

DYE FREE INFANTS PAIN AND FEVER- acetaminophen suspension CVS

CVS Dye Free Acetaminophen 160mg/5 ml suspension - Infants Grape flavor

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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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

Directions

Do not take more than directed.

See overdose warning

- **this product does not contain directions or complete warnings for adult use.**
- **shake well before using**
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- push air out of syringe. Insert syringe tip into the bottle opening
- flip bottle upside down. Pull yellow part of syringe to 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 (lbs)	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

- **each 5ml contains:** sodium 2mg
- store between 20-25°C (68-77°F)

Inactive ingredientsanhydrous citric acid, flavor, glycerin, hydroxyethyl cellulose,

microcrystalline cellulose and carboxymethylcellulose sodium, propylparaben, purified water, sodium benzoate, sorbitol solution, sucralose, sucrose, xanthan gum

Questions or comments? Call 1-877-290-4008

Varnish Omit Area

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
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 - headache
 - sore throat
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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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- hives
- rash

If a skin reaction occurs, stop use and seek medical help right away. **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 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
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Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

CVS Health. Oral Suspension

Infants' Pain & Fever

ACETAMINOPHEN 160 mg / 5 mL

CVS Health. Compare to the active ingredient in Infants' Tylenol® Oral Suspension*
Oral Suspension

NDC 51316-643-04

Infants' Pain & Fever

ACETAMINOPHEN 160 mg / 5 mL

Pain reliever; Fever reducer

Ages 2 to 3 years

No added alcohol

DYE FREE



Grape Flavor

Use only with enclosed syringe. See side panel for more information. Free of aspirin and ibuprofen.

2 FL OZ (60 mL)

Package Contains One Bottle and One Syringe

DANGER: DO NOT USE IF SHIRING AND SEAL AROUND THE BOTTLE IS BROKEN OR MISSING

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

STEP 1. Shake well before using.



STEP 2. Push air out of syringe.



STEP 3. Insert syringe tip into bottle opening.



STEP 4. Flip bottle upside down.



STEP 5. Pull yellow part of syringe to correct dose.



*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, owner of the registered trademark Infants' Tylenol® Oral Suspension.

Varnish Omit Area

#858818

FPO 100%
UPC# 050428135358

X XXXXXX XXXXXX X

654L 1224

LOT:
EXP:

Print/Varnish Omit Area



Oral Suspension
NDC 51316-643-04

Infants' Pain & Fever

DYE FREE

ACETAMINOPHEN
160 mg / 5 mL

Pain reliever;
Fever reducer

Ages 2 to 3 years
No added alcohol

Grape Flavor
Use only with enclosed syringe.
Free of aspirin and ibuprofen.

2 FL OZ (60 mL)



TAMPER EVIDENT: DO NOT USE IF SHRINK-BAND SEAL AROUND THE BOTTLE IS BROKEN OR MISSING
RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg. **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

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness

■ hives ■ rash. If a skin reaction occurs, stop use and seek medical help right away.

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

Directions: Do not take more than directed. See overdose warning

■ **Product does not take directions for adult use.** ■ **Shake well before using**

■ **Fill a pillifier** and do not drop on floor or desk to keep from spilling. If you do not have a pillifier, use a clean, dry, shallow container to hold the pills to avoid crushing them.

■ **Use the pillifier** to place the pills in the container. ■ **Do not use** if the container is damaged or if the pills are out of their original packaging. ■ **Dispense** rapidly slowly into child's mouth, toward inner cheek. ■ **Use** every 4 hours while needed.

Drug Facts (continued under label)

Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895

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654L 1224

LOT:

EXP:



Varnish Omit Area

Drug Facts (continued)

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

DOSSING CHART

Weight (lbs)	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.

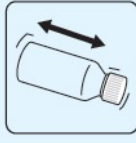
Other information ■ each 5 mL contains sodium 2mg ■ store between 20-25°C (68-77°F)

Inactive ingredients antihypnotic citric acid, flavor, hydroxyethyl cellulose, microcrystalline cellulose, and antioxydant hydroxybenzoin, propylparaben, purified water, sodium benzoate, sorbitol solution, sucrose, sucrose, xanthan gum

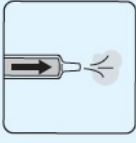
Overdose or comment? Call 1-877-290-4088

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

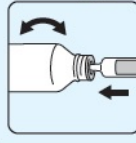
STEP 1. Shake well before using.



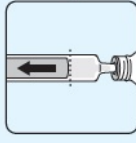
STEP 2. Push air out of syringe.



STEP 3. Insert syringe tip into bottle opening.



STEP 4. Flip bottle upside down.



STEP 5. Pull yellow part of syringe to correct dose.



Adhesive Area

DYE FREE INFANTS PAIN AND FEVER
acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-643
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
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
SUCROSE (UNII: C151H8M554)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	white (white to off white)	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-643-04	1 in 1 BOX	02/15/2025	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/15/2025	

Labeler - CVS (062312574)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		677604129	manufacture(51316-643)

Revised: 2/2025

CVS