

CHILDRENS NORTEMP- acetaminophen solution
Ballay Pharmaceuticals, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Childrens Nortemp

Drug Facts

Active Ingredient: Acetaminophen 160mg (in each 5 mL (tsp.))

Purpose

Purpose: Pain reliever/Fever reducer

Uses

- Temporarily reduces fever
- Temporarily relieves minor aches and pains associated with a cold, flu, sore throat, headache and toothache.

Warnings

Liver warning:This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Sore throat 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.

Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts for more than 5 days
- fever gets worse or lasts for more than 3 days.

These could be signs of serious condition.

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center immediately . Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions: Shake well

Age (year)	Under 2	2 - 3	4 - 5	6 - 8	9 - 10	11
Weight (lb)	Under 24	24 - 35	36 - 47	48 - 59	60 - 71	72 - 95
Dose (tsp.)	Consult Doctor	1	1 1/2	2	2 1/2	3

All dosages may be repeated every 4 hours, but not more than 5 times daily. **this product does not contain directions or complete warnings for adult use.**

Other information

Store between 20°-25°C (68°-77°F) in a tight container.

Each teaspoon contains: **Sodium 7 mg**

Inactive ingredients

citric acid, FD&C Red No. 40, flavor, glycerin, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol and sucralose.

Manufactured by:

Ballay Pharmaceuticals, Inc.

200 Stillwater

Wimberley, TX 78676

NDC 63162-510-12

Children's
Nortemp

acetaminophen

Pain Reliever/
Fever Reducer

See new warnings
information

ALCOHOL FREE
ASPIRIN FREE
COTTON CANDY
FLAVOR

4 fl oz
(118mL)

BALLAY

Drug Facts		Purpose	
Active ingredient (in each tsp.)		Acetaminophen 160mg Pain Reliever/Fever Reducer	
Uses			
<ul style="list-style-type: none"> • Temporarily reduces fever • Temporarily relieves minor aches & pains associated with a cold, flu, sore throat, headache & toothache. 			
Warnings			
<p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes</p> <ul style="list-style-type: none"> • More than 5 doses in 24 hours, which is the maximum daily amount. • With other drugs containing acetaminophen. <p>Sore throat 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.</p> <p>Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</p> <p>Ask your doctor before use if your child has liver disease.</p> <p>Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • New symptoms occur • Pain gets worse or lasts for more than 5 days • Fever gets worse or lasts for more than 3 days • Redness or swelling is present <p>These could be signs of a serious condition.</p>			

Drug Facts (continued)	
Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center immediately. Prompt medical attention is critical even if you do not notice any signs or symptoms.	
Directions: Shake well	
Age(year)	Under 2 2-3 4-5 6-8 9-10 11
Weight(lb)	Under 24 24-35 36-47 48-59 60-71 72-95
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Ballay Pharmaceuticals, Inc.
200 Stillwater, Wimberley, TX 78676

0 63162 51012 1

LOT:
EXP:
R01/14

CHILDRENS NORTEMP

acetaminophen solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63162-510
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63162-510-12	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/26/2014	

Labeler - Ballay Pharmaceuticals, Inc (035888200)