1. NAME OF THE MEDICINAL PRODUCT
Rexall 100mg/5ml drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Paracetamol oral solution contains 100mg Paracetamol in each 5ml

For the full list of excipients, see 6.1

3. Pharmaceutical form
Oral solution
A clear, pink, viscous solution with an odour of raspberry

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

Paracetamol solution is indicated in the management of pain and fever associated with such conditions as the common cold, influenza and headache.
For patients who are unable to tolerate solid dose formulations or lower strength preparations of paracetamol containing products.

4.2 Posology and method of administration

Posology:
Recommended Doses and Dosage Schedules
Adults and young persons 16 years and over:
The Optimal dosage range is 100mg (5ml) to 200mg (10ml) up to three to four times a day, as required, to a maximum of 4 g paracetamol/ day (40 ml paracetamol oral solution).
The dose should not be repeated more frequently than every four hours, and not more than four doses should be taken in any 24 hour period.
Older people:
In older people, the rate and extent of paracetamol absorption is normal but plasma half-life is longer and paracetamol clearance is lower than in young adults.

Method of administration
For oral administration only.
It is important to shake the bottle for at least 10 seconds well before use.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the excipients listed in section 6.1.

Patients with severe hepatic dysfunction.
Do not use this medicine in children and adolescents under 16 years.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with (non-cirrhotic) alcoholic liver disease.
Do not take with any other paracetamol-containing products.
Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.
Do not exceed the recommended dose.
Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

The hepatotoxicity of Paracetamol, particularly after overdosage, may be increased by drugs which induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants and alcohol.
Alcohol can increase the hepatotoxicity of paracetamol overdosage.
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.
The anticoagulant 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.
Antivirals: Regular use of Paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

4.6 Pregnancy and lactation

Pregnancy:
Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.
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 clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Undesirable effects

The information below lists reported adverse reactions, ranked using the following frequency classification:
Very common (Ó1/10); common (Ó1/100 to <1/10); uncommon (Ó1/1,000 to <1/100); rare (Ó1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).
Immune system disorders:
Not known: Anaphylactic shock, angioedema, anaphylactic reaction, Urticaria, Hypersensitivity, rash

Blood and lymphatic system disorders:
Not known: Blood dyscrasia including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to Paracetamol.
Skin and subcutaneous disorders:
Very Rare: Serious skin reactions.
Gastrointestinal disorders:
Not known: Cases of acute pancreatitis have been reported. Paracetamol has been widely used and reports of adverse reactions are rare, and are generally associated with overdosage.
Renal and urinary disorders:
Not known: Nephropathy toxic*
*Nephrotoxic effects are uncommon and have not been reported in association with therapeutic doses, except after prolonged administration.

4.8 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol.
Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has the risk factors.
Risk Factors:
If the patient
a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
OR
b) Regularly consumes ethanol in excess of recommended amounts.
OR
c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.
Symptoms:
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. Hyperglycaemia has been reported. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.
Management
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.
Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol; however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of

the antidote however declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who represent with serious hepatic dysfunction beyond 24h ingestion should be discussed with the NPIS or a liver unit.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics; Anilides
Mechanism of action:
The site and mechanism of the analgesic effect of paracetamol is unclear. Paracetamol reduces fever by a direct action on the hypothalamic heat-regulating centers, which increases dissipation of body heat (via vasodilation and sweating). The action of endogenous pyrogen on heat-regulating centers is inhibited.
Paracetamol is almost as potent as aspirin in inhibiting prostaglandin synthetase in the CNS but its peripheral inhibition of prostaglandin synthesis is minimal, which may account for its lack of clinically significant anti-rheumatic or anti-inflammatory effects. Paracetamol does not inhibit platelet aggregation, affect prothrombin response or produce GI ulceration.

5.2 Pharmacokinetic properties

Absorption: Paracetamol is rapidly an almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations occur within 0.5 to 2 hours, with slightly faster absorption of liquid preparations.
Distribution: Usual analgesic doses produce total serum concentrations of 5 to 20mcg/ml; a good correlation between serum concentration and analgesic effect has not been found. Serum protein binding varies from 20 to 50% at toxic serum concentrations.
Metabolism: Paracetamol is extensively metabolized in the liver by glucuronisation and conjugation with sulphates. Approximately 4% is metabolized via cytochrome P-450 to a toxic metabolite which is normally detoxified by preferential conjugation with hepatic glutathione and excreted in the urine as conjugates of cysteine and mercapturic acid. When paracetamol is used chronically or taken acutely in large doses, glutathione stores are depleted and hepatic necroses may occur.
Elimination: Paracetamol is excreted in the urine, mostly as metabolites; 2 to 4% is excreted unchanged. The average elimination half-life is 1 to 4 hours; half-life is slightly prolonged in neonates (2.2 to 5 hours) and in cirrhotics.

5.3 Preclinical safety data

Data in the literature on toxic doses and serum levels of Paracetamol is limited, but Paracetamol is relatively non-toxic in therapeutic doses.
Paracetamol toxicity may result from a single toxic dose or from long term ingestion of the drug. It has been reported in the literature that children may be less susceptible to acute Paracetamol poisoning than adults. Hepatic necrosis is dose dependent and is the most serious acute toxic effect associated with over dosage. It is potentially fatal,

and nausea, vomiting and abdominal pain usually occur within 2-3 hours after ingestion of toxic doses of the drug.
Acute toxic doses of Paracetamol in laboratory animals produce animals produce death from liver and renal damage.
Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Ethanol (96%)
Glycerol
Methyl paraben
Propyl paraben
Povidone K30
Saccharin Sodium
Sunset Yellow
Banana flavor
Raspberry flavor
Sugar Syrup
Purified Water

6.2 Incompatibilities

Not relevant

6.3 Shelf life

Unopened: 24 months
Opened: 3 months

6.4 Special precautions for storage

Do not store above 25° C.
Do not refrigerate or freeze.
Store in the original container.

6.5 Nature and contents of container

Amber glass bottle with LD-polyethylene, tamper evident and child resistant cap. The bottle is packed in an outer carton.
Pack size: 15ml

6.6 Special precautions for disposal and other handling

No special instruction

7. MARKETING AUTHORISATION HOLDER

Daily-Need Industries Limited
Plots 9/10 Unity close, Oshodi Scheme, Industrial Estate, Lagos
www.dailyneedgroup.com, info@dailyneedgroup.com

8. MARKETING AUTHORISATION NUMBER(S)

B4-3727

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

August 2015/ August 2020

10. DATE OF REVISION OF THE TEXT

August 2020

Company Contact Details

Daily-Need Industries Limited
Plots 9/10 Unity close, Oshodi Scheme Industrial Estate, Lagos
www.dailyneedgroup.com,
info@dailyneedgroup.com