**SCHEDULING STATUS:** **S2**

**PROPRIETARY NAME: (AND DOSAGE fORM):**
## SUPRAGESIC SYRUP

**COMPOSITION:**
Each 5 ml contains:

| | |
|---|---|
| Paracetamol | 150 mg |
| Codeine phosphate | 4 mg |
| Nipastat | 0.1 % m/v |
| Contains Alcohol | 10.37 % v/v |

Contains sugar and glucose

**PHARMACOLOGICAL CLASSIfICATION:**
A 2.9 Other Analgesics

**PHARMACOLOGICAL ACTION:**
Paracetamol has analgesic and antipyretic actions, and is a suitable alternative for patients sensitive to aspirin.
Codeine phosphate is an analgesic with a mild hypnotic action and is often used in combination with antipyretics and with other analgesics.

**INDICATIONS:**
For the relief of mild to moderate pain and fever.

**CONTRA-INDICATIONS:**
Hypersensitivity to any of the ingredients.
Codeine must be used with caution in any situation in which there is decreased respiratory reserve such as emphysema, kyphoscoliosis and including severe obesity; after operations in the biliary tract; in the presence of acute alcoholism, head injuries and conditions in which intracranial pressure is raised; during an attack of bronchial asthma or in heart failure secondary to lung disease.
The depressant actions of codeine are exaggerated and prolonged by phenothiazines, monoamine oxidase inhibitors and imipramine-like drugs.

**WARNINGS:**
**SUPRAGESIC SYRUP** should be used with caution in patients with impaired renal and liver function. Liver necrosis is the common manifestation of paracetamol overdosage. **SUPRAGESIC SYRUP** must not be used continually for more than 10 days without consulting a doctor.
Codeine should be given with extreme caution in patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
Exceeding the prescribed dose, together with prolonged and continuous use of this medication, may lead to dependency and addiction.

**DOSAGE AND DIRECTIONS fOR USE:**

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|---|---|---|
| Infants | 6 months to 1 year: | 2,5 ml ($^1/_2$ medicine measure) |
| Children | 1 to 3 years: | 5 ml (1 medicine measure) |
| Children | Older than 3 years: | 5-10 ml (1-2 medicine measures) |
| Adults: | | 10-20 ml (2-4 medicine measures) |

Three to four times a day.

**SIDE EffECTS AND SPECIAL PRECAUTIONS:**
Warning:
Dosages in excess of those recommended may cause severe liver damage.
Special precautions:
1. Consult your doctor if no relief is obtained with the recommended dosage.
2. Do not use continuously for longer than 10 days without consulting your doctor.
3. Store in a safe place, out of reach of children.
4. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

Side-effects:
Sensitivity reactions resulting in reversible skin rash or blood disorders may occur, but these are rare.
Rarely, patients taking paracetamol have been known to suffer from slight nausea, dizziness and mild gastro-intestinal disturbance. Skin eruptions may occur. Codeine may produce nausea, vomiting, mental clouding, dysphoria, constipation, increased pressure in the biliary tract, drowsiness, dry mouth, sweating, facial flushing, vertigo, circulatory failure, hypotension, deepening coma, muscle rigidity, bradycardia, palpitations, orthostatic hypotension, hypothermia, changes of mood and miosis. Micturation may be difficult and there may be ureteric or biliary spasm. Raised intracranial pressure may occur. Reactions such as urticaria and pruritis may occur.
Codeine may have an antidiuretic effect.

Codeine should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, myasthenia gravis, impaired renal function, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly or debilitated patients.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, phenothiazines and tricyclic antidepressants. The prolonged use of high doses of codeine has produced dependence of the morphine type.
The administration of codeine during labour may cause respiratory depression in the new born infant.

**KNOWN SYMPTOMS Of OVERDOSAGE AND PARTICULARS Of ITS TREATMENT:**
Paracetamol:
In the event of overdosage with paracetamol consult a doctor or take the patient to the nearest hospital immediately. Specialized treatment is essential as soon as possible. The latest information regarding the treatment of overdosage can be obtained from the nearest poison centre. Symptoms of overdosage include nausea and vomiting. Liver damage which may be fatal may only appear after a few days. Kidney failure has been described following acute intoxication.

Codeine:
Symptoms include restlessness, excitement, respiratory depression and hypotension with circulatory failure and coma. In children convulsions may occur. The specific antagonist, naloxone hydrochloride is used to counteract the severe respiratory depression. In the event of overdosage, consult a doctor or take the patient to the nearest hospital immediately. Treatment is symptomatic and supportive.

**IDENTIfICATION:**
Pale, straw-coloured, mobile syrup, faint menthol-like odour and taste.

**PRESENTATION:**
100 ml amber glass bottle in a unit carton.

**STORAGE INSTRUCTIONS:**
Store in a cool place, at or below 25 °C, protected from light.
**KEEP OUT Of REACH Of CHILDREN**

**REGISTRATION NUMBER:**
H/2.9/129

**NAME AND BUSINESS ADDRESS Of THE APPLICANT:**
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