

**NORTEMP - acetaminophen solution/ drops**  
**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.*

-----

**Nortemp Infants Drops**

**Drug Facts**

Active Ingredient: Acetaminophen 80 mg (in each 0.8 mL)

Purpose: Fever reducer/pain reliever

**Uses**

temporarily:

- reduces fever
- relieves minor aches and pains due to: ■ the common cold ■ flu ■ headaches ■ sore throat ■ toothaches

**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.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

**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.

**When using this product**

- **do not exceed recommended dosage. (see overdose warning)**

**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.**

**Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In

case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms.

### Directions

■ this product does not contain directions or complete warnings for adult use ■ do not give more than directed (see overdose warning) ■ find right dose chart, if possible use weight to dose; otherwise, use age ■ use only enclosed dropper designed for use with this product, do not use any other dosing device ■ fill to dose level ■ dispense liquid slowly into child's mouth, toward inner cheek ■ may be given alone or mixed with formula, milk, juice etc. ■ if needed repeat dose every 4 hours ■ do not give more than 5 times in 24 hours ■ Replace dropper tightly to maintain child resistance

Weight (lb)	Age (yr)	Dose (mL)
Under 24	under 2 years	Ask a Doctor
24-35	2-3 years	1.6 mL (0.8mL +0.8mL)

For accurate dosing follow dosing instructions using the enclosed dropper. Fill dropper to 0.8 mL or prescribed level, and dispense with a single firm squeeze of the dropper bulb

### Other information

Store between 20°-25°C (68°-77°F)

### Inactive ingredients

citric acid, FD&C yellow no. 6, cherry flavor, methylparaben, saccharin sodium, sodium benzoate, sodium citrate, propylene glycol and purified water.

### Comments

1-800-847-1921

Manufactured for:

BallayPharmaceuticals, Inc.

200 Stillwater St.

Wimberley, TX 78676

Exp. Date

Control No.

# Nortemp concentrated Infants' Drops

NDC 63162-518-30

## Drug Facts

**Active ingredient (in each 0.8 mL)** **Purposes**  
Acetaminophen 80 mg ..... Fever reducer/pain reliever

### Uses temporarily:

- reduces fever
- relieves minor aches and pains due to:
  - the common cold ■ flu ■ toothaches ■ sore throat ■ headaches

### 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.
- if your child is allergic to acetaminophen or any of the inactive ingredients in this product

**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.**

**When using this product do not exceed recommended dosage. (see overdose warning)**

**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. Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222). Quick medical attention is critical even if you do not notice any signs or symptoms. ➤

## Drug Facts (continued)

### Directions

■ this product does not contain directions or complete warnings for adult use ■ do not give more than directed (see overdose warning) ■ find right dose on chart, if possible use weight to dose; otherwise, use age ■ use only enclosed dropper designed for use with this product, do not use any other dosing device ■ fill to dose level ■ dispense liquid slowly into child's mouth, toward inner cheek ■ may be given alone or mixed with formula, milk, juice etc. ■ if needed, repeat dose every 4 hours ■ do not give more than 5 times in 24 hours ■ Replace dropper tightly to maintain child resistance

Weight (lb)	Age (yr)	Dose (mL)
under 24	under 2 years	ask a doctor
24-35	2-3 years	1.6 mL (0.8+0.8 mL)

For accurate dosing follow dosing instructions using the enclosed dropper. Fill dropper to 0.8 mL or prescribed level, and dispense with a single firm squeeze of the dropper bulb.

### Other information

Store between 20°-25°C (68°-77°F)

### Inactive ingredients

cherry flavor, citric acid, FD&C yellow no. 6, methylparaben, propylene glycol, purified water, saccharin sodium, sodium benzoate, and sodium citrate.

**Comments** © 1-800-847-1921

See top or bottom flap of the carton for control # and expiration date.  
SAVE THIS CARTON FOR FULL LABELING INFORMATION

NDC 63162-518-30

See New Warnings  
Information

concentrated  
**Nortemp**  
Infants' Drops  
acetaminophen  
Pain Reliever/  
Fever Reducer

Alcohol Free  
Aspirin Free  
Sugar Free



1 fl oz (30 mL)



Do not accept if imprinted safety seal around cap is broken or missing.



Attr: Use only enclosed dropper designed for use with this product. Do not use any other dosing device.

Reports of serious side effects associated with the use of the product can be sent to the address below.

Manufactured by:  
Bailay Pharmaceuticals, Inc.  
200 Stillwater St.  
Wimberley, TX 78676

Rev. 12/10

## NORTEMP

acetaminophen solution/ drops

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63162-518
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	80 mg in 0.8 mL

## Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
methylparaben (UNII: A2I8C7HI9T)	
saccharin sodium dihydrate (UNII: SB8ZUX40TY)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate (UNII: 1Q73Q2JULR)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0K00R)	

## Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY (wild cherry)	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63162-518-30	30 mL in 1 BOTTLE, DROPPER		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/01/1997	

**Labeler** - Ballay Pharmaceuticals, Inc (035888200)

Revised: 12/2013

Ballay Pharmaceuticals, Inc