

**CALMOUR CHILDRENS ACETAMINOPHEN STRIPS CHEWABLE- acetaminophen  
oral chewable 80 mg strip  
Calmour**

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**Children's Acetaminophen Chewable Strips**

***Drug Facts***

**Active ingredient (in each strip)**

Acetaminophen 80 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

Temporarily: ■ reduces fever ■ relieves minor aches and pains due to: ■ flu ■ the common cold ■ headache ■ 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.

**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.

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

**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:** In case of overdose, get medical help or contact a Poison Control Center (**1-800-222-1222**) right away. Quick medical attention is critical 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)**
- find the right dose on the chart below. If possible, use weight to dose; otherwise, use age.
- remove the strip from the pouch, place in the child's mouth then wait for 45 seconds, and anything remaining can be chewed.
- repeat dose every 4-6 hours while symptoms last
- do not give more than 5 doses in 24 hours

**OPEN**



**REMOVE**



**CHEW**



## Dosing Chart

Age in Years	Wt in lbs	Number of strips given every 4-6 hours of acetaminophen 80 mg*
under 2 years	< 24 lbs	consult a doctor
2 to under 4 years	24-35 lbs	2 strips of 80 mg
4 to under 6 years	36-47 lbs	3 strips of 80 mg
6 to under 9 years	48-59 lbs	4 strips of 80 mg

Wt: weight; lb: pound; mg: milligram

\* or as directed by a doctor

### **Other information**

- store below 77°F (25°C)
- do not refrigerate
- do not use it if the pouch containing strip is open
- see lot number and expiration date on pouch containing strip and box

### **Inactive ingredients**

citric acid anhydrous, glycerin, HP-betacyclodextrin oral, hydroxypropyl methylcellulose, monoammonium glycyrrhizinate, Neelicert FD&C yellow 6, orange flavor, peppermint flavor, polysorbate 80, pregelatinized hydroxypropyl pea starch, pullulan, sodium carbonate, sucralose and xylitol.

### **Questions or comments?**

Call 1-802-861-4111

Monday-Friday, 9 am-5 pm EST

### **Distributed by:**

CALMOUR, LLC

1775 Williston Road

South Burlington, VT 05403

Phone (802) 861-4111

Calmourhealth.com

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## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

