ACETAMINOPHEN- acetaminophen suspension
CHAIN DRUG MARKETING ASSOCIATION 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.

Infants' Oral Suspension
Pain Reliever
Fever Reducer
Acetaminophen
Cherry 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 red no. 40, 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:63868-678
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 RED NO. 40 (UNII: WZB9127XOA)	
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	CHERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-678-60	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 not final	part343	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(63868-678)

Revised: 6/2021 CHAIN DRUG MARKETING ASSOCIATION INC