

**ANALGESIC / ANTIPYRETIC** 

### **FORMULATION**

Each tablet contains 500 mg Paracetamol .

### PRODUCT DESCRIPTION

Paracetamol 500 mg Tablet (\*\* United Home® Fevertab) is a white, round, flat beveled edge and plain on both sides tablet.

### WHAT IS IN THE MEDICINE?

This product contains Paracetamol, a fever reducer and pain reliever.

### STRENGTH OF THE MEDICINE

### 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 old and above

1 to 2 tablets every 4 to 6 hours, as needed for pain and/or fever, or as directed by a

Do not take more than 4 g (8 tablets) of paracetamol in each 24-hour period

# WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If patient is allergic to paracetamol or any ingredient in this product.
  Avoid long-term use of paracetamol in patients with anemia or with heart, lung, kidney,

## **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

- The speed of absorption of paracetamol may be accelerated by metoclopramide or domperidone and 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 I DO IF I MISS A DOSE?

If a dose is missed, give 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

### SIGNS AND SYMPTOMS OF OVERDOSAGE

Overdosage of paracetamol 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 occasional decreased urine
- 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 WHEN 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

### 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 (8 tablets) in 24 hours, which is the maximum daily dose.
- Taken with other medicines containing paracetamol (or acetaminophen)
- An adult has 3 or more alcoholic drinks everyday while using this product.
- » Ask the doctor before use if the patient has liver disease
- » Ask the 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 doctor if:
  - New symptoms occur
  - Symptoms do not get better
  - Headache is persistent
  - Pain gets worse or lasts more than 10 days
  - Fever gets worse or lasts for more than 3 days

# HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children. Do not store above 30°C.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine

# **AVAILABILITY**

Paracetamol 500 mg Tablet ( United Home Fevertab) Blister pack by 10's (Box of 100's)

DATE OF REVISION: March 2013

**DATE OF FIRST AUTHORIZATION:** July 2017

Manufactured by Am-Europharma Corporation Brgy. Saimsim, Calamba City, Laguna, Philippines Distributed by UNILAB, Inc.

No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

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