

PARACETAMOL

Unigesic

500 mg Tablet
250mg/5mL Oral Solution
100mg/mL Oral Solution Drops

Analgesic / Antipyretic

Formulation:

Each tablet contains:
Paracetamol, USP 500mg
Each 5 mL of Oral Solution contains:
Paracetamol, USP 250 mg
Each 1 mL of Oral Solution (Drops) contains :
Paracetamol, USP 100 mg

Description of the Product:

Paracetamol is a white crystalline powder that is sparingly soluble in water but freely soluble in ether and in methylene chloride. Paracetamol belongs to a group of medicines called Analgesics and Antipyretics. It works by relieving pain and reducing high temperature and fever.

What is in the Medicine?

Unigesic contains Paracetamol which is indicated for the treatment of mild to moderate pain and as antipyretic.

Strength of the Medicine: (Refer to the formulation)

What is Paracetamol (Unigesic) used for?

Paracetamol (Unigesic) is indicated for the treatment of mild to moderate pain and as antipyretic. It is also indicated for symptomatic relief of headache, migraine, neuralgia, toothache and teething pains, sore throat, rheumatic aches and pains, influenza and colds. Paracetamol tablets are also recommended for menstrual pains and for the relief of pain associated with osteoarthritis.

How much and how often should you use Paracetamol (Unigesic)?

Paracetamol oral formulations should not be taken for more than three consecutive days without seeking medical advice.

Tablet: (500mg)

Adults and Children over 12 years: 1 – 2 tablets 3 to 4 times a day to a maximum of 8 tablets or 4g Paracetamol.
Or as prescribed by the physician.

Oral Solution (250mg/5mL)

Adults and children over 12 years: 10 – 20mL (2 – 4 tsp.)
Children: 6 – 12 years: 5 – 10mL (1 – 2 tsp.)
Children: 1 – 6 years: 2.5 – 5 mL (1/2 – 1 tsp.)
The dose may be repeated 3 – 4 times a day but with an interval of 4 hours or more between each dose.
Or as prescribed by the physician.

Infant Solution (Oral Drops) 100mg/mL

Children 1 – 2 years: 1.2 – 1.8mL
Infants 6 – 12 months: 0.6 – 1.2mL
Infants 0 – 6 months: 0.3 – 0.6mL
The doses may be repeated 3 – 4 times a day
Or as prescribed by the physician.

When should you NOT take Paracetamol (Unigesic)?

- If you are allergic to paracetamol or any of the other ingredients of Paracetamol tablets
- If you are taking any other products that contain Paracetamol.

Care that should be taken when taking Paracetamol (Unigesic) :

- Check with your doctor if you have severe kidney or liver damage, including non-cirrhotic alcoholic liver disease.
- *Tell your doctor if you are taking any other medicines.

What are the undesirable effects of Paracetamol (Unigesic)?

Like all medicines, Paracetamol can cause side effects, although not everybody gets them. If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

- Severe allergic reactions include: difficulty in breathing, skin rash and itching, swelling of the face and throat, runny nose
- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.

What other medicine or food should be avoided while taking Paracetamol (Unigesic)?

- Patient who have taken barbiturates, tricyclic antidepressants and alcohol may show diminished ability to metabolize large doses of paracetamol.
- Chronic ingestion of anticonvulsants or oral steroids contraceptives induce liver enzymes and may prevent attainment of therapeutic paracetamol levels by increasing first pass metabolism or clearance.

What should you do if you miss a dose of Paracetamol (Unigesic)?

If you miss a dose, leave it out and take the next dose whenever it is due. After that, just carry on as before. Do not take double the dose. If you have any further questions, ask your doctor or pharmacist.

What are the signs and symptoms of overdose?

Paracetamol overdosage signs and symptoms: pallor, anorexia, nausea and vomiting are frequent early symptoms of paracetamol overdosage. Hepatic necrosis is a dose related complication of paracetamol overdosage. Hepatic enzymes may become elevated and prothrombin time prolonged within 12 to 48 hours but clinical symptoms may not be apparent for 1 to 6 days after ingestion.

What should you do when you have taken more than the recommended dosage?

Contact your doctor, or hospital immediately for consult. Bring the container or label with you to help doctors with necessary information.

How should you keep/ store Paracetamol (Unigesic)?

Tablet : Store at temperatures not exceeding 30°C. Keep dry.
Oral Solution/Solution (Oral) Drops : Store at temperatures not exceeding 30°C. Protect from light.
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.

When should you consult your doctor?

- If any undesirable effect occur.
- If the patient is taking any vitamin or medicines.

Pregnancy and breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine. Paracetamol (Unigesic) should be taken with precaution for women who are pregnant and breastfeeding.

Name and Address of the Manufacturer and Marketing Authorization

Holder:
St. Martin Pharm Lab Co.
55 Lakandula Street, Parang, Marikina City, Philippines

Registration Number:

Tablet : **DRP - 1408**
Oral Solution : **DRP - 3644**
Oral Solution Drops : **DRP - 3529**

Date of Renewal of the Authorization:

Tablet : **Dec. 28, 2023**
Oral Solution : **Aug. 11, 2024**
Oral Solution Drops : **Aug. 1, 2024**

Date of Revision of Patient Information Leaflet: Dec. 14, 2022

**“For suspected adverse drug reaction, report to the FDA:
www.fda.gov.ph”**

Seek medical attention immediately at the first sign of any adverse drug reaction.