ACETAMINOPHEN- acetaminophen suspension
CHAIN DRUG MARKETING ASSOCIATION INC

Infants' Oral Suspension
Pain Reliever
Fever Reducer
Acetaminophen
Grape Flavor

Active Ingredient (in each 5 mL)	**Purpose**
Acetaminophen 160 mg	Pain reliever/fever reducer

- Pain reliever
- fever reducer

Uses temporarily:
- reduces fever
- relieves minor aches and pains

due to:

- the common cold
- headache
- flu
- 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.

When using this product do not exceed recommended dose (see overdose warning)

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

Stop use and ask a doctor if

- new symptoms occur
- redness or swelling is present
- pain gets worse or lasts more than 5 days
- fever gets worse or lasts 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 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

- this product does not contain directions or complete warnings for adult use.
- do not give more than directed (see overdose warning)
- shake well before using
- ml= milliliter
- find right dose on chart below.

If possible, use weight to dose; otherwise, use age.

- only use enclosed measuring syringe
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours

Weight (lb)	Age (yr)	Dose (mL)*
Under 24	Under 2 years	Ask a doctor
24-35	2-3 years	5 mL

* or as directed by doctor

Other information

- store between 20° -25°c (68°-77 °F)
- protect from freezing
- protect from light

Questions or comments?
1-800-935-2362 (Mon-Fri 9am-5pm EST)

Inactive ingredients

acesulfame potassium, avicel, citric acid, FD&C blue no. 1, FD&C red no. 33, flavor, glycerine, high fructose corn syrup, polysorbate, propylene glycol, prosweet N & AK, purified water, sodium benzoate, sucralose, sorbitol, xanthan gum

"This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Tylenol®

Distributed by C.D.M.A. Inc.
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
Question: 800-935-2362

PRINCIPAL DISPLAY PANEL

ACETAMINOPHEN

acetaminophen suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-677
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	grape	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-677-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/01/2021	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Registrant - Seaway Pharma Inc. (117218785)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma Inc.		117218785	manufacture(63868-677)

Revised: 12/2024 CHAIN DRUG MARKETING ASSOCIATION INC