

Tylenol®

TYLENOL® Suppositories

Tylenol Suppositories 100 mg, 200 mg and 350 mg for Children

Composition

Active constituent: Paracetamol (acetaminophen).

List of excipients:

Antioxidants: butyl hydroxyanisole (E 320), butyl hydroxytoluene (E 321);

Other excipients: colloidal silica, polysorbate 20, vegetable oil

Indications

- For temporary relief of mild to moderate aches and pains such as: Headache - sore throat - tooth ache (including teething pain) - mild to moderate aches and pains due to the common cold and flu.
- Fever reduction (including post immunisation fever)

Dosage /Application

The administration of Tylenol Suppositories to children under 3 months and use for more than 3 days in children of any age should always be subject to continuous medical supervision. In cases where the weight of the child is outside that of the associated age-range shown below, dosing should be based on body weight. The dosage interval for all ages is 4 to 8 hours.

Age Range	Body Weight	Dose	Maximum dose /day
3-12 Months 100 mg Suppositories			
3-6 months	5-7 kg	1 suppository 2-3 times a day	4 x 1 suppositories (400 mg) /day
6-12 months	7-10 kg	1 suppository 3-4 times a day	5 x 1 suppositories (500 mg) /day
1-6 Years 200 mg Suppositories			
1-3 years	10-15 kg	1 suppository 2-3 times a day	3-4 x 1 suppositories (600-800 mg) / day
3-6 years	15-22 kg	1 suppository 3-4 times a day	4-5 x 1 suppositories (800-1,000 mg) /day
6-12 Years 350 mg Suppositories			
6-9 years	22-30 kg	1 suppository 2-3 times a day	3-4 x 1 suppositories (1,050-1,400 mg) / day
9-12 years	30-40 kg	1 suppository 3-4 times a day	5-6 x 1 suppositories (1,750-2,100 mg) /day

Instructions for application

- Lubricate the tip of the suppository with either water or a water-based lubricant.
- Insert the lubricated tip of the suppository up into the rectal opening.
- Push it in using your index finger (or small finger for younger children) and hold against the rectal wall for a few seconds, this will keep it in place.

Contraindications

If allergic to paracetamol (acetaminophen) or any of the formulation excipients.

Special Warnings and Special Precautions for Use

- Do not use with any other product containing paracetamol (acetaminophen).
- Do not exceed recommended dose.
- If pain or fever persists or gets worse, or if new symptoms occur, a physician should be consulted promptly. These could be signs of a serious condition.
- Keep out of reach of children.
- Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, even if you do not notice any signs or symptoms, get medical help immediately.
- Consult the doctor in case of severe liver or kidney problem before using this product.

Use in Hepatic Disease

Paracetamol can be used in patients with liver disease and has been studied in both one-time single and multiple doses in adult patients with chronic stable liver disease. Following a single (10mg / kg) dose of paracetamol, the pharmacokinetic profile in paediatric patients with mild, moderate or severe liver disease were not significantly different.

Use in Renal Disease

There is no evidence that patients with renal disease have altered hepatic metabolism. Well-controlled, prospective data indicate that paracetamol can be used in patients with moderate-to-severe renal failure, with no dosage adjustment.

Interactions

Concomitant administration of paracetamol and anticonvulsants at recommended doses does not increase the risk of hepatotoxicity.

Undesirable Effects

Adverse drug reactions identified during post-marketing experience with therapeutic doses of paracetamol are listed below by frequency category as estimated from spontaneous reporting rates:

- Immune System Disorders

Very rare (<1/10,000, including isolated reports): Anaphylactic reaction, hypersensitivity

- Skin and Subcutaneous Tissue Disorders

Very rare (<1/10,000, including isolated reports): Urticaria, pruritic rash, rash

Overdose

Paracetamol in massive overdose may cause hepatic toxicity; therefore prompt medical attention is critical even if there are no apparent signs or symptoms. Early symptoms following a potentially hepatotoxic overdose may include: anorexia, nausea, vomiting, diaphoresis, pallor and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. In children (<12 years of age), an acute over dosage of less than 150 mg/kg has not been associated with hepatic toxicity. If more than 150-200 mg/kg or an unknown amount was administered, obtain a plasma paracetamol level as soon as possible, but no sooner than 4 hours following ingestion. If the serum paracetamol level can be obtained within 8 hours post-ingestion, initiating acetylcysteine treatment is not necessary until the result is obtained. However, if the estimated time post-ingestion approaches 8 hours, acetylcysteine treatment should be initiated immediately. If an assay cannot be obtained and the estimated paracetamol ingestion exceeds 150 mg/kg, dosing with acetylcysteine should be initiated and continued for a full course of therapy.

Other Information

Drugs containing paracetamol must not be administered to children who have consumed alcohol in error.

Shelf Life

Tylenol Children must not be used after the date marked 'EXP' on the container.

Special Precautions for Storage

Do not store above 30°C
Keep blister in the outer carton

Special Precautions for Handling

Tylenol Children's Suppositories become fluid or soften at temperature exceeding 35°C. To restore the suppositories rapidly to an application-ready state, cool them briefly by holding them under running cold water. This does not alter the quality of the suppositories. When cooling a suppository, make sure that the tip is pointing downwards. This ensures that the suppositories regain their firmness in the form necessary for use.

Packages

Tylenol Suppositories 100 mg: (Box of 10's)
Tylenol Suppositories 200 mg: (Box of 10's)
Tylenol Suppositories 350 mg: (Box of 10's)

Manufacturer

Lusomedicamenta Sociedade Técnica Farmacêutica, SA.
Estrada Consiglieri Pedroso 69 B
Queluz de Baixo, 2730-055 Barcarena
Portugal

Marketing Authorisation Holder in Switzerland

Janssen-Cilag AG: Sihlbruggstrasse 111
6340 Baar, Switzerland

Date of Revision of the Text

March 2010

PHARMACIAI.COM

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers
Union of Arab Pharmacists

Keep all medicaments out of reach of children.