### **Pouch Label**

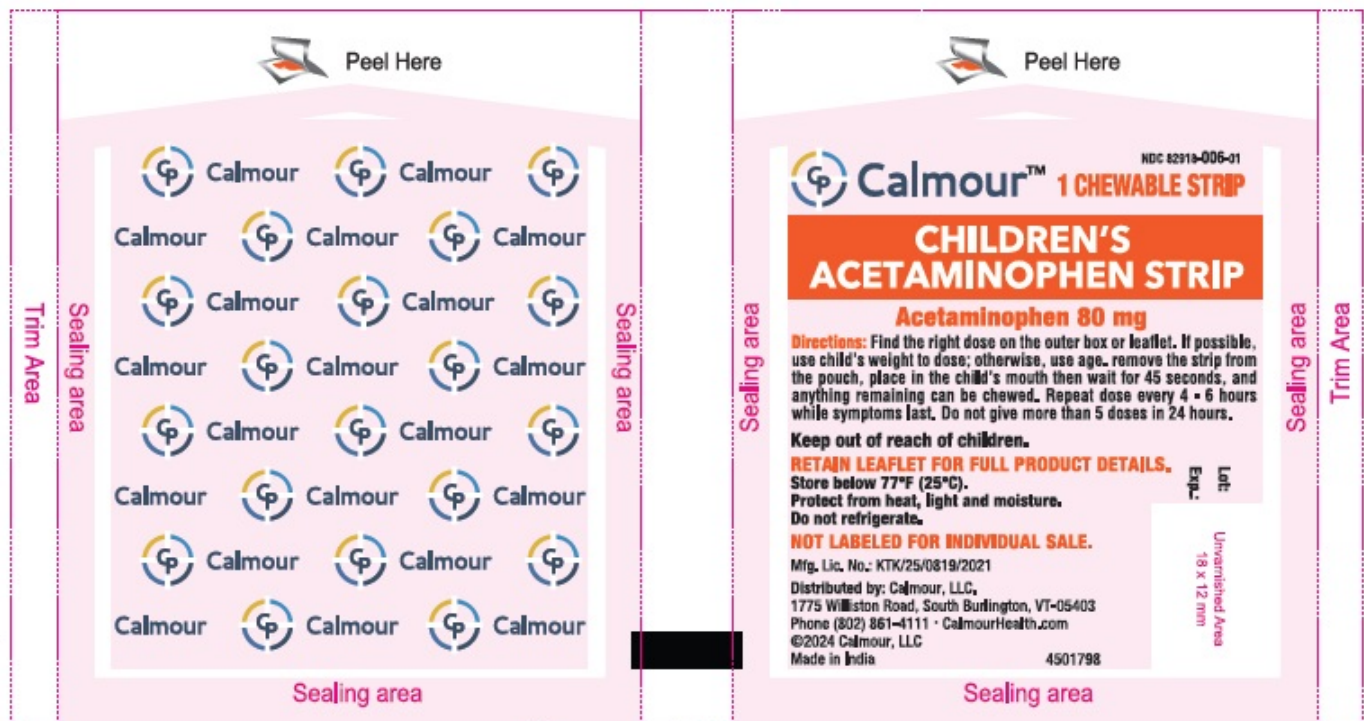
**NDC 82918-006-01**

**CHILDREN'S ACETAMINOPHEN STRIP**

# CALMOUR

Acetaminophen 80 mg

1 Chewable Strip



## POUCH LABEL

### CARTON LABEL

NDC 82918-006-24

CHILDREN'S ACETAMINOPHEN STRIPS

Oral Chewable Strip

- Pain Reliever
- Fever Reducer
- For Ages 2-9 Years

**ACETAMINOPHEN 80 mg**

Aspirin Free

Ibuprofen Free

Alcohol Free

**24 Strips**

(packed individually)

(shall be printed during packing)

Lot:  
Exp.:

Unvarnished  
Panel

**NEW**

NDC 82918-006-24

**CHILDREN'S  
ACETAMINOPHEN  
STRIPS**

**Oral Chewable Strips**

- Pain Reliever
- Fever Reducer
- For Ages 2-9 Years

ORANGE FLAVOR

**80 mg**

ACETAMINOPHEN

Aspirin Free  
Ibuprofen Free  
Alcohol Free

**24 Strips**  
(Packed Individually)

4501799

8 50053563119

**OPEN REMOVE CHEW**

4501799

Take Orally, Chew and Swallow

**Drug Facts**

<b>Active ingredient (in each strip)</b>	<b>Purpose</b>
Acetaminophen 80 mg	Pain reliever/fever reducer

**Uses** temporarily: ■ reduces fever ■ relieves minor aches and pains due to: ■ flu ■ the common cold ■ headache ■ 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.  
**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**  
**When using this product, do not exceed recommended dose (see overdose warning)**  
**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:** In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

©

**Drug Facts (continued)**

**Other information:**

- store below 77°F (25°C)
- do not refrigerate
- do not use if the pouch containing strip is open
- see lot number and expiration date on pouches and box

**Inactive ingredients:**

citric acid, ambroxol, glycerin, HP-beta-cyclodextrin, oral, hydroxypropyl methylcellulose, nonoxonium glycyrrhizate, Medivent FD&C Yellow 6, orange flavor, peppermint flavor, polyvinylpyrrolidone 80, pregelatinized hydroxypropyl pea starch, pullulan, sodium carbonate, sucralose and xylitol.

