

RESFRIOL-ITO CHILDREN- acetaminophen tablet, chewable
OPMX LLC

Resfriol-ito Children's w24 Chewables

Drug Facts

Active ingredients (in each chewable tablet)

- Acetaminophen 160 mg

Purposes

- Pain reliever/ Fever reducer

Uses

Temporarily relieves minor aches and pains due to:

- Headache
- Toothache
- Flu
- Sore throat
- The common cold
- Temporarily reduces fever

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 nonprescription). 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 or pharmacist before use if your child is

taking the blood thinning drug warfaron.

When using this product do not exceed recommended dosage.

Ask a doctor before use if your child has liver disease.

Stop use and ask a doctor if

- Pain gets worse or lasts more than 5 days
- Fever gets worse or lasts more the 3 days
- New symptoms occur
- Redness or swelling is present.

These could be signs of a serious condition.

Keep out of reach of children.

Keep out of reach of children.

In case of overdose, get medical help or contact a Posin Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or syptoms.

Directions

- **This product does not contain directions or complete warnings for adult use.**
- **Do not give more than directed.**
- Find the right dose on chart below. If possible, use weight to dose; otherwise, use age.
- Chew or crush tablets completely before swallowing; do not swallow tablets whole.
- Repeat dose every 4 hours while symptoms last.
- Do not give more than 5 times in 24 hours.
- Do not give for more than 5 days unless directed by a doctor.

Weigh (lb)	Age (yr)	Dose (chewable tablets)*
Under 24	Under 2	Ask a doctor
24-35	2-3	1 tablet
36-47	4-5	1 1/2 tablets
48-59	6-8	2 tablets
60-71	9-10	2 1/2 tablets
72-95	11	3 tablets

*or as directed by a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- Avoid high humidity
- Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- See end flap for expiration date and lot number

Inactive ingredients

Citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrans hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose.

Questions or comments?

Call **(619)600-5632** (Mon-Fri 9am - 5pm PST)

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

Phone: 619-600-5632

NDC 69729-161-24

RESFRIOL-ITO®

Children

Acetaminophen 160 mg

2-11

YEARS/AÑOS

Auxiliar en el alivio del DOLOR Y FIEBRE

Pain Reliever / Fever Reducer

- Aspirin Free / Sin Aspirina
- Ibuprofen Free / Sin ibuprofeno

Sabor Uva

Grape Flavor

24 Tabletas Masticables Chewable Tablets

NO VARNISH AREA

NO VARNISH AREA

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- Do not give more than 5 times in 24 hours.
- Do not give for more than 5 days unless directed by a doctor.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

These could be signs of a serious condition:

- Redness or swelling is present.
- New symptoms occur.
- Fever gets worse or lasts more than 5 days.
- Pain gets worse or lasts more than 5 days.

Stop use and ask a doctor if:

- When using this product do not exceed recommended dosage. Ask a doctor before use if your child has liver disease.

Drug Facts (continued)

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

Do not use

With any other drug containing acetaminophen (prescription or nonprescription). 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.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Severe liver damage may occur if your child takes more than 5 doses in 24 hours, which is the maximum daily amount.

Other drugs containing acetaminophen may cause severe skin reactions. Symptoms may include:

- Skin redness
- Rash
- Blister

Temporarily relieves minor aches and pains due to:

- Flu
- Headache
- Toothache
- The common cold
- Sore throat
- Temporarily reduces fever

Warnings

Acetaminophen 160 mg (in each chewable tablet)

Pain reliever / Fever reducer

Purposes

Auxiliar en el alivio del DOLOR Y FIEBRE
Pain Reliever / Fever Reducer

RESFRIOL-ITO[®]
Children

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NDC 69729-161-24

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2-11
YEARS / AÑOS

Auxiliar en el alivio del DOLOR Y FIEBRE

Pain Reliever / Fever Reducer

- Aspirin Free / Sin Aspirina
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Sabor Uva
Grape Flavor

24 Tabletas Masticables
Chewable Tablets

Batch:
Exp Date:

