

ACETAMINOPHEN- acetaminophen elixir
Akron Pharma 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.

Acetaminophen Elixir

Bubble Gum Flavor

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 non-prescription). 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

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 (1-800-222-1222) right away. 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**
- **shake well before using**
- **mL=milliliter**
- find the right dose on chart below, if possible, use weight to dose; otherwise use age
- use only the enclosed dosing cup designed for use with this product.
- Do not use any other dosing device.
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by doctor.

Weight (lbs.)

Age (years)

dosage-teaspoonful (tsp.)

under 24	under 2	ask a doctor
24 to 35	2 to 3	1 tsp or 5 mL
36 to 47	4 to 5	1 1/2 tsp or 7.5 mL
48 to 59	6 to 8	2 tsp or 10 mL
60 to 71	9 to 10	2 1/2 tsp or 12.5 mL
72 to 95	11	3 tsp or 15 mL

Other information

- Store at room temperature 15°-30° C (59°-86°F)
- Protect from Freezing.
- Protect from Light.

TAMPER EVIDENT: DO NOT USE IF BREAKAWAY BAND ON CAP IS BROKEN OR MISSING.

Inactive Ingredients:

bubble gum flavor, citric acid, glycerin, polyethylene glycol 400, purified water, sodium citrate, saccharin sodium, sorbitol solution & sodium benzoate.

Questions or Comments?

Call (877) 225-6999 Monday - Friday 9AM-5PM EST

**Manufactured for
Akron Pharma, Inc.,
Fairfield, NJ - 07004**

Rev 07/22

Manufactured In USA

* This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol Elixir

4 OZ Package

NDC 71399-0160-4

Compare to the active ingredient in Children's Tylenol® Elixir

Dye-free
Children's PAIN RELIEF
Pain Reliever and Fever Reducer
Acetaminophen 160 mg per 5 mL
Oral Elixir

- Alcohol Free
- Aspirin Free

For Ages 2 to 11 years
Bubble Gum Flavored

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Made in USA

Akron Pharma 4 FL. OZ (118 mL)

Drug Facts																									
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Rev: 0722

Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004

3 171399 101604 1

8 OZ Package

NDC 71399-0160-8

Compare to the active ingredient in Children's Tylenol® Elixir

Dye-free
Children's PAIN RELIEF
Pain Reliever and Fever Reducer
Acetaminophen 160 mg per 5 mL
Oral Elixir

- Alcohol Free
- Aspirin Free

For Ages 2 to 11 years
Bubble Gum Flavored

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

Made in USA

Akron Pharma 8 FL. OZ (236 mL)

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 or 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 the 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 for more than 5 days ■ fever gets worse or lasts for 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 (1-800-222-1222) right away. 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 ■ shake well before using ■ mL = milliliter ■ find right dose on chart below. If possible, use weight to dose; otherwise, use age. ■ use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device. ■ if needed, repeat dose every 4 hours while symptoms last ■ do not give more than 5 times in 24 hours ■ do not give more than 5 days unless directed by doctor.																						
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Questions or comments? call toll-free 1-877-225-6999																						

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Rev: 0722

Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004
www.akronpharma.com

3 171399 101608 9

16 OZ Package

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: ■ 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 or 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 non prescription). 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 the child has liver disease.	
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NDC 71399-0160-6

Compare to the active ingredient in Children's Tylenol® Elixir

Dye-free Children's PAIN RELIEF

Pain Reliever and Fever Reducer

Acetaminophen 160 mg per 5 mL
Oral Elixir

- Alcohol Free
- Aspirin Free



For Ages
2 to 11 years
Bubble Gum Flavored

Akron Pharma

Made in USA 16 FL.OZ (473 mL)

Drug Facts (continued)

Do not use any other dosing device. ■ if needed, repeat dose every 4 hours while symptoms last ■ do not give more than 5 times in 24 hours ■ do not give more than 5 days unless directed by doctor.

Weight (lbs.)	Age (yrs.)	Dose (tsp or mL)
under 24	under 2	ask a doctor
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Other Information

store at room temperature 15°-30°C (59°-86°F). Protect from Freezing. Protect from Light.

Inactive Ingredients bubble gum flavor, citric acid, glycerin, polyethylene glycol 400, purified water, sodium citrate, saccharin sodium, sorbitol solution & sodium benzoate.

Questions or comments? call toll-free 1-877-225-6999

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Akron Pharma

Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004
www.akronpharma.com

Rev.:07/22



ACETAMINOPHEN

acetaminophen elixir

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-0160
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

SODIUM BENZOATE (UNII: OJ245FE5EU)

Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0160-4	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2021	
2	NDC:71399-0160-8	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2021	
3	NDC:71399-0160-6	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/18/2021	

Labeler - Akron Pharma Inc. (067878881)

Registrant - Akron Pharma Inc. (067878881)

Revised: 2/2023

Akron Pharma Inc.