UNILAB

PARACETAMOL

BIOGESIC®

100 mg/mL Syrup (Oral Drops)
120 mg/5 mL Syrup
250 mg/5 mL Syrup

ANALGESIC / ANTIPYRETIC (Anilide)

FORMULATION
Each mL syrup (oral drops) contains: Paracetamol.....100 mg
Each 5 mL syrup contains: Paracetamol.....120 mg or 250 mg

PRODUCT DESCRIPTION
Paracetamol (Biogesic®) 100 mg/mL Syrup (Oral Drops), 120 mg/5 mL Syrup, and 250 mg/5 mL Syrup (Orange Flavor)
• An orange-colored, clear syrup with an orange odor and taste

Paracetamol (Biogesic®) 120 mg/5 mL Syrup, and 250 mg/5 mL Syrup (Melon Flavor)
• An orange-colored, clear syrup with a melon odor and taste

These products use the *TasteRite®* technology of *PediaTech®*. The *TasteRite®* technology is a unique tastemasking system developed specifically for liquid dosage forms.
This technology significantly reduces the bitterness of medicine so that children taste the flavor and not the medicine.

In addition, these products use Tooth Friendly technology *TFTech®* to significantly reduce or eliminate enamel loss that leads to tooth decay.

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

STRENGTH OF THE MEDICINES
See Formulations

WHAT IS THE MEDICINE USED FOR?

MEDICINE	USES
100 mg/mL Syrup (Oral Drops)	• For the relief of minor aches and pains due to the common cold, flu, sore throat, toothache, headache, earache, and post-immunization reactions • For fever reduction.
120 mg/5 mL Syrup and 250 mg/5 mL Syrup	• For the relief of minor aches and pains due to the common cold, flu, headache, toothing, sore throat, earache, post-immunization reactions, and toothache • For fever reduction.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

General Recommendations:
• Infants and children should not exceed 5 doses in each 24-hour period.
• Leave at least 4 hours between doses.
• Do not use continuously for more than 5 days at a time unless directed by a doctor.
• Do not use more than the recommended dose.
• Avoid potential liver damage by giving lower doses of paracetamol in patients classified under the lower body weight / group.

This medicine should be taken orally every 4 to 6 hours, as needed for pain and/or fever, or, as directed by a doctor.

Dosing in Children: 10 mg/kg body weight per dose given every 4 to 6 hours, as needed; or, you can follow the dose in the dosing table below:

	Recommended Paracetamol Dose in Children Based on 10 mg/kg body weight per dose		
Age Group	**100 mg/mL Syrup (Oral Drops)**	**120 mg/5 mL Syrup**	**250 mg/5 mL Syrup**
Infants:			
0 to 3 months	0.3 to 0.6 mL	---	---
4 to 6 months	0.6 to 1 mL	---	---
7 months to under 1 year	1 mL	---	---
Children:			
1 to 2 years	1 to 1.2 mL	5 mL (1 teaspoonful)	2.5 mL (1/2 teaspoonful)
3 to 6 years	---	5 to 10 mL (1 to 2 teaspoonful)	2.5 to 5 mL (1/2 to 1 teaspoonful)
7 to 12 years	---	10 to 15 mL (2 to 3 teaspoonsful)	5 to 7.5 mL (1 to 1 1/2 teaspoonsful)

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
• If you are allergic to paracetamol or any ingredient of the product
• If you are taking other medicines that contain paracetamol

UNDESIRABLE EFFECTS
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects.

