PARACETAMOL CAFFEINE

REXIDOL® FORTE

500 mg / 65 mg Tablet

ANALGESIC - ANTIPYRETIC

FORMULATION
Each tablet contains:
Paracetamol..... 500 mg
Caffeine..... 65 mg

PRODUCT DESCRIPTION
A white, oval-shaped tablet, engraved with "SPL" on one side and with a break line on the other side.

WHAT IS IN THE MEDICINE?
This product contains Paracetamol, a fever reducer and pain reliever. Caffeine enhances and prolongs the effect of Paracetamol on pain relief.

STRENGTH OF THE MEDICINE
See Formulation.

WHAT IS THE MEDICINE USED FOR?
- For the relief of mild to moderate pain including headache, migraine, backache, muscular aches, menstrual cramps, arthritis pain, toothache, and pain associated with the common cold and flu;
- For fever reduction

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Adults and children 12 years old and above: 1-2 tablets every 6 hours, as needed for pain and/or fever, or, as directed by a doctor.
Do not take more than 4 g of Paracetamol and 520 mg of Caffeine (8 tablets) in each 24-hour period.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If the patient is allergic to Paracetamol, Caffeine or any ingredient in the product;
- If the patient has high blood pressure or an irregular heartbeat;
- Avoid long-term use of Paracetamol in patients with anemia or with heart, lung, kidney, or liver disease;
- If the patient is recovering from severe alcoholism and taking Disulfiram. Disulfiram reduces Caffeine clearance, which might complicate alcohol withdrawal, by increasing nervousness and restlessness;
- If the patient is below 12 years old;
- If the patient is taking any of these medicines:
  - Medicines for high blood pressure (e.g., Propranolol, Atenolol); Caffeine can increase blood pressure and counter the blood pressure-lowering action of these medicines.
  - Medicines for depression or anxiety (e.g., Sertraline, Clozapine), Lithium Carbonate
  - Decongestants containing Ephedrine
  - Theophylline (for breathing problems); Caffeine and Theophylline share the same metabolic pathway which leads to increased clearance times for Theophylline when used together with Caffeine.
  - Levothyroxine (for thyroid problems)

UNDESIRABLE EFFECTS
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects.
Hypersensitivity including skin rashes and minor stomach and intestinal disturbances have been reported with Paracetamol use.
In doses up to 520 mg/day, undesirable effects of Caffeine are not normally observed in healthy individuals. However, some users who are not used to Caffeine, who have abstained from Caffeine for a period of time and who are more sensitive to Caffeine may experience effects more commonly seen with higher doses.
Effects of Caffeine include tremor, difficulty in sleeping, nervousness, restlessness, irritability, anxiety, headache, ringing in the ears, fast or irregular heartbeat, rapid breathing, frequent urination, and stomach upset. Caffeine use may also increase blood pressure. Those who experience these signs must discontinue taking this medicine and other dietary Caffeine-containing products.
Following regular use of Caffeine, end of intake may lead to withdrawal symptoms which could last one week. Signs include headache, tiredness and decreased alertness.

WHAT OTHER MEDICINES OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

PARACETAMOL:
- The speed of absorption of Paracetamol may be accelerated by Metoclopramide or Domperidone and absorption reduced by Cholestyramine;
- Medicines which stimulate the enzymes responsible for the metabolic activation of Paracetamol such as medicines for convulsion (e.g., Phenobarbital, Phenytoin, Carbamazepine) may increase susceptibility to the harmful effects to the liver;
- Warfarin, a blood thinning medicine; an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using Paracetamol and Warfarin at the same time. Paracetamol increases the anticoagulation effect of Warfarin;
- An increased risk of liver toxicity may be expected when used together with alcohol (e.g., Ethanol) or Isoniazid (for tuberculosis);
- The possibility of severe hypothermia (abnormally low body temperature) may occur if Phenothiazine is taken together with Paracetamol;
- Pretreatment with Probenecid may decrease Paracetamol clearance and increase the effects of Paracetamol.

