SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Product name: Sonadol Extra Caplets

1.2 Dosage Strength:

Each Uncoated Tablet contains:

Paracetamol BP.....500 mg.

Caffeine Anhydrous BP....65 mg.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

* - Evaporates during the manufacturing process.

Definitions: BP: British Pharmacopoeia IH: In House

3. PHARMACEUTICAL FORM

Oral Tablet

White oblong uncoated tablet with SONADOL EXTRA engraving on one side and plain on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SONADOL EXTRA is a combination of Paracetamol and caffeine. It has analgesic and antipyretic properties. Caffeine stimulates the central nervous system, acts on smooth muscle and the myocardium. It has some diuretic effect. It is used in the symptomatic management of pain and fever. It acts mainly by inhibiting prostaglandin synthesis. It is indicated in the mild to moderate pain and pyrexia. Sonadol extra relieves headache, back ache, rheumatic pain, muscle pain, neuralgia, toothache, period pain, discomfort in cold and flu, sore throat and fever.

4.2 Posology and method of administration

Adults: 2 caplets every 8 hours. Do not exceed 8 caplets in a day (24 hours).
Do not give to children under 12 years of age.
Children above 12 years: Consult a doctor.
Route of Administration: Tablet (Oral)

4.3 Contraindications

Known hypersensitivity to paracetamol, caffeine or any of the other ingredients.

4.4 Special warnings and precautions for use

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 liver transplant or death.

Cases of paracetamol induced hepatotoxicity, including fatal cases, have been reported in patients taking paracetamol at doses within the therapeutic range.

These cases were reported in patients with one or more risk factors for hepatotoxicity including low body weight (<50 Kg), renal and hepatic impairment, chronic alcoholism, concomitant intake of hepatotoxic drugs, sepsis and in acute and chronic malnutrition (low reserves of hepatic glutathione). Paracetamol should be administered with caution to patients with these risk factors.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency

Doses of paracetamol should be reviewed at clinically appropriate intervals and patients should be monitored for emergence of new risk factors for hepatoxicity which may warrant dosage adjustment. 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.

Excessive intake of caffeine (e.g. coffee and some canned drinks) should be avoided while taking this product.

Contains Sodium methyl parahydroxybenzoate (E219), Sodium ethyl parahydroxybenzoate (E215) and Sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).

Prolonged use except under medical supervision may be harmful. In general, medicinal products containing paracetamol should be taken for only a few days without the advice of a doctor or dentist and not at high doses

Do not exceed the stated dose.

Take only when necessary.

If high fever or signs of secondary infection occur or if symptoms persist for longer than 3 days, a physician should be consulted.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products

Paracetamol

Paracetamol may increase the elimination half-life of chloramphenicol. The absorption of paracetamol may be increased by metoclopramide and decreased by colestyramine. Oral contraceptives may increase the rate of clearance of paracetamol.

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.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis, especially in patients with risks factors (see section 4.4)

Caffeine

Caffeine can increase the elimination of lithium from the body. Concomitant use is therefore not recommended.

4.6 Pregnancy and lactation

Pregnancy Paracetamol

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.

Caffeine

Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of spontaneous abortion associated with caffeine consumption.

Lactation

Paracetamol and caffeine are excreted in breast milk. Not recommended for use during breastfeeding

4.7 Effects on ability to drive and use machines

None

4.8 Adverse Reactions

Skin rashes and blood disorder particularly thrombocytopenia may occur. Gastrointestinal irritation and stimulation of the central nervous system,nausea, vomiting, abdominal pain.

Caffeine should be given with care to patients with a history of peptic ulceration.

4.9 Symptoms of Overdosage & Treatment

Paracetamol

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases. Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic

Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis,

resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may lead to coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration.

Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Some patients may be at increased risk of liver damage from paracetamol toxicity. Risk Factors include: If the patient;

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

Emergency Procedure: Immediate transfer to hospital. Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion. Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour. The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines Symptomatic treatment should be implemented.

Caffeine

Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).

It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related liver toxicity. No specific antidote is available, but supportive measures such as beta adrenceptor antagonists to reverse the cardiotoxic effects may be used.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: N02B E51

The combination of paracetamol and caffeine is a well established analgesic combination.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed, widely distributed in body fluids, and has a half-life of 1–4 hours. It is metabolized in the liver and excreted

in urine mainly as glucuronide and sulphate conjugates. Caffeine is readily absorbed, has a plasma half-life of 4– 5 hours, and is excreted in urine as xanthine derivatives. Both have similar total absorption across formulations, though onset and early exposure may vary.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch BP, Sodium Starch Glycollate USP, Geletin BP, Methyl Hydroxy Benzoate BP, Propyl Hydroxy Benzoate BP, Magnesium Stearate BP, Colloidal Silicon Dioxide USP/NF,

Croscarmellose Sodium USP/NF

6.2 Incompatibilities

None.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool & dry place below 30°C. Protect from direct sunlight. Keep medicines out of reach of children

6.5 Nature and contents of container

1) 10 Tablets to be packed in a blister. Such 2 blister to be packed in carton along with leaflet.
2) 10 Tablets to be packed in a blister. Such 10 blister to be packed in carton along with leaflet.

7. MARKETING AUTHORISATION HOLDER

Shalina Healthcare Kenya Limited
Shalina House, Baba Dogo Road,
P.O Box 39597 – 00623 Nairobi, Kenya

Manufacturing Site Address:

Bal Pharma Limited
21 & 22 Bommasandra Industrial Area,

Bangalore 560 099, India.

8. Marketing Authorization Number

H2006/17609/546

9. Date of First <Registration> /Renewal of the <Registration>

Date of first authorization: 09/07/2006
Date of latest renewal: 25/7/2026