Blood and lymphatic system disorders: Anemia (decreased number of healthy red blood cells), changes in the number of white blood cells and platelets such as agranulocytosis (decrease in the number of granulocytes), leukopenia (decrease in the number of leukocytes), methemoglobinemia (presence of methemoglobin in the blood), neutropenia (decrease in the number of neutrophils), pancytopenia (deficiency of all cellular elements in the blood), thrombocytopenia (decrease in the number of platelets); thrombocytopenic purpura (small purple-red marks in the skin or other tissue caused by low number of platelets)
Immune system disorders: Allergic reactions (some are life-threatening) which may cause difficulty swallowing, unexplained wheezing, shortness of breath or difficulty in breathing, skin rash, hives, or angioedema (swelling of face, tongue, lips, or throat); prominesse to infections, swelling around the eyes
Metabolism and nutrition disorders: Hyperchloremia (increased chlorine ion in the blood), hypercuricemia (increased uric acid in the blood), loss of appetite, metabolic acidosis (too much acid in the body), sudden weight loss
Nervous system disorders: Headache
Vascular disorders: Unusual bleeding or bruising
Respiratory, thoracic, and mediastinal disorders: Respiratory distress (noisy, congested breathing), runny nose, laryngeal edema (swelling of the voice box)
Gastrointestinal disorders: Mouth ulcers, nausea, sore throat, vomiting
Skin and subcutaneous tissue disorder: Fixed eruption (an allergic reaction described as well-defined, round or oval patches of redness and swelling in skin that recurs in the same site each time a particular drug is taken), Itchy rash, severe skin reactions (i.e., Stevens–Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis) which may include symptoms such as skin redness, blisters, rash, itching, and peeling of the upper surface of the skin
Hepatobiliary disorders: Chronic hepatic necrosis (death of liver tissues) in prolonged use, liver dysfunction, liver injury, yellowing of eyes and skin
Renal and urinary disorders: Kidney toxicity, papillary necrosis in prolonged use
General disorders and administration site conditions: Fatigue or unusual tiredness
Investigations: Decreased serum bicarbonate, serum calcium, serum sodium; increases in serum alkaline phosphatase, serum glucose, and transaminase levels

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

• 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.
• Prolonged use of paracetamol with other painkillers [e.g., drugs called nonsteroidal anti-inflammatory drugs (NSAIDs), aspirin] is not recommended since it may increase the risk of toxic effects to the kidneys and eventually of kidney failure.
• Chronic intake of alcohol may increase the risk of paracetamol-induced liver toxicity. Acute intake of alcohol may diminish the ability of the body to metabolize large doses of paracetamol. It is advised to consult a doctor before intake of paracetamol.
• The absorption of paracetamol may be increased by metoclopramide or domperidone. Cholestyramine, narcotic pain relievers, and some antidepressants that slow down gastric emptying reduce the absorption of paracetamol. If you are taking these medicines, talk to your doctor first before taking paracetamol.
• Medicines which stimulate the enzymes responsible for the metabolic activation of paracetamol such as medicines for convulsion (e.g., phenobarbital), depression (e.g., tricyclic antidepressants), and oral contraceptives may reduce the efficacy of paracetamol and increase susceptibility to the harmful effects to the liver.
• Phenothiazines (medicines for serious mental and emotional disorder) may increase the risk of severe hypothermia (abnormally low body temperature).
• Paracetamol increases exposure to chloramphenicol. This interaction should be considered when both medicines are given together in malnourished patients.
• Probenecid may reduce elimination of paracetamol.
• There may be an increased risk of bleeding when using paracetamol and warfarin (a blood thinning medicine) at the same time. Paracetamol, especially its prolonged regular use, increases the blood thinning effect of warfarin and other coumarins. If you are taking warfarin, ask the doctor first before taking paracetamol.

Tell your doctor if you are taking other medicines (especially other paracetamol-containing medicines), including vitamins, supplements, and herbal medicines.

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 doses every 4 to 6 hours thereafter.