**Questions or comments?**  
 Call 1-802-861-4111  
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Mfg. Lic. No.: KTK/25/0819/2021

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**CARTON LABEL**

**CARTON LABEL**

**NDC 82918-006-36**

## **CHILDREN'S ACETAMINOPHEN STRIPS**

### **Oral Chewable Strip**

- Pain Reliever
- Fever Reducer
- For Ages 2-9 Years

### **ACETAMINOPHEN 80 mg**

Aspirin Free

Ibuprofen Free

Alcohol Free

### **36 Strips**

(packed individually)

(shall be printed during packing)

Lot:  
Exp.:

Unvarnished  
Panel

ORANGE  
FLAVOR



• Pain Reliever  
• Fever Reducer  
• For Ages 2-9 Years

Oral Chewable Strips

# CHILDREN'S ACETAMINOPHEN STRIPS

**NEW**

NDC 82918-006-36



**36 Strips**  
(Packed Individually)

Aspirin Free  
Ibuprofen Free  
Alcohol Free  
**80 mg**  
ACETAMINOPHEN



**Take Orally, Chew and Swallow**

**Drug Facts (continued)**

**Directions**

- this product does not contain directions or complete warnings for adult use
- do not give more than directed (see overdose warning)
- find the right dose on the chart below. If possible, use weight to dose; otherwise, use age.
- remove the strip from the pouch, place in the child's mouth then wait for 45 seconds, and anything remaining can be chewed.
- repeat dose every 4 - 6 hours while symptoms last
- do not give more than 5 doses in 24 hours

**Dosing Chart**

Weight (lb)	Age (yr)	Dose (80mg strip)
under 24 lbs	under 2 years	consult a doctor
24-35 lbs	2-4 years	2 strips
36-47 lbs	4-6 years	3 strips
48-59 lbs	6-9 years	4 strips

or as directed by a doctor

4501800

**Drug Facts**

**Active ingredient (in each strip)** .....Pain reliever/ fever reducer  
Acetaminophen 80 mg

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

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

**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.

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**Inactive ingredients:**  
citric acid anhydrous, glycerin, HP-beta-cyclodextrin oral, hydroxypropyl methylcellulose, monoammonium glycyrrhizinate, Neelcent F&C yellow 6, orange flavor, peppermint flavor, polysorbate 80, pregelatinized hydroxypropyl peps starch, pullulan, sodium carbonate, sucralose and xylitol.

**Drug Facts (continued)**  
**Other information:**  
■ store below 77°F (25°C)  
■ do not refrigerate  
■ do not use if the pouch containing strip is open  
■ see lot number and expiration date on pouches and box

**CARTON LABEL**

**CALMOUR CHILDRENS ACETAMINOPHEN STRIPS CHEWABLE**  
acetaminophen oral chewable 80 mg strip

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82918-006
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	80 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYDROXYPROPYL BETADEX</b> (UNII: 1I96OHX6EK)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>ORANGE</b> (UNII: 5EVU04N5QU)	
<b>PEPPERMINT</b> (UNII: V95R5KMY2B)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PULLULAN</b> (UNII: 8ZQ0AYU1TT)	
<b>SODIUM CARBONATE</b> (UNII: 45P3261C7T)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>HYDROXYPROPYL CORN STARCH (5% SUBSTITUTION BY WEIGHT)</b> (UNII: 9M44R3409A)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:82918-006-36	36 in 1 CARTON	03/01/2025	
1	NDC:82918-006-01	1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:82918-006-24	24 in 1 CARTON	02/25/2025	
2	NDC:82918-006-01	1 in 1 POUCH; Type 0: Not a Combination Product		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/25/2025	

**Labeler** - Calmour (118597110)

**Registrant** - Shilpa Medicare Limited, Unit-VI (854193706)

## Establishment

Name	Address	ID/FEI	Business Operations
Shilpa Medicare Limited, Unit-VI		854193706	ANALYSIS(82918-006) , MANUFACTURE(82918-006) , PACK(82918-006) , LABEL(82918-006)

Revised: 2/2025

Calmour