

TYLOPHEN[®]

Acetaminophen

■ Description

Tylophen[®] is an antipyretic and analgesic medication for controlling fever and mild pain.

■ Clinical pharmacology

Analgesic:

The mechanism of analgesic action has not been fully determined. Acetaminophen may act predominantly by inhibiting prostaglandin synthesis in the central nervous system and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or action of other substances that sensitize pain receptors to mechanical or chemical stimulation.

Antipyretic:

Acetaminophen probably produces antipyretic by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flows through the skin, sweating, and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

■ Pharmacokinetics

Oral absorption	95%
Presystemic metabolism	20%
Plasma half-life	
Range	1-4h
Mean	2.3h
Volume of distribution	0.9 L.kg ⁻¹
Plasma protein binding	≤ 20 %

■ Indication

Temporarily relieves minor aches and pain

due to: the common cold, flu, headaches, sore throat, immunizations, toothaches. Temporarily reduces fever.

■ Contraindication

Tylophen[®] should not be administered to patients who have previously exhibited hypersensitivity to any components of the formulation.

■ Precaution

- This drug should be given with caution to certain patients such as those with severe impairment of hepatic or renal function and viral hepatitis.

■ Patient consultation

- Shake well.
- Take doses properly.
- Don't take more medication than the amount prescribed because Acetaminophen may cause liver damage with long term or high-dose usage.
- If the medication is less effective after a few weeks don't increase the dose and check with your physician.
- Make regular visit to physician to check progress during long-term or high-dose therapy.
- Do not use with any other product containing Acetaminophen.
- Stop use and ask a doctor if: new symptom occur, redness or swelling is present, pain get worse or lasts for more than 5 days, or fever gets worse or lasts for more than 3 days.

■ Dosage

Tylophen[®] suspension (5 ml 1 Tsp ~ 120 mg

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Acetaminophen) is prescribed as follow:

Age	Average weight	Dose
1 - 2 yrs	10 - 12 kg	6 - 7.5 ml
2 - 3 yrs	12 - 14 kg	7.5 - 9 ml
3 - 4 yrs	14 - 16 kg	9 - 10 ml
4 - 5 yrs	16 - 18 kg	10 - 11 ml
5 - 6 yrs	18 - 20 kg	11 - 13 ml
6 - 7 yrs	20 - 22 kg	13 - 14 ml
7 - 8 yrs	22 - 25 kg	14 - 16 ml
8 - 9 yrs	25 - 28 kg	16 - 18 ml
9 - 10 yrs	28 - 32 kg	18 - 20 ml
10 - 11 yrs	32 - 36 kg	20 - 23 ml
11 - 12 yrs	36 - 41 kg	23 - 26 ml

- Maximum doses/24 hrs ~ 5 times in 24 hrs

■ Warning

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 promptly.

■ Interaction

Tylophen[®] should not be used by any other product containing Acetaminophen.

■ Adverse reactions

- The most frequently observed adverse reactions include: agranulocytosis, anemia, dermatitis, renal colic, renal failure, sterile pyuria, thrombocytopenia, and black, terry stools.

■ Overdose

In case of overdose contact a physician or poison center

Signs and Symptoms- In acute Acetaminophen over dosage, dose-dependent potentially fetal hepatic necrosis is the most

serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.

Young children seem to be more resistant than adults to the hepatotoxic effect of an Acetaminophen overdose.

Early symptoms following a potentially hepatotoxic overdose may include nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post ingestion.

Treatment - The stomach should be emptied promptly by lavage or by induction of emesis with syrup of Ipecac.

The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours.

■ Storage and stability condition

- Store below 30°C.
- Protect from light and freezing.
- Keep out of the reach of children.

■ Packaging

Acetaminophen oral suspension 120 mg/5 ml. Bottles of 60 & 120 ml.



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