

# PARACETAMOL

**OCTAGESIC**  
500 mg TABLET

ANALGESIC / ANTIPYRETIC

**FORMULATION:**

Each tablet contain:  
Paracetamol ..... 500 mg

**DESCRIPTION:**

Paracetamol, a para-aminophenol derivative, has analgesic and antipyretic properties and weak anti-inflammatory activity. The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes.

Octagesic Tablet, Pink Round biconvex Tablet Blister Pack of 10's (box of 100's)

**WHAT IS IN THE MEDICINE?**

This medicine contains paracetamol. It belongs to a group of medicines called analgesic (pain killer).

**STRENGTH OF THE MEDICINE:**

See Formulation

**WHAT IS THIS MEDICINE USED FOR?**

For the relief of pain and discomfort from headache, colds, flu, minor muscular aches, overexertion, menstrual cramps, toothache and minor arthritic pain.

**HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?**

Three to four times a day.

Children 5-12 years old: ½ tablet - 1 tablet

Adults: 1 tablet. The dose may be doubled in severe cases.

Or as prescribed by the physician.

**WHEN SHOULD YOU NOT TAKE THIS MEDICINE?**

If you are allergic to the active substance or any ingredients of this product.

**CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?**

Paracetamol should be given with care to patients with impaired kidney or liver function. It should be given with care to patients with alcohol dependence.

Do not take greater than 4 doses in any 24 hour period or greater than 3 days.

**UNDESIRABLE EFFECTS OF THIS MEDICINE:**

Hematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia and agranulocytosis.

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

Alcohol, oral anticoagulants, chloramphenicol, aspirin, phenobarb, liver enzyme inducers, hepatotoxic agents. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because paracetamol can affect the way some other medicines work. Also, some other medicines can affect the way paracetamol works.

**WHAT SHOULD YOU DO IF YOU MISS A DOSE?**

If you forget to take a dose at the right time, take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose. Remember to leave at least 4 hours between doses.

**SIGNS AND SYMPTOMS OF OVERDOSE**

It usually involves four phases with the following signs and symptoms: Eating disorder, nausea, vomiting, malaise, and excessive sweating. Right upper abdominal pain or tenderness, liver enlargement with may be characterized by abdominal discomfort of "feeling full," elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time (how long it takes for blood to clot), and occasionally decreased urine output. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure; Recovery or progression to fatal complete liver failure.

**WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?**

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

**WHEN SHOULD YOU CONSULT YOUR DOCTOR?**

Tell your doctor as soon as possible if you

notice any of these:

- allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath, rash or hives.
- becoming unusually tired, unexpected bruising or bleeding and getting more infections (such as colds) than usual. These are very rare effects in people taking paracetamol.
- very rare cases of serious skin reactions have been reported. Symptoms may include skin reddening, blisters, rash. If skin reactions occur or existing skin symptoms worsen, stop use and seek medical help right away.

**ADR REPORTING STATEMENT:**

"For suspected adverse drug reaction, report to the FDA: [www.fda.gov/ph](http://www.fda.gov/ph)." Patient must seek medical attention immediately at the first sign of any adverse drug reaction.

**PHARMACOKINETICS:**

Paracetamol is readily absorbed from the gastrointestinal Tract with peak plasma concentrations occurring about 10 to 30 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentration. The elimination half-life of paracetamol varies from about 1 to 3 hours.

**HOW SHOULD YOU KEEP THIS MEDICINE?**

Store at temperatures not exceeding 30°C

**AVAILABILITY:**

Clear PVC/Aluminum Blister pack of 10's (Box of 100's)

**SHELF-LIFE: 24 months**

**REFERENCE: Martindale 38th edition**

**DATE OF REVISION OF PATIENT INFORMATION LEAFLET:**

06 May 2020

**DATE OF THE FIRST/RENEWAL OF THE AUTHORIZATION**

02 February 2011

**REGISTRATION NUMBER: DRP-3174**



Manufactured by:  
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