

**APAP ELIXER (ACETAMINOPHEN)- acetaminophen elixir**  
**GERITREX LLC**

*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.*

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**APAP ELIXER (ACETAMINOPHEN)**

**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.

<b>Weight (lbs.)</b>	<b>Age (years)</b>	<b>dosage-teaspoonful (tsp.)</b>
under 24	under 2	consult Physician
24-35	2 to 3	1 tsp. (5 mL)
36-47	4 to 5	1 1/2 tsp. (7.5 mL)
48-59	6 to 8	2 tsp. (10 mL)
60-71	9 to 10	2 1/2 tsp. (12.5 mL)
72-95	11 to 12	3 tsp. (15 mL)
over 95	12 to adult	4 tsp. (20 mL)

**Other information**

- Store at room temperature 15°-30°C (59°-86°F)
- protect from freezing
- protect from light
- **each teaspoon (5mL) contains:** sodium 7 mg

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

**Inactive Ingredients:**

citric acid, FD&C red #40, glycerin, PEG 400, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water, art. cherry flavor



NDC 54162-129-16

# APAP ELIXIR

(Acetaminophen)  
ALCOHOL FREE

Fast, Safe, Pain Reliever  
without Aspirin Complications

Cherry Flavor

This is a bulk package. Dispense contents with a child resistant closure in a tight, light-resistant container as defined in the USP.

\*Compare to the active ingredients of Tylenol® liquid.

16 FL. OZ. (473 mL)

## Drug Facts

**Active ingredient** (In each 5 mL= 1 teaspoonful) **Purpose**  
Acetaminophen 160 mg.....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 nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product.

Ask a doctor before use if the user ■ has liver disease ■ is on a sodium-restricted diet.

Ask a doctor or pharmacist before use if the user 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.

Weight (lbs.)	under 24	24-35	36-47	48-59	60-71	72-95	over 95
Age (years)	under 2	2 to 3	4 to 5	6 to 8	9 to 10	11 to 12	12 to adult
Dosage-teaspoonful (tsp.)	consult Physician	1 tsp. (5 mL)	1 1/2 tsp. (7.5 mL)	2 tsp. (10 mL)	2 1/2 tsp. (12.5 mL)	3 tsp. (15 mL)	4 tsp. (20 mL)

**Other information** ■ Store at room temperature 15°-30°C (59°-86°F) ■ protect from freezing ■ protect from light ■ each teaspoon (5 mL) contains: sodium 7 mg

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

**Inactive ingredients:** citric acid, FD&C red #40, glycerin, PEG 400, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water, art. cherry flavor

\*This product is not manufactured or distributed by the owner of the registered trademark of Tylenol®

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## APAP ELIXIR (ACETAMINOPHEN)

acetaminophen elixir

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-129
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	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
FD&C RED NO. 40 (UNII: WZB9127XOA)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				
WATER (UNII: 059QF0KO0R)				
<b>Product Characteristics</b>				
Color	RED	Score		
Shape		Size		
Flavor	CHERRY (CHERRY)	Imprint Code		
Contains				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-129-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/20/2018	
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	08/20/2018		

**Labeler** - GERITREX LLC (112796248)

### Establishment

Name	Address	ID/FEI	Business Operations
GERITREX LLC		112796248	manufacture(54162-129)

Revised: 9/2018

GERITREX LLC