

ACETAMINOPHEN- acetaminophen syrup
CHAIN DRUG MARKETING ASSOCIATION INC.

Active Ingredient

Purpose

(In each 15 mL)

in Acetaminophen 500 mg..... Pain reliever/fever reducer

- Pain Reliever
- Fever Reducer

Uses

- temporarily relieves minor aches and pains due to:
 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - muscular aches
 - premenstrual and menstrual cramps
 - temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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

- skin reddening
- blisters
- rash

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

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 you have

liver disease.

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 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 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)**
- do not take more than 4 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- mL=milliliter
- keep dosing cup with product
- adults and children 12 years and over
- 30 mL every 6 hours while symptoms last
- do not take more than 10 days unless directed by a doctor
- children under 12 years: do not use

Other information

- each 15 mL contains: sodium 10 mg
- store between 20-25°C (68-77°F). Do not refrigerate.
- protect from light.

Questions or comments

1-800-935-2362 (Mon-Fri 9am-5pm EST)

Inactive ingredients

citric acid, D&C red #33, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

- **TAMPER EVIDENT: Do not use if the safety seal around or under the cap is broken or missing**
- ***Compare to Active Ingredient in Tylenol® Extra Strength***
- ***This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Extra Strength Tylenol®**

Distributed by C.D.M.A, Inc. ©

43157 W 9 Mile Rd

Novi, MI 48375

www.qualitychoice.com

PRINCIPAL DISPLAY PANEL



Drug Facts	
Active ingredients (in each 15 mL)	Purpose
Acetaminophen 500 mg	Pain reliever/fever reducer
Uses	
<ul style="list-style-type: none"> Temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> the common cold headache backache minor pain of arthritis toothache muscular aches premenstrual and menstrual cramps temporarily reduces fever 	
Warnings	
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: <ul style="list-style-type: none"> more than 4,000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product 	
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: <ul style="list-style-type: none"> skin redness hives rash If skin reaction occurs, stop use and seek medical help right away.	

Drug Facts (continued)	Drug Facts (continued)
Do not use: <ul style="list-style-type: none"> with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 	<ul style="list-style-type: none"> new symptoms occur redness or swelling is present These could be signs of a serious condition.
Ask a doctor before use if you have liver disease Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin	Continued on back label fold-out
Stop use and ask a doctor if: <ul style="list-style-type: none"> pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days 	



Drug Facts (continued)	Drug Facts (continued)
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 as well as for children even if you do not notice any signs or symptoms.	<ul style="list-style-type: none"> do not take more than 4 doses in any 24-hour period measure only with dosing cup provided. Do not use any other dosing device. 1 mL=milliliter keep dosing cup with product adults and children 12 years and over: 30 mL every 6 hours while symptoms last do not take more than 10 days unless directed by a doctor children under 12 years: do not use
Directions	
do not take more than directed (see Overdose warning)	

Drug Facts (continued)	
Other information	
<ul style="list-style-type: none"> each 15 mL contains: sodium 10 mg store between 20-25°C (68-77°F). Do not refrigerate. protect from light. 	
Inactive Ingredients	
citric acid, D&C red #33, FD&C red #40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol	
Questions or comments	
1-800-935-2362 (Mon-Fri 9am-5pm EST)	

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Novi, MI 48375
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ACETAMINOPHEN

acetaminophen syrup

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63868-809

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-809-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2023	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC. (011920774)

Registrant - Seaway Pharma Inc. (117218785)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(63868-809)

Revised: 12/2024

CHAIN DRUG MARKETING ASSOCIATION INC.