

**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.*

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**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

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Weight (lb)

Age (yr)

Dose (mL)\*

Under 24  
24-35

Under 2 years  
2-3 years

Ask a doctor  
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](http://www.qualitychoice.com)  
Question: 800-935-2362

### PRINCIPAL DISPLAY PANEL

The image shows the principal display panel for 'Infants' Oral Suspension'. The panel is divided into several sections. At the top left is the 'QC QUALITY CHOICE' logo. To its right is the NDC number 'NDC 63868-678-60'. Below the logo is a comparison statement: '\* Compare to Active Ingredient in Infants' Tylenol®'. The product name 'Infants' Oral Suspension' is prominently displayed in large, bold letters. Below it, the text '\* Pain Reliever • Fever Reducer' is shown. The active ingredient is listed as 'Acetaminophen' with a strength of '160 mg (in each 5 mL)'. A 'Cherry Flavor' is also indicated. The volume '2 fl oz (60 mL)' is shown at the bottom left. A vertical warning strip on the right side of the panel reads: 'TAMPER EVIDENT: Do not use if the safety seal under the cap is broken or missing.' Below this is a 'Drug Facts' section with a yellow background. It includes 'Purpose' (Pain reliever/fever reducer), 'Active ingredient' (Acetaminophen 160 mg), 'Uses' (temporarily reduces fever, relieves minor aches and pains due to the common cold, flu, sore throat, toothache), and 'Warnings' (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). At the bottom right, there is a 'Satisfaction Guaranteed' logo and distribution information: 'Distributed by C.D.M.A., Inc., 43157 W 9 Mile Rd, Novi, MI 48375, www.qualitychoice.com, Question: 800-935-2362'. A small note at the bottom right states: 'This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Tylenol®'.

NDC 63868-678-60

QC QUALITY CHOICE

\* Compare to Active Ingredient in Infants' Tylenol®

**Infants' Oral Suspension**

• Pain Reliever • Fever Reducer

Acetaminophen  
Aspirin Free  
Ibuprofen Free  
Alcohol Free

Cherry Flavor

2 fl oz (60 mL)

TAMPER EVIDENT: Do not use if the safety seal under the cap is broken or missing.

**Drug Facts**

**Purpose**  
Pain reliever/fever reducer

**Active ingredient**  
(in each 5 mL)  
Acetaminophen 160 mg

**Uses** temporarily:  
■ reduces fever  
■ relieves minor aches and pains due to:  
■ the common cold ■ headache  
■ flu ■ sore throat ■ toothache

**Warnings**  
**Liver warnings:** 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

**Satisfaction Guaranteed**

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## 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)