

ACETAMINOPHEN INFANTS- acetaminophen suspension/ drops
Physicians Total Care, 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.

Amerisource Bergen Infants' Pain Relief Concentrated Drops Drug Facts

Active ingredient (in each 0.8 mL)

Acetaminophen 80 mg

Purpose

Fever reducer/pain reliever

Uses

temporarily:

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

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

These could be signs of a serious condition.

Keep out of reach of children.

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

- do not give more than directed (see Liver warning)
- shake well before using
- 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
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor
- replace dropper tightly to maintain child resistance
- this product does not contain directions or complete warnings for adult use

Dosing Chart		
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)

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

Other information

- store at 20°-25°C (68°-77°F)
- do not use if printed bottle wrap is broken or missing

Inactive ingredients

anhydrous citric acid, butylparaben, carboxymethylcellulose sodium, carrageenan, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, hydroxyethyl cellulose, microcrystalline cellulose, propylene glycol, purified water, sodium benzoate, sorbitol solution

Questions or comments?

1-800-719-9260

Principal Display Panel

See New Warnings Information

Acetaminophen Infant Drops

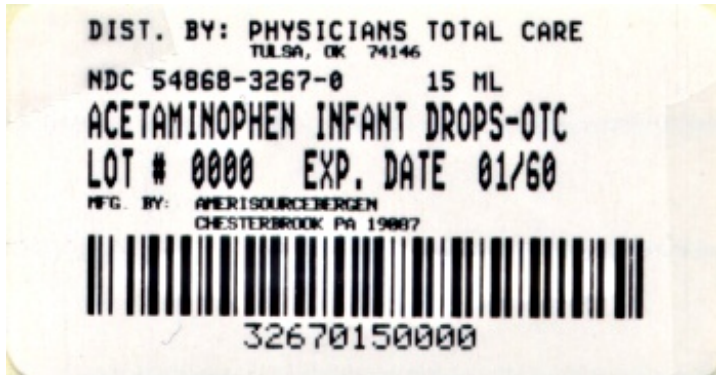
Fever Reducer -Pain Reliever

Use Only with Enclosed Dropper

Cherry Flavor - Alcohol-Free - Aspirin-Free - Ibuprofen-Free

80 mg per 0.8 mL

NDC 54868-3267-0



Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

ACETAMINOPHEN INFANTS

acetaminophen suspension/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-3267(NDC:24385-313)
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)	
BUTYLPARABEN (UNII: 3QP1U3FV8)	

CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)

Product Characteristics

Color	RED (opaque)	Score	
Shape		Size	
Flavor	CHERRY (sweet)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3267-0	1 in 1 CARTON		
1		15 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	05/13/1994	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel

Revised: 1/2012

Physicians Total Care, Inc.