

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 = 1 teaspoonful)

Acetaminophen 160 mg

Purpose

Pain Reliever/Fever Reducer

Uses

To reduce fever and for the temporary relief of minor aches and pains due to:

- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- premenstrual and menstrual cramps.

Temporarily reduces fever.

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 6 doses in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks everyday while using this product.

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
- is on a sodium-restricted diet.

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.

If pregnant or breast-feeding, ask a health professional before use.

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. Quick medical attention is critical for adults/children even if you do not notice any signs or symptoms.

Directions

- shake well before using
- find the right dose on chart below, if possible, use weight to dose; otherwise use age
- dosage may be repeated every 4 hours, or as directed by your doctor
- do not use more than 5 doses in 24 hours
- do not use more than 5 days unless directed by a doctor.
- find right dose on chart below, If possible, use weight to dose; otherwise, use age.

Weight (lbs.)	Age (years)	dosage-teaspoonful (tsp.)
under 24	under 2	consult Physician
24 to 35	2 to 3	1 tsp. (5 mL)
36 to 47	4 to 5	1 1/2 tsp. (7.5 mL)
48 to 59	6 to 8	2 tsp. (10 mL)

60 to 71
72 to 95

9 to 10
11

2 1/2 tsp. (12.5 mL)
3 tsp. (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, FD C RED #40, Glycerin, Polyethylene Glycol 400, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sodium Benzoate.

Questions or Comments?

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

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

Rev 09-19

Manufactured In USA

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

4 Oz

Drug Facts (continued)

■ find right dose on chart below, if possible, use weight to dose; otherwise, use age.

Weight (lbs.)	Age (yrs.)	Dose (tsp or mL)
under 24	under 2	ask a doctor
24 to 35	2 to 3	1 tsp or 5 mL
35 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.

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TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF INNER FOIL SEAL OVER MOUTH OR THE BOTTLE IS CUT, TORN, BROKEN OR MISSING.

Akron Pharma
Manufactured for
Akron Pharma, Inc.,
Fairfield, NJ - 07004
Rev 09-19
Manufactured In USA

Lot

Exp



Compare To Active Ingredient of Children's Tylenol Elixir[®] NDC 71399-0160-4

Children's Pain Relief

Pain Reliever and Fever Reducer

Acetaminophen 160 mg per 5 mL Oral Elixir

- Alcohol Free
- Aspirin Free
- For Ages 2-11 Years

Bubble Gum Flavor

4 FL OZ (118 mL) Akron Pharma

Drug Facts

Active ingredient (in each 5 mL)

Acetaminophen 160 mg.....Pain reliever/fever reducer

Purpose

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 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 (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 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 (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 ■ 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.

8 Oz

Drug Facts (continued)

■ Find right dose on chart below, if possible, use weight to dose; otherwise, use age.

Weight (lbs.)	Age (yrs.)	Dose (tsp or mL)
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.

Inactive Ingredients Bubble Gum Flavor, Citric Acid, FD C RED #40, Glycerin, Polyethylene Glycol 400, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol Solution 70% & Sodium Benzoate.

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Fairfield, NJ - 07004
Rev 09-19
Manufactured in USA

Lot

Exp



Compare To Active Ingredient of Children's Tylenol Elixir¹ NDC 71399-0160-8

Children's Pain Relief

Pain Reliever and Fever Reducer

Acetaminophen 160 mg per 5 mL

Oral Elixir

- Alcohol Free
- Aspirin Free
- For Ages 2-11 Years

Bubble Gum Flavor

8 FL OZ (236 mL)



Akron Pharma

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. **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 (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 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 (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

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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: B6978945GQ)	
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	

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)**Establishment**

Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC		081225162	manufacture(71399-0160)

Revised: 5/2021

Akron Pharma Inc.