

MEJORALITO- acetaminophen suspension

OPMX Chula Vista

Mejoralito

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:
- sore throat
- the common cold
- flu
- headache
- toothache

Warnings

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

- 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 (yrs.)	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

*always 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, 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

PRINCIPAL DISPLAY PANEL

NDC 69729-068-04 Temporal-ito

NDC 69729-068-04

Mejoralito®

ORAL SUSPENSION

Quick Relief of Fever & Pain

Children 2 to 11 Years



Cherry Flavor

4 fl oz (118 mL) 160 mg per 5 mL

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

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:
 ■ the common cold ■ flu ■ headache ■ toothache
 ■ sore throat

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.

4 fl oz (118 mL) Cherry Flavor

Mejoralito®

ORAL SUSPENSION

Quick Relief of Fever & Pain

Children 2 to 11 Years



NDC 69729-068-04

Mejoralito®

ORAL SUSPENSION

Rápido Alivio para Fiebre y Dolor

Infantil de 2 a 11 Años



Sabor Cereza

4 fl oz (118 mL) 160 mg cada 5 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)
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

Always 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

Exclusively distributed by:

 Chula Vista, CA 91910
 Phone: 619-600-5632

Manufactured in FDA Registered Facility in the USA



Glue - No Coating

ITEM #: INX045
 REV: 05/2023



8 50043 16903 1

Lot:

Exp:

NON VARNISH AREA

MEJORALITO
 acetaminophen suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-068
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
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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-068-04	1 in 1 CARTON	06/02/2023	
1		118 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 Drug	M013	06/02/2023	

Labeler - OPMX Chula Vista (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma		117218785	manufacture(69729-068)

Revised: 11/2024

OPMX Chula Vista