# PARACETAMOL
# BIOGESIC®

## 500 mg Tablet
## Analgesic - Antipyretic

**FORMULATION**
Each tablet contains: Paracetamol.....500 mg

**PRODUCT DESCRIPTION**
Paracetamol (Biogesic®) 500 mg Tablet is an orange, convex, 0.662" x 0.300" in diameter, plain, elliptical tablet, embossed with "BIOGESIC" on one side and "500" insignia on the other side.

**WHAT IS IN THE MEDICINE?**
This product contains paracetamol, a fever reducer and pain reliever.

**STRENGTH OF THE MEDICINE** See Formulation.

**WHAT IS THE MEDICINE USED FOR?**
- For the relief of minor aches and pains such as headache, backache, menstrual cramps, muscular aches, minor 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 and older:** Orally, 1 to 2 tablets every 4 to 6 hours, as needed for pain and/or fever, or, as directed by a doctor.
- Do not take more than 4 g (8 tablets) in each 24-hour period.
- Do not use more than the recommended dose.

**WHEN SHOULD YOU NOT TAKE THIS MEDICINE?**
- If the patient is allergic to paracetamol or any ingredient in the product
- Avoid long-term use of paracetamol in patients with anemia or with heart, lung, kidney, or liver disease.

**UNDESIRABLE EFFECTS**
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects.
Skin rashes, hypersensitivity reactions, changes in the number of white blood cells and platelets, and minor stomach and intestinal disturbances have been reported.

**WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?**
- The 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) 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.

**WHAT SHOULD YOU DO IF YOU MISS A DOSE?**
If you miss a dose, take the next dose if still needed for pain and/or fever and the subsequent dose every 4 to 6 hours thereafter.
Do not double the dose

**HOW SHOULD YOU KEEP THIS MEDICINE?**
Keep the product out of sight and reach of children.
Store at temperatures not exceeding 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

**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 of paracetamol 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.
- 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
  - > Redness or swelling is present
  - > Fever gets worse or lasts more than 3 days
  - > Pain gets worse or lasts more than 10 days

**AVAILABILITY:** In Box of 500's (blister strips x 20's) and box of 10's (blister strips x 10's)
**DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL):** April 2014

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Manufactured by PT Medifarma Laboratories
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