

**TEMP X- 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.*

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**Temp X**

**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

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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

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\*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 69729-047-04 Temp X

4 fl oz (118 mL) NDC 69729-047-04

# Temp X

Acetaminophen 160 mg / 5mL  
Oral Suspension

**PAIN Reliever & FEVER Reducer**

**6 hours**

Cherry Flavor

**FOR CHILDREN**  
from 2 to 11 years

Glue - No Coating

**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: ■ 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**

**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) NDC 69729-047-04

# Temp X

Acetaminofén 160 mg / 5mL  
Suspensión Oral

**Alivia el DOLOR y Baja la FIEBRE**

**6 horas**

Sabor Cereza

**USO INFANTIL**  
de 2 a 11 años

**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	5mL
36 - 47	4 - 5	7.5 mL
48 - 59	6 - 8	10mL
60 - 71	9 - 10	12.5mL
72-95	11	15mL



† 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, polyorbate, 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

ITEM #: IN1047  
REV: 05.2023



8 10053 18114 0

Lot: \_\_\_\_\_  
Exp: \_\_\_\_\_

NON VARNISH AREA

<b>TEMP X</b> acetaminophen suspension			
<b>Product Information</b>			
<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
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: 230V73Q5G9)	
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:69729-047-04	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 not final	part343	06/02/2023	

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## Establishment

Name	Address	ID/FEI	Business Operations
Bajaj Medical, LLC		078774921	manufacture(69729-047) , pack(69729-047) , label(69729-047)

Revised: 6/2023

OPMX Chula Vista