

TEMPERAL-ITO- acetaminophen suspension
OPMX Chula Vista

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.

Temperal-ito

Active Ingredient(in each 5 mL) Purpose - 118 mL

Acetaminophen 160 mg..... Pain reliever/fever reducer

Pain Reliever & Fever Reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
 - sore throat
 - the common cold
 - flu
 - headache
 - toothache

Warnings -118 mL

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if your child takes takes

- more than 5 doses in 24 hours. which is the maximum daily amount.
- with other drugs containing acetaminophen.

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: 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 - 118 mL

- this product does not contain directions or complete warnings for adult use. Shake well before using
- mL= millilitar
- find right dose on chart below, if possible, use weight to dose; otherwise, use age
- repeat dose every 4 hours while symptoms last
- only use enclosed measuring syringe
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (mL) *
under 24	under 2	ask a doctor
24-35	2-3	5 mL
36-47	4-5	7.5 mL
48-59	6-8	10 mL
60-71	9-10	12.5 mL
72-95	11	15 mL

*

Other information

- Each teaspoon (5 mL) contains: sodium 3 mg
- Store between 15°-30°C (59°-86°F)
- Protect from freezing. Protect from light

Inactive ingredients

acesulfame potassium, citric acid, FD&C red no. 40, flavor, glycerine, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, polysorbate, propylene glycol, prosweet N&AK, purified water, sodium benzoate, sucralose, sorbitol, xanthan gum.

Questions or comments?

Call toll free 619-600-5632

Monday through Friday 9AM - 5PM EST

Active Ingredient(In each 5 mL) Purpose - 60 mL

Acetaminophen 160 mg.....Pain reliever/fever reducer

Purpose

Pain Reliever & Fever Reducer

Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to:
- the common cold
- headache
- flu
- sore throat
- toothache

Warnings - 60 mL

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
- blister
- 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: 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 - 60 ml

- 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

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.

Questions or comments?

Call toll free 619-600-5632
Monday through Friday 9AM - 5PM EST

PRINCIPAL DISPLAY PANEL

NDC 69729-006-04 Temporal-ito



NDC 69729-006-04

Tamper Evident: Do not use this product if the safety seal under the cap is broken or missing.

NDC 69729-006-04

Temporal-ito

Acetaminophen 160 mg / 5mL

Support in relief of **PAIN & FEVER**



6 hours
RELIEF

For CHILDREN
SAFE FOR 2-11 YEARS



Cherry Flavor

4 fl oz (118 mL)

Drug Facts

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

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

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: 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.

Temporal-ito

Acetaminofén 160 mg / 5mL

Rápido Alivio de **FIEBRE y DOLOR**



6 hours
RELIEF

Uso INFANTIL
de 2 a 11 años



Sabor Cereza

4 fl oz (118 mL)

Drug Facts (continued)

Directions

- this product does not contain directions or complete warnings for adult use. Shake well before using
- mL = milliliter
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.
- repeat dose every 4 hours while symptoms last
- only use enclosed measuring cup
- do not give more than 5 times in 24 hours
- do not give more than 5 days unless directed by a doctor.

Weight (lb.)	Age (yrs.)	Dose (mL) ¹
Under 24	Under 2	Ask a doctor
24 - 35	2 - 3	5mL
36 - 47	4 - 5	7.5 mL
48 - 59	6 - 8	10mL
60 - 71	9 - 10	12.5mL
72 - 95	11	15mL

¹always check with your doctor before administering medicine to your infant/child

Other information

- each teaspoon (5 mL) contains: sodium 3 mg
- Store between 15°-30° C (59°-86° F)
- Protect from Freezing, Protect from light

Inactive ingredients

acesulfame potassium, citric acid, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, microcrystalline cellulose and carboxymethylcellulose sodium, polysorbate, propylene glycol, prosweet N & AK, purified water, sodium benzoate, sucralose, sorbitol, xanthan gum

Questions or comments

Call toll free 619-600-5632
Monday through Friday 9AM - 5PM EST

VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA



Manufactured in
FDA Registered Facility
in the USA



PLATA O PLOMO IMPORTACIONES
Hecho en Estados Unidos bajo derechos
de distribución para el plomo
Atención N° 24 - 57 Bogotá D.C.

ITEM #: PLO03
REV: 05.2023



Lot:

Exp:

NON VARNISH AREA

NDC 69729-006-02



TEMPERAL-ITO acetaminophen suspension			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-006
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
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
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: 059QF0K00R)	
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:69729-006-04	1 in 1 CARTON	06/02/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69729-006-02	1 in 1 CARTON	06/02/2023	
2		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/02/2023	

Labeler - OPMX Chula Vista (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Bajaj Medical, LLC		078774921	manufacture(69729-006) , pack(69729-006) , label(69729-006)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma		117218785	manufacture(69729-006)

Revised: 6/2023

OPMX Chula Vista