CAFFEINE:
- Xanthine derivatives such as Caffeine can weaken the vasodilating effect of substances used for myocardial imaging (e.g., Adenosine, Dipyridamole). Thus, Caffeine should be avoided for 24 hours before myocardial imaging;
- Caffeine, as a central nervous system stimulant, has an antagonistic effect on the action of sedatives and tranquilizers (e.g., Diazepam, Zolpidem);
- Caffeine may further increase the action of Phenylpropanolamine in increasing heart rate;
- Caffeine competitively inhibits Clozapine metabolism. Hence, Clozapine and Caffeine must not be used together;
- Lithium Carbonate and Caffeine should not be used together because their combination may cause a small to moderate increase in Serum Lithium levels;
- The use of Monoamine Oxidase inhibitors (e.g., Phenelzine, Moclobemide, Selegiline) with Caffeine should be avoided since it may increase the stimulant effects of Caffeine;
- Methoxsalen (for psoriasis) reduces Caffeine clearance and may increase the effects of Caffeine;
- Pipemidic acid (for infections) reduces Caffeine clearance, thus enhancing the action of Caffeine;
- Levothyroxine, like Caffeine, can increase blood pressure; hence they should not be used together;
- Phenytoin (for epilepsy) increases Caffeine clearance and may decrease the effects of Caffeine;
- The use of Ephedrine and Caffeine should be avoided since it could lead to increased blood sugar and lactate concentrations.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?
If a dose is missed, give the next dose if still needed for pain and/or fever and the subsequent doses every 6 hours thereafter.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children.

Do not store above 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Overdosage of Paracetamol usually involves 4 phases with the following signs and symptoms:
I. Eating disorder, nausea, vomiting, malaise, and excessive sweating;
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output;
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure;
IV. Recovery or progression to fatal complete liver failure

Signs of acute overdose of Caffeine include vomit similar to ground coffee, frequent urination, increased heart rate, tremors and convulsions. Metabolic acidosis, ketosis and hyperglycemia have also been reported.

Chronic intake of over 500 mg of Caffeine a day is associated with caffeinism, a syndrome of low grade irregular fever, difficulty in sleeping, anorexia, anxiety, and irritability.

WHAT TO DO IF YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE
If more than the recommended dosage has been given, consult a doctor or contact a Poison Control Center right away. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms because of the risk of delayed, serious liver damage.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

Liver Warning: This product contains Paracetamol.
Severe liver damage may occur if:
- An adult or child 12 years old and above takes more than 4 g (8 tablets) in 24 hours, which is the maximum daily amount;
- Taken with other medicines containing Paracetamol (or Acetaminophen);
- An adult has 3 or more alcoholic drinks everyday while using this product.

Caffeine Warning: The recommended dose of this product (65-130 mg of Caffeine) contains about as much Caffeine as 1-2 cups (150-300 mL) of instant coffee. The use of Caffeine-containing medicines, food (e.g., chocolate) or beverages (e.g., coffee, tea, cola) should be limited while taking this product.

Caffeine Content of Common Beverages/Food

	mg of Caffeine	
Coffee: per cup (150 mL)	**Average**	**Range**
Brewed, percolator	115	60-180
Brewed, drip method	80	40-170
Instant	65	30-120
Decaffeinated	3	-
Tea: per cup (150 mL)		
Brewed	40-60	20-110
Instant	30	25-50
Iced (360 mL)	70	67-76
Other products		
Soft drinks, 360 mL	36	30-50
Cocoa, 150 mL	4	2-20
Chocolate milk, 240 mL	5	2-7
Semisweet chocolate, 30 mL	20	5-35
Milk chocolate, 30 mL	6	1-15
Chocolate syrup, 30 mL	4	4-5

- Do not use with any other medicine containing Paracetamol (prescription or nonprescription).
  If you are not sure whether a medicine contains Paracetamol, ask a doctor.
- Ask a doctor before use if the patient has kidney or liver problems.
- Ask a doctor before use if the patient is taking Warfarin, a blood thinning medicine.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
- If you are pregnant or breastfeeding, consult your doctor before use.
- Stop use and ask a doctor if:
  - New symptoms occur
  - Symptoms do not get better
  - Headache is persistent
  - Pain gets worse or lasts more than 10 days
  - Fever gets worse or lasts more than 3 days

AVAILABILITY
Box of 100s (in blister pack of 10s)

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