Paracetamol

Kiddilets® *120 mg Chewable Tablet*

ANTIPYRETIC • ANALGESIC

FORMULATION
Each chewable tablet contains:
Paracetamol.....120 mg

PRODUCT DESCRIPTION
Paracetamol (Kiddilets®) is a fruit-flavored (lemon, orange or strawberry) chewable tablet that comes in three colors (yellow, orange or pink). It is mottled, round, 1/2" diameter, flat, bevel-edged tablet that is plain on both sides.

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

STRENGTH OF THE MEDICINE
Each chewable tablet contains 120 mg of the active ingredient Paracetamol.

WHAT IS THE MEDICINE USED FOR?
- For fever reduction
- For the temporary relief of minor aches and pains such as toothache, headache, backache, menstrual cramps, muscular aches, minor arthritis pain, and pain associated with the common cold and flu

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
This medicine should be taken orally every 4 hours, as needed for pain and/or fever, or, as directed by a doctor.

Age (Years)	Recommended Oral Dose (every 4 hours, as needed)
2-3	1 tablet
4-6	1-2 tablets
7-12	2-3 tablets
Adults and Children over 12 years	3-4 tablets

- A child should not exceed 5 doses in each 24-hour period.
- An adult should not take more than 4 g in each 24-hour period.
- Chew before swallowing.
- Do not use continuously for more than 5 days at a time unless directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If the patient is allergic to Paracetamol or to any other ingredient in the product
- Avoid long-term use of Paracetamol in patients with anemia or with heart, lung, kidney, or liver disease.

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

Skin rashes and minor stomach and intestinal disturbances have been reported.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
- 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 YOU DO IF YOU 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 hours thereafter.

Do not double the dose.

HOW SHOULD YOU KEEP THESE MEDICINES?
Keep the product out of sight and reach of children.
Do not store above 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Overdosage of Paracetamol usually 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 occasionally decreased urine output
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 IF 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 takes more than 4 g in 24 hours, which is the maximum daily amount;
  - A child takes more than 5 doses in 24 hours, which is the maximum daily amount;
  - Taken with other medicines containing Paracetamol (or Acetaminophen);
  - An adult has 3 or more alcoholic drinks everyday while using this product.
- 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.
- Ask a doctor before use if the patient has liver disease.
- Ask a 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?
- 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.
- Consult a doctor before use if the patient is phenylketonuric. This product contains Phenylalanine as one of the metabolites of aspartame.
- If you are pregnant or breastfeeding, consult your doctor before use.

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Stop use and ask a doctor if:
- New symptoms occur
- Pain gets worse or lasts more than 5 days
- Redness or swelling is present
- Fever gets worse or lasts more than 3 days

AVAILABILITY: Box of 500 (in blister strip x 20's)

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): 22 Oct 2009

Manufactured by UNITED LABORATORIES, INC.
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From the maker of
Ferrous Sulfate
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