

Biogesic tablet

Paracetamol 500mg

Patient Information Leaflet

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1. What Biogesic tablet is used for:

For the relief of fever, headache and muscular pain.

2. How Biogesic tablet works

The tablet 500mg Paracetamol. Paracetamol works by relieving pain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

3. Before you use Biogesic tablet

- When you must not use it

Do not take this medicine if you have an allergy to:

- Paracetamol or any of the other ingredients listed at the end of this leaflet
- any other similar medicines

Do not take Biogesic tablet if you:

- are taking any other paracetamol-containing products

If any of these apply to you, get advice from a doctor or pharmacist.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of

tampering. If it has expired or is damaged, return it to your pharmacist for disposal. If you are not sure whether you should start taking this medicine, talk to your doctor

Use in pregnancy and breastfeeding: Safe to use in normal therapeutic dose as an analgesic. Considered to be the analgesic of choice in pregnant patients. Excreted in breast milk. Maternal ingestion of paracetamol in normal therapeutic doses does not appear to present a risk to the nursing infant.

- Before you start to use it

Tell your doctor if you have:

- allergies to any other medicines, foods, preservatives or dyes.
- impaired kidney or liver function.
- alcohol dependency

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breastfeeding.

If you have not told your doctor about any of the above, tell him/her before you start taking Biogesic tablet.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including warfarin and coumarins.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

4. How to use Biogesic tablet

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions, ask your doctor or pharmacist for help.

- How much to use

Adults and children aged 12 years and over: 500mg – 1g, taken every 4-6 hours as required up to a maximum of 4g daily.

Children 6 to 11 years: 250mg – 500mg every 4 to 6 hours as required. Maximum daily dose: 60mg/kg presented in divided doses of 10-15mg/kg throughout 24 hour period.

- When to use it

Take Biogesic tablet as your doctor has prescribed.

- How long to use it

Continue taking your medicine for as long as your doctor tells you. Please contact your doctor immediately if the pain lasts for more than 10 days, or if there is redness or fever lasts more than 3 days

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for advice.

- If you use too much (overdose)

Toxic symptoms include vomiting, abdominal pain, low blood pressure and sweating.

The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal

hepatic necrosis. Clinical and laboratory evidence of hepatotoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.

Immediately telephone your doctor for advice, or go to Accident and Emergency department at the nearest hospital, if you think that you or anyone else may have taken too much Biogesic tablet.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

5. While you are using it

- Things you must do

Always follow your doctor's instructions carefully. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Biogesic tablet.

- Things you must not do

Do not take Biogesic tablet to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

6. Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Adverse effects of paracetamol are rare and usually mild, although haematological reactions have been reported. Skin rashes and other hypersensitivity reactions may occur occasionally.

Skin rashes and other allergic reaction may occur occasionally. Liver damage

may occur when 10g or more is consumed.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Consumers → Reporting).

7. Storage and disposal of Biogesic tablet

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a dry place where the temperature stays below 30°C. Protect from light.

Keep out of children's reach.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product description

- What it looks like

Plain tablet, orange, round 1/2" in diameter, flat face, beveled-edge, bisected, debossed with "BIOGESIC 500" logo on one side and plain on the other side.

- Ingredients

Active Ingredient:

Each tablet contains 500mg Paracetamol.

Inactive Ingredient:

- Corn Starch
- Magnesium Sterate
- Povidone K-30
- Sodium Starch Glycolate
- FD&C Yellow No.6

- MAL number

MALXXXXXX

9. Manufacturer & Product Registration Holder

Manufacturer

PT Medifarma Laboratories
Jl. Raya - Bogor Km. 33, Cimanggis,
Depok, Indonesia.

Product Registration Holder

UNAM Pharmaceutical (M) Sdn. Bhd.
Suite 803, Block F, Phileo Damansara 1,
No. 9, Jalan 16/11, 46350 Petaling Jaya,
Selangor, Malaysia

10. Date of Revision

28/07/2017

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

This preparation contains PARACETAMOL Do not take any other paracetamol containing medicine at the same time.
