

UP AND UP DYE FREE INFANTS PAIN AND FEVER ACETAMINOPHEN- acetaminophen liquid

Target Corporation

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.

Target Corporation Dye Free Infants' Pain and Fever Acetaminophen Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg

Purpose

Pain reliever/fever reducer

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.
- if your child has ever had an allergic reaction to this product or any of its ingredients

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 dose (see overdose warning)

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.

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)
- shake well before using
- mL = milliliter
- find right dose on chart. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Firmly push syringe into bottle opening.
- turn bottle upside down. Pull syringe to the first dose line and then push product back into bottle.
- pull syringe until it reaches and stays at the correct dose
- dispense liquid slowly into child's mouth, toward inner cheek
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- replace cap tightly to maintain child resistance

Dosing Chart

Weight (lb)	Age (yr)	Dose (mL)*
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

*or as directed by a doctor

Attention: use only enclosed syringe 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 neckband is broken or missing

Inactive ingredients

anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

Questions? Call

Call 1-800-910-6874

Principal Display Panel

Compare to active ingredient in Infants' Tylenol® Oral Suspension

dye free infants' pain and fever acetaminophen

suspension liquid

fever reducer/pain reliever

see side panel for more information

alcohol free, aspirin free, ibuprofen free

no high fructose corn syrup

use only with enclosed syringe

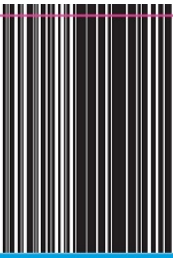
non-staining

CHERRY FLAVOR

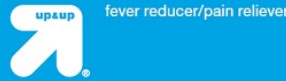
2 FL OZ (59 mL)

160 mg per 5 mL

SEE NEW DOSAGE AND DIRECTIONS



dye free infants' pain and fever acetaminophen suspension liquid

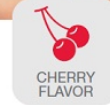


NDC 11673-590-16

Compare to active ingredient in Infants' Tylenol® Oral Suspension**

dye free infants' pain and fever acetaminophen suspension liquid
fever reducer/pain reliever

see side panel for more information
alcohol free, aspirin free, ibuprofen free
no high fructose corn syrup
use only with enclosed syringe
non-staining



2 FL OZ (59 mL) 160 mg per 5 mL

SEE NEW DOSAGE AND DIRECTIONS



- STEP 1. See *Directions* for the correct dose for your child.
- STEP 2. Shake well before using.
- STEP 3. Push air out of syringe. Firmly push syringe into bottle opening.



- STEP 4. Turn the bottle upside down. Pull syringe to the first dose line and then push product back into bottle.
- STEP 5. Pull syringe until it reaches and stays at the correct dose.



- STEP 6. Dispense liquid slowly into child's mouth.

IMPORTANT:
New Dosage and Directions. Please see dosing chart or ask a doctor for your child's correct dose.

Drug Facts

Active ingredient (in each 5 mL) *Purpose*
Acetaminophen 160 mg.....Pain reliever/fever reducer

Uses temporarily:
 ■ reduces fever
 ■ relieves minor aches and pains due to:
 ■ flu ■ headache ■ sore throat ■ toothache
 ■ the common cold

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 has ever had an allergic reaction to this product or any of its ingredients

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 dose (see overdose warning)

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. 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

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 ■ dispense liquid slowly into child's mouth, toward inner cheek

Drug Facts (continued)

■ repeat dose every 4 hours while symptoms last
 ■ do not give more than 5 times in 24 hours
 ■ replace cap tightly to maintain child resistance

Dosing Chart

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Attention: use only enclosed syringe 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 neckband is broken or missing

Inactive ingredients anhydrous citric acid, calcium sulfate, carrageenan, flavor, glycerin, hydroxyethyl cellulose, microcrystalline cellulose and carboxymethylcellulose sodium, propylene glycol, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, tribasic sodium phosphate

Questions? Call
1-800-910-6874

GLUTEN FREE

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Infants' Tylenol® Oral Suspension.

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LOT NO.

EXP.

: 59016 UW C2

UP AND UP DYE FREE INFANTS' PAIN AND FEVER ACETAMINOPHEN
acetaminophen liquid

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:11673-590
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (ACETAMINOPHEN)	ACETAMINOPHEN	160 mg in 5 mL
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Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID	
CALCIUM SULFATE	
CARRAGEENAN	
GLYCERIN	
CELLULOSE, MICROCRYSTALLINE	
CARBOXYMETHYLCELLULOSE SODIUM	
PROPYLENE GLYCOL	
PROPYLPARABEN	
WATER	
SODIUM BENZOATE	
SORBITOL	
SUCRALOSE	
SODIUM PHOSPHATE, TRIBASIC	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-590-10	1 in 1 CARTON		
1		30 mL in 1 BOTTLE		
2	NDC:11673-590-16	1 in 1 CARTON		
2		59 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	11/02/2011	

Labeler - Target Corporation (006961700)

Revised: 1/2014

Target Corporation