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?
Store at temperatures not exceeding 30°C.
Keep the product out of sight and reach of children.
For oral drops: **Do not refrigerate.**

SIGNS AND SYMPTOMS OF OVERDOSE
Overdosage of paracetamol usually involves four phases with the following signs and symptoms:

I. Reduced or loss of appetite, nausea, vomiting, malaise (a general feeling of being unwell), 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. Reduced or loss of appetite, nausea, vomiting, and malaise recur (usually 3 to 5 days after initial symptom onset); signs of liver failure (e.g., jaundice, hypoglycemia, coagulopathy, encephalopathy), and possibly kidney failure and cardiomyopathy (disorder of the heart muscle) may develop;
IV. Recovery or progression to fatal complete liver failure

Metabolic acidosis (excessive acid in the body), encephalopathy (abnormal brain function), coma, and death may also occur. Clinical and laboratory evidence of hepatic toxicity may not be apparent 48 to 72 hours post-ingestion, and reach a maximum after 4 to 6 days.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor or contact a poison control center right away, even if you seem well, as there is a risk of delayed serious liver damage. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

• **Liver Warning:** This product contains paracetamol. Severe liver damage may occur if:
o A child takes more than 5 doses in 24 hours, which is the maximum daily amount;
o An adult or child 12 years old and above takes more than 4 g of paracetamol in 24 hours;
o Taken with other medicines containing paracetamol (or acetaminophen);
• **Allergy alert:** Paracetamol may cause allergic reactions. Symptoms may include:
o Skin redness
o Blisters
o Skin rash or hives
o Swelling of the face, tongue or throat
o Difficulty swallowing
o Unexplained wheezing or shortness of breath
• Ask a doctor before use if patient has liver or kidney disease.
• Use with caution in patients with glucose-6-phosphate deficiency (G6PD), a hereditary condition which can lead to decreased blood cell count and possible hemolytic anemia (anemia resulting from destruction of red blood cells).
• Do not take more than the recommended dose.
• Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Ask a doctor before use if:
• The patient has kidney or liver problems (including alcoholic liver disease)
• The patient is taking other pain killers or any other medicines (See ***What Other Medicine or Food Should Be Avoided While Taking This Medicine?***)
• The patient has G6PD
• The cause of the patient's illness is not clear or it is accompanied by a rash, breathing difficulties, diarrhea or excessive tiredness or lethargy
• The patient is severely malnourished, anorexic, have a low body mass index (underweight), or excessively drinks alcohol

Stop use and ask a doctor if:
• If symptoms of allergic reaction occur (such as skin redness, blisters, or rash), stop use and seek medical help right away (See ***Care that Should be Taken when Taking this Medicine).***
• Symptoms worsen or do not improve
• New symptoms occur
• Any undesirable effect occurs
• Redness or swelling is present
• Fever gets worse or lasts more than 3 days
• Pain gets worse or lasts more than 5 days in children (<12 years old) and 10 days in adults
• Patient had unexpected bruising or bleeding, and had more infections than usual
• Consult a doctor promptly if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting.

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY
Paracetamol (Biogesic®) 100 mg/mL Syrup Orange (DRHR-1747)
- Pediatech HDPE Plastic Bottle with Child Resistant Plastic Cap x 15 mL (Box of 1's)
Paracetamol (Biogesic®) 120 mg/5 mL Syrup Orange (DRHR-1748)
- Pediatech HDPE Plastic Bottle with Child Resistant Plastic Cap x 60 mL (Box of 1's)
Paracetamol (Biogesic®) 120 mg/5 mL Syrup Melon (DRHR-1843)
- Pediatech HDPE Plastic Bottle with Child Resistant Plastic Cap x 60 mL (Box of 1's)
Paracetamol (Biogesic®) 250 mg/5 mL Syrup Orange (DR-XY4563)
- Pediatech HDPE Plastic Bottle with Child Resistant Plastic Cap x 60 mL (Box of 1's)
Paracetamol (Biogesic®) 250 mg/5 mL Syrup Melon (DR-XY4636)
- Pediatech HDPE Plastic Bottle with Child Resistant Plastic Cap x 60 mL (Box of 1's)

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for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City
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DATE OF FIRST AUTHORIZATION
Paracetamol (Biogesic®) - Orange Flavor: November 2016
Paracetamol (Biogesic®) – Melon Flavor: June 2018

DATE OF REVISION OF PATIENT INFORMATION LEAFLET: May 2023 (CCDS 17-047)

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