

**ACETAMINOPHEN- acetaminophen suspension**  
**TEMP X- acetaminophen suspension**  
**MEJORALITO- acetaminophen suspension**  
**OPMX LLC**

*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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**Active Ingredient(in each 5mL) 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 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 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= millilitar
- 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

<b>Weight (lb)</b>	<b>Age (yr)</b>	<b>Dose (mL) *</b>
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?**

Call toll free 619-600-5632

Monday through Friday 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.

**Distributed by:**

OPMX, Chula Vista CA 91910

**PRINCIPAL DISPLAY PANEL**

NDC 69729-028-02

# PENTREXCILINA

## Fiebre Infantil

ACETAMINOPHEN 160 mg / 5 mL  
Suspension Oral

Glue - No Coating

### Rápido alivio contra Fiebre y Dolor

Uso infantil Seguro para:  
**2-3 años**

- ✓ Libre de Ibuprofeno
- ✓ Libre de Alcohol
- ✓ Libre de Aspirina



2 fl oz (60 mL)

**TAMPER EVIDENT: Do not use 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
  - headache
  - flu
  - sore throat
  - toothache

**Warnings**  
**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you 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

# PENTREXCILINA

## Fever Infant

ACETAMINOPHEN 160 mg / 5 mL  
Oral suspension

### Pain Reliever & Fever Reducer

NDC 69729-028-02

SEE NEW DIRECTIONS AND WARNINGS

# PENTREXCILINA

## Fever Infant

ACETAMINOPHEN 160 mg / 5 mL  
Oral suspension

### Pain Reliever & Fever Reducer

Safe & Effective for:  
**2-3 years**

- ✓ Ibuprofen Free
- ✓ Alcohol Free
- ✓ Aspirin Free



2 fl oz (60 mL)

### Drug Facts (continued)

**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

**Inactive ingredients**  
 acesulfame potassium, avicel, citric acid, FD&C red no. 40, flavor, glycerine, high fructose corn syrup, polyorbate, propylene glycol, prosweet N&A, 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:

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

Made for:

**RX**  
 San Diego, CA

Manufactured in FDA Registered Facility in the USA



Item No: RRX1051 Rev.: 01.2022



Lot No.:

Exp. Date:

NON VARNISH AREA

2 fl oz (60 mL)

NDC 69729-047-02

# Temp X

Acetaminophen 160 mg/5mL

Infant Fever  
Oral Suspension



FOR INFANTS  
safe & effective for 2-3 years

**PAIN & FEVER**  
Reliever & Reducer

Cherry Flavor



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

### Drug Facts

**Active ingredient (in each 5 mL)**  
Acetaminophen 160 mg.....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 you 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 redness ■ 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

2 fl oz (60 mL)

NDC 69729-047-02

# Temp X

Paracetamol 160 mg/5mL

Fiebre Infantil  
Suspensión Oral



USO INFANTIL  
seguro para 2-3 años

Rápido alivio contra  
**FIEBRE y DOLOR**

Sabor Cereza



### Drug Facts (continued)

**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) <sup>†</sup>
under 24	under 2 years	ask a doctor
24-35	2-3 years	5 mL

<sup>†</sup> or as directed by doctor

**Other information**  
■ store between 20°-25°C (68°-77°F)  
■ protect from freezing ■ protect from light

**Inactive ingredients**  
ascorbic acid, potassium, citric acid, FD&C red no. 40, flavor, glycerine, high fructose corn syrup, polysorbate, propylene glycol, presweet NAAK, 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:

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

**inovx**  
PHARMACEUTICALS

Manufactured in  
FDA Registered Facility  
in the USA



Glue - No Coating

REV. 01.2022 (N0071)



Lot No.:

Exp. Date:

NON VARNISH AREA

Glue - No Coating

**Mejoralito**  
Pediatric Acetaminophen  
SUSPENSION

From **2** years to **3** years  
Quickly relieves ✓  
fever and pain

Cherry Flavor  
**SUSPENSION**  
2 fl oz (60 mL)

**Mejoralito**  
Pediatric Drops  
ACETAMINOPHEN

Quickly relieves ✓  
fever and pain

From **2** years to **3** years

**Mejoralito**  
Acetaminofén Pediátrico  
SUSPENSION

De **2** años a **3** años  
Alivio rápido ✓  
para la fiebre  
y el dolor

Sabor Cereza  
**SUSPENSION**  
2 fl oz (60 mL)

REL. 01.2022 (INV030)

8 60006 09516 1

Lot No.: \_\_\_\_\_

Exp. Date: \_\_\_\_\_

NON VARNISH AREA

**TAMPER EVIDENT:** Do not use 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 ■ headache ■ flu  
■ sore throat ■ toothache

**Warnings**  
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you 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 redness ■ 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

**Drug Facts (continued)**

**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

**Inactive ingredients**  
acesulfame potassium, avicel, citric acid, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, polyorbate, propylene glycol, prosweet NSAK, purified water, sodium benzoate, sucralose, sorbitol, xanthan gum.

**Questions or comments?**  
Call toll free 619-600-6632  
Monday through Friday 9AM - 5PM EST

VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA

Exclusively distributed by:  
OPMX  
Ocala Vista, CA 91910  
Phone: 619-600-6632

Manufactured in  
FDA Registered Facility  
in the USA

## ACETAMINOPHEN

acetaminophen suspension

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-028
<b>Route of Administration</b>	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: 230V73Q5G9)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)
<b>SORBITOL</b> (UNII: 506T60A25R)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)

Product Characteristics			
<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-028-02	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	

## TEMP X

acetaminophen suspension

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-047
<b>Route of Administration</b>	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)	
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: 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:69729-047-02	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	

## 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
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<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HIGH FRUCTOSE CORN SYRUP</b> (UNII: XY6UN3QB6S)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-068-02	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** - OPMX LLC (029918743)

**Registrant** - Seaway Pharma (117218785)

### Establishment

Name	Address	ID/FEI	Business Operations
Seaway Pharma		117218785	manufacture(69729-028, 69729-047, 69729-068)

