

PATIENT INFORMATION LEAFLET
(PA 12) PARACETAMOL SUSTAINED RELEASE TABLETS 1000 MG
[Paracetamol BP]

Read all of this leaflet carefully before you start using this medicine.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

WHAT IS IN THIS LEAFLET:

1. What Paracetamol Sustained Release Tablets 1000 mg is and what it is used for
2. Before you use Paracetamol Sustained Release Tablets 1000 mg
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4. Possible side effects
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1. WHAT PARACETAMOL SUSTAINED RELEASE TABLETS 1000 MG IS AND WHAT IT IS USED FOR

It contains the active substance Paracetamol. This belongs to a group of medicines called 'Analgesic and antipyretic agent.' Paracetamol, Para-aminophenol derivative is a peripherally acting analgesic and is well absorbed orally. Paracetamol produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat regulating center. It is indicated in follow treatments for: Fever, Acute Pain, Chronic Pain'.

2. BEFORE YOU USE PARACETAMOL SUSTAINED RELEASE TABLETS 1000 MG

Do not use paracetamol sustained release tablets 1000 mg. If you are allergic to paracetamol or any of the other ingredients. Hypersensitivity to paracetamol or to any of the excipients of the product.

Warnings and precautions: It should be administered with caution to patients with hepatic or renal dysfunction. Adults who are using warfarin should consult with a doctor or pharmacist before taking paracetamol. **Not recommended for children under 12 years of age.** Adults should not take paracetamol sustained release tablets 1000 mg for pain for more than 10 days or for fever for more than 3 days unless directed by a physician: **Severe liver damage may occur if:**

- Adult takes more than 4000 mg in 24 hours, which is the maximum daily amount.
- Taken with other drugs containing paracetamol.
- Adult has 3 or more alcoholic drinks everyday while using this product.

Pediatric population: It should not be used in children age below 12 years since no data is available.

Using other medicines:

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines. Tell your doctor if you are taking any of the following medicines: The absorption of paracetamol may be altered by metoclopramide & anticholinergic agents (e.g propantheline, glycopyrolate and exanatide). The metabolism of paracetamol may be altered by alcohol, isoniazid, ascorbic acid, ciprofloxacin, diflunisal, lamotregine, rifampicin, omeprazole, chloramphenicol, oral contraceptives, probenecid, propranolol, sulfinpyrazone, zidovudin, lamotregine. Paracetamol is also having Drug interaction with oral anticoagulants, frusemide,

anticonvulsants (e.g. hydention, carbamazepine). If you have any further questions about this you should speak to your doctor.

Taking Paracetamol Sustained Release Tablets 1000 mg with food and drink: You can take your tablets with or without food. Patients should avoid to intake alcohol with treatment with paracetamol. **Pregnancy and Lactation: Pregnancy:** If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency or better to consult a doctor before taking the medicine. **Lactation:** It is excreted in very low concentrations in the mother's milk and is not known to cause adverse effects to breast-fed children. It should not be used during breast-feeding. **Driving and using machines:** There are no data for adverse influence on the active attention, coordination of movements and reflexes when paracetamol is taken.

3. HOW TO USE PARACETAMOL SUSTAINED RELEASE TABLETS 1000 MG

Always use paracetamol sustained release tablets 1000 mg exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure. It can be taken administered orally once daily without meals or as directed by physician.

Method of administration: Oral, The tablets should be swallowed whole with or without food. The tablets should not be chewed or crushed. For patients who have difficulty in swallowing, the tablets can also be dispersed in half a glass of non-carbonated water.

Adults and children over 12 years: One tablet orally twice daily.

Hepatic and renal impairment patients: It should be used with caution in patients with hepatic and renal impairment as a reduced dose or prolonged dosing interval may be necessary.

If you more Paracetamol Sustained Release Tablets 1000 mg than you should: Do not use more than the recommended dose of paracetamol sustained release tablets 1000 mg talk to your doctor or pharmacist straight away. Taking more than the recommended dose of paracetamol may cause liver damage. Following suspected over dosage, evaluate necessity of antidote therapy.

If you forget to Paracetamol Sustained Release Tablets 1000 mg: If you forget to take a dose, Do not take a double dose (two doses at the same time) to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist. If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with paracetamol sustained release tablets 1000 mg.

4. POSSIBLE SIDE EFFECTS

Like all medicines can cause side effects, although not everybody gets them. Dermatologic: Rash & Endocrine metabolic: May increase chloride, uric acid, glucose; may decrease sodium, bicarbonate, calcium. Hematologic: Anemia, blood dyscrasias (neutropenia, pancytopenia, leukopenia). **Hepatic:** Bilirubin increased, alkaline phosphatase increased. Renal: Ammonia increased, nephrotoxicity with chronic overdose, analgesic nephropathy. If any of above the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

5. HOW TO STORE PARACETAMOL SUSTAINED RELEASE TABLETS 1000 MG

Keep this medicine out of the sight and reach of children. Store under normal storage conditions (15°C - 30°C). Protect from Light.. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. FURTHER INFORMATION

It contain active substances as paracetamol BP. Each uncoated bi-layered tablet contains: paracetamol BP 300 mg (As Immediate Release), paracetamol BP 700 mg (As Sustained Release), Excipients: Microcrystalline Cellulose (Plain), Maize Starch, Colour Carmoisine Supra, Povidone (P.V.P.K-30), Glycerol, Sodium Starch Glycolate, Magnesium Stearate, Purified Talc, Colloidal Anhydrous Silica (Aerosil), Hypromellose (Metolose K-100M), Hypromellose (Metolose 90SH 4000), Isopropyl Alcohol, Purified water. **Size:** White and pink coloured, capsule shaped, bi-layered uncoated tablets, plain on both sides. Such 12 Tablets are packed in a blister pack. Such 1 blister packed in printed baby carton with Packing Insert. Such 10 Baby Cartons are packed in a printed carton.

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