



Panadol Extra with Optizorb
(Film Coated Tablets)
Patient Information leaflet



What is Panadol Extra with Optizorb and what is it used for?

Active ingredient Each tablet contains paracetamol 500mg and Caffeine 65mg.
Other ingredients: Starch pregelatinised, Povidone K-25, Calcium carbonate, Croscopollose, Sodium methyl parahydroxybenzoate (E219), Sodium ethyl parahydroxybenzoate (E215), Sodium propyl parahydroxybenzoate (E217), Alginate Acid and Magnesium stearate.
Film coat: Titanium dioxide, Hypromellose, Macrogol and Polysorbate 80.
Polishing agent: Carnauba wax.

Panadol Extra with Optizorb Tablets contains paracetamol, which has an analgesic and antipyretic effects, and caffeine which is synergistically adding to the analgesic effect of paracetamol.
Panadol Extra with Optizorb Tablets are recommended for the relief of mild to moderate pain associated with rheumatism, musculoskeletal disorders, headache and of discomfort associated with influenza, feverishness and feverish chills, toothache and dysmenorrhoea

How to use Panadol Extra with Optizorb?

For oral administration only.

Adults (including the elderly) and children aged 16 years and over:

2 tablets up to four times daily. Do not exceed 8 tablets in 24 hours.

Children aged 12 – 15 years:

1 tablet up to four times daily. Do not exceed 4 tablets in 24 hours.

Not recommended for children under 12 years of age.

Minimum dosing interval: 4 hours.

The lowest dose necessary to achieve efficacy should be used.

Should not be used with other paracetamol-containing products

Renal and Hepatic Impairment:

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

The maximum daily dose of paracetamol should not exceed 60mg/kg/day (up to a maximum of 2g per day) in the following situations, unless directed by a physician:

- Weight less than 50kg
- Chronic alcoholism
- Dehydration
- Chronic malnutrition

Before taking Panadol Extra with Optizorb:

A. Do not take Panadol Extra with Optizorb:

If you have known or previous history of hypersensitivity to paracetamol, caffeine or any other ingredients.

B. Take special care with Panadol Extra with Optizorb:

- 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.
- Caution is also advised in patients on concomitant treatment with drugs that induce hepatic enzymes and in conditions which may predispose to glutathione deficiency (see sections 4.2 and 4.9). In patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.
- Doses of paracetamol should be reviewed at clinically appropriate intervals and patients should be monitored for emergence of new risk factors for hepatotoxicity 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).
- Each tablet contains 0.446mg per tablet, that is to say essentially 'sodium-free'.
- Prolonged use except under medical supervision may be harmful.
- Do not exceed the stated dose.
- Take only when necessary.
- If symptoms persist for longer than 3 days, consult your doctor.
- Keep out of the sight and reach of children.

C. Driving and using machines: No significant effect on ability to drive and use machines.

D. Pregnancy & Lactation:

Pregnancy

Paracetamol

Human and animal studies have not identified any risk of paracetamol in pregnancy or embryo-fetal development.

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.

E. Drug Interactions:

Paracetamol:

- Paracetamol may increase the elimination half-life of Chloramphenicol.
- Talk to your doctor or pharmacist before taking this product if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]) or cholestyramine (for high cholesterol)
- 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.

Caffeine

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

Possible side effects.

Paracetamol:

Blood and lymphatic system disorders:

Thrombocytopaenia - Very rare

Immune System disorders:

Anaphylaxis-Very rare

Cutaneous hypersensitivity reactions, including skin reactions, angioedema and Stevens Johnson syndrome and toxic epidermal necrolysis. Very rare cases of serious skin reactions have been reported.

Respiratory, thoracic and mediastinal disorders: Bronchospasm in patients sensitive to aspirin and other NSAIDs -Very rare.

Hepatobiliary disorders: Hepatic dysfunction- Very rare.

Caffeine:

Central Nervous System: Nervousness, Dizziness-Not known.

- When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Overdose

If you know that you have exceeded the stated dose, please consult your doctor immediately.

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, arrhythmia, insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions). The amount ingested would be associated with serious Paracetamol-related liver toxicity. No specific antidote is available, but supportive measures such as beta adrenoceptor antagonists to reverse the cardiotoxic effects may be used.

How to Store Panadol Extra with Optizorb:

- Store below 30°C.
- This product is protected in a sealed blister. Do not use if blister is broken.
- Do not use this medicine after the expiry date, which is stated on the carton, Blister. The expiry date refers to the last day of that month.
- Pack sizes: 24Tablets (12TabletsX2strips), 48Tablets (12TabletsX4 strips) & 72Tablets (12TabletsX6 strips), not all pack sizes might be available in all markets.

THIS IS A MEDICINE

- Medicine is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctors' prescription, the method of use and the instructions of the pharmacist who sold the medicine.
 - The doctor and pharmacist are experts in the use of medicines, its benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribe for you.
 - Do not repeat the same prescription without consulting your doctor.
- KEEP MEDICINE OUT OF REACH OF CHILDREN
Council of Arab Health Ministers
Union of Arab Pharmacists

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