per ml have been measured in breast milk 1 to 2 hours following maternal ingestion of a single 650mg dose, neither acetaminophen not its metabolites were detected in the urine of the nursing infants. The half-life breast milk is 1.35 to 3.5 hours.