CALPOL SUSPENSION
Paracetamol Suspension 120mg/5ml

QUALITATIVE AND QUANTITATIVE COMPOSITION
Calpol Suspension 120mg/5ml. Each 5ml contains 120mg Paracetamol

PHARMACEUTICAL FORM
Suspension

CLINICAL PARTICULARS
Indications
Calpol Suspension is an analgesic used for the treatment of mild-to-moderate pain including:
- Headache
- Sore throat
- Musculoskeletal pain
- Fever and pain after vaccination
- Pain after dental procedures / tooth extraction
- Toothache
Calpol Suspension is also used for relief of fever.

Dosage and Administration
Do not exceed the stated dose
The lowest dose necessary to achieve efficacy should be used.
For Oral administration only

Children aged 3 months and above:
Minimum dosing interval: 4 hours.
Maximum daily dosage: 60mg/kg presented in divided doses of 10 – 15 mg/kg throughout the 24-hour period
No more than four doses in any 24-hour period.
Maximum duration of continued use without medical advice: 3 days.

Children aged 2 to 3 months:
A single dose of 10 - 15 mg/kg for symptomatic relief of reaction due to vaccination. Medical advice should be sought if pyrexia persists after a second dose. For other indications, use only under medical advice.

Dosage in renal impairment
Patients who have been diagnosed with kidney impairment must seek medical advice before taking this medication.
The restrictions related to the use of paracetamol products in patients with renal impairment are primarily a consequence of the paracetamol content of the drug.

Dosage in hepatic impairment
Patients who have been diagnosed with liver impairment must seek medical advice before taking this medication. The restrictions related to the use of paracetamol products in patients with hepatic impairment are primarily a consequence of the paracetamol content of the drug.

Contraindications
This product is contraindicated in patients with a previous history of hypersensitivity to paracetamol or excipients

Warnings and Precautions
Contains paracetamol. Do not use with any other paracetamol – containing products. The concomitant use with other products containing paracetamol may lead to an overdose.
Paracetamol overdose may cause liver failure which can lead to death or require liver transplant. Underlying liver disease increases the risk of paracetamol-related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.
Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol. In patients with glutathione depleted states such as sepsis, the use of paracetamol may increase the risk of metabolic acidosis.
If symptoms persist, medical advice must be sought.

Keep out of sight and reach of children

Interactions
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Pregnancy and Lactation
Fertility: No relevant data available.

Pregnancy
All formulations:
- Human and animal studies with paracetamol have not identified any risk to pregnancy or embryo-foetal development
Lactation

Human studies with paracetamol have not identified any risk to lactation or the breast-fed Offspring. Paracetamol crosses the placental barrier and is excreted in breast milk.

Effects on Ability to Drive and Use Machines

Ability to perform tasks that require judgement, motor or cognitive skills

All formulations:
It is unlikely to cause an effect on ability to drive and use machines.

Adverse Reactions

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency.

The following convention has been utilised for the classification of undesirable effects: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through

<table>
<thead>
<tr>
<th>Body System</th>
<th>Undesirable effect</th>
<th>Frequency</th>
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</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td>Thrombocytopenia</td>
<td>Very rare</td>
</tr>
<tr>
<td>Immune System disorders</td>
<td>Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, and Stevens Johnson syndrome and Toxic Epidermal Necrolysis</td>
<td>Very rare</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Bronchospasm in patients sensitive to aspirin and other NSAIDs.</td>
<td>Very rare</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>Hepatic dysfunction</td>
<td>Very rare</td>
</tr>
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</table>

Overdose
Paracetamol overdose may cause liver failure which can lead to death or require liver transplant. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

Treatment of Overdose
Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present. Administration of N-acetylcysteine or methionine may be required.

Mechanism of Action
Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

Pharmacodynamic Effects
The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for: patients with a history of disease or patients taking concomitant medication, where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of gastrointestinal bleeding or the elderly).

Pharmacokinetics
Absorption
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.

Distribution
Binding to the plasma proteins is minimal at therapeutic concentrations.

Metabolism
Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.

Elimination
Less than 5% is excreted as unmodified paracetamol.

Special Patient Populations
See Dosage and Administration.

List of Excipients
Carmoisine Eurocert 800804; Glycerin, Vegetable Grade BP; Sorbitol Solution 70%; Straw berry Flavour, 500018E; Sucrose, BP Granulated Sugar; Xanthan Gum (Keltrol F); Methyl Paraben (Nipagen M)
**Changes to the consumer information**

<table>
<thead>
<tr>
<th>S/N</th>
<th>Section</th>
<th>Consumer information</th>
</tr>
</thead>
</table>
| 1   | Dosage and Administration | **Adults and children over 12 years**  
 Always use the lowest effective dose to relieve your symptoms.  
 Do not take more than 4000mg* paracetamol per day.  
 Do not exceed the stated dose.  
 Do not take more frequently than every 4 hours.  
 Do not take with any other product containing paracetamol. |
| 2   | Dosage and Administration | **Children**  
 Do not take more than 60mg/ kg* presented in divided doses of 10-15mg/kg throughout the 24-hour period.  
 **Suspension:** Not recommended in children under 2 months.  
 Do not take for more than 3 days without asking your doctor.  
 Do not exceed the stated dose.  
 Do not take more frequently than every 4 hours.  
 Do not take with any other product containing paracetamol.  
 * please state equivalent number of doses per day (e.g. for Paracetamol Tablets 500mg: Do not take more than 8 tablets per 24 hours) |
| 3   | Contraindications    | **Do not use if:**  
 You are allergic to paracetamol or any of the other ingredients in the product. |
| 4   | Warnings and Precautions | Contains paracetamol.  
 Taking too much paracetamol can cause serious harm to your liver.  
 Do not use this medicine if you are taking any other prescription or non-prescription medicines containing paracetamol to treat pain, fever, symptoms of cold and flu, or to aid sleep.  
 Always read and follow the label.  
 **Check with your doctor before use if you:**  
 - have liver or kidney problems.  
 - are underweight or malnourished.  
 - regularly drink alcohol.  
 You may need to avoid using this product altogether or limit the amount of paracetamol that you take.  
 Check with your doctor before use if you:  
 - have a severe infection as this may increase the risk of metabolic acidosis.  
 Signs of metabolic acidosis include:  
 • deep, rapid, difficult breathing  
 • feeling sick (nausea), being sick (vomiting)  
 • loss of appetite  
 Contact a doctor immediately if you get a combination of these symptoms.  
 Please see your doctor if your symptoms do not improve.  
 Keep out of sight and reach of children. |
| 5   | Warnings and Precautions | **Important information about some of the ingredients in your product:**  
 **Formulations containing sodium:**  
 Contain xxx mg sodium per tablet. |
<table>
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<tr>
<th>6</th>
<th>Drug Interactions</th>
<th>Before taking this medicine, make sure you consult your doctor if you are taking warfarin or similar medicines used to thin the blood.</th>
</tr>
</thead>
</table>
| 7 | Adverse reactions | **Stop taking this medicine and tell your doctor immediately if:**  
- You experience allergic reactions such as skin rash or itching, sometimes with breathing problems or swelling of the lips, tongue, throat or face.  
- You experience a skin rash or peeling, or mouth ulcers.  
- You have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction with this product.  
- You experience unexplained bruising or bleeding.  
These reactions are rare. |
| 8 | Overdose | **If you take more of the medicine than you should:**  
Seek medical advice immediately because of the risk of liver failure. |