NO VARNISH AREA

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Children

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



inov
FARMACEUTIQUE



8 10053 18157 7
Rev: 10-2025
Item #: R0X1151

ABRA HININAV ON	<p>Datos del medicamento</p> <p>Ingredientes Activos Propósito (in each chewable tablet) Acetaminofén 160 mg.....Analgésico/ Reductor de Fiebre</p>	<p>Datos del medicamento (continuación)</p> <p>Consulta a un médico o farmacéutico antes de usar este medicamento si tu hijo está tomando el anticoagulante warfarina.</p> <p>Cuando uses este producto, no excedas la dosis recomendada. Consulta a un médico antes de usar este medicamento si tu hijo tiene enfermedad hepática.</p>	NO AVRINISH VREB																				
	<p>Usos Alivia temporalmente dolores menores y molestias debido a:</p> <ul style="list-style-type: none"> Dolor de Cabeza Dolor de Muela Flu Dolor de Garganta Resfriado Común Reduce temporalmente la fiebre 	<p>Suspenda el uso y consulte a un médico si:</p> <ul style="list-style-type: none"> El dolor empeora o dura más de 5 días. La fiebre empeora o dura más de 3 días. Aparecen nuevos síntomas. Hay enrojecimiento o hinchazón. <p>Estos podrían ser signos de una condición grave.</p>																					
	<p>Advertencias</p> <p>Advertencia sobre el hígado: Este producto contiene acetaminofén. Puede causar daño hepático grave si tu hijo toma:</p> <ul style="list-style-type: none"> Más de 5 dosis en 24 horas (límite máximo diario) Otros medicamentos que también contengan acetaminofén <p>Advertencia de alergia: El acetaminofén puede causar reacciones cutáneas graves. Los síntomas pueden incluir:</p> <p>Enrojecimiento de la piel Ampollas Erupción cutánea</p> <p>Si ocurre una reacción en la piel, suspender el uso y buscar ayuda médica de inmediato.</p> <p>Advertencia sobre el dolor de garganta: Si el dolor de garganta es severo, dura más de 2 días o se acompaña de fiebre, dolor de cabeza, sarpullido, náuseas o vómitos, consultar a un médico.</p>	<p>Manténgase fuera del alcance de los niños. En caso de sobredosis, busque ayuda médica o comuníquese de inmediato con un Centro de Control de Envenenamientos. La atención médica rápida es crucial tanto para adultos como para niños, incluso si no nota ningún signo o síntoma.</p>																					
	<p>No usar</p> <p>Con otros medicamentos que contengan acetaminofén (de prescripción o sin receta). Si no estás seguro, consulta con un médico o farmacéutico.</p> <p>Si tu hijo es alérgico al acetaminofén o a alguno de los ingredientes inactivos de este producto.</p>	<p>Indicaciones</p> <ul style="list-style-type: none"> Este producto no contiene instrucciones ni advertencias completas para el uso en adultos. No dé más de lo indicado. Encuentre la dosis correcta en la tabla a continuación. Si es posible, utilice el peso para la dosis; de lo contrario, utilice la edad. Mástique o triture completamente las tabletas antes de tragarlas; no trague las tabletas enteras. Repita la dosis cada 4 horas mientras duren los síntomas. No dé más de 5 veces en 24 horas. No dé por más de 5 días a menos que lo indique un médico. 																					
	<p>Datos del medicamento (continuación)</p> <table border="1"> <thead> <tr> <th>Weight (lb)</th> <th>Age (yr)</th> <th>Dose (chewable tablets)*</th> </tr> </thead> <tbody> <tr> <td>Menos de 24</td> <td>Menos de 2</td> <td>Consulte a un doctor</td> </tr> <tr> <td>24-35</td> <td>2-3</td> <td>1 tableta</td> </tr> <tr> <td>36-47</td> <td>4-5</td> <td>1 1/2 tabletas</td> </tr> <tr> <td>48-59</td> <td>6-8</td> <td>2 tabletas</td> </tr> <tr> <td>60-71</td> <td>9-10</td> <td>2 1/2 tabletas</td> </tr> <tr> <td>72-95</td> <td>11</td> <td>3 tabletas</td> </tr> </tbody> </table> <p>*o según lo indicado por un médico</p>	Weight (lb)	Age (yr)	Dose (chewable tablets)*	Menos de 24	Menos de 2	Consulte a un doctor	24-35	2-3	1 tableta	36-47	4-5	1 1/2 tabletas	48-59	6-8	2 tabletas	60-71	9-10	2 1/2 tabletas	72-95	11	3 tabletas	<p>Otra Información</p> <ul style="list-style-type: none"> EVIDENCIA DE ALTERACIÓN: NO USE SI EL PAQUETE EXTERIOR ESTÁ ABIERTO O EL BLISTER ESTÁ ROTO O QUEBRADO. Evite la alta humedad. Conservar a 25°C (77°F); se permiten variaciones entre 15° -30°C (59° -86°F). Consulte el reverso para la fecha de vencimiento y el número de lote.
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	<p>Ingredientes Inactivos</p> <p>Ácido cítrico, crospovidona, D&C rojo #27 laca de aluminio, D&C rojo #30 laca de aluminio, dextratos hidratados, etilcelulosa, FD&C azul #1 laca de aluminio, sabores, estearato de magnesio, manitol, polietileno, ácido estearico, sucralosa.</p>	<p>¿Preguntas o comentarios?</p> <p>Llame al (619)600-5632 (Mon- Fri 9am - 5pm PST)</p>																					

RESFRIOL-ITO CHILDREN

acetaminophen tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-161
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg

Inactive Ingredients

Ingredient Name	Strength
ETHYLCELLULOSE (UNII: 7Z8S9VY24B)	
CITRIC ACID (UNII: 2968PHW8QP)	
D&C RED NO. 30 ALUMINUM LAKE (UNII: GE75M6YV5W)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSPVIDONE (UNII: 2S7830E561)	
POLYETHYLENE (UNII: UG00KM4WR7)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
DEXTRATES (UNII: G263MI44RU)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
MANNITOL (UNII: 3OWL53L36A)	

Product Characteristics

Color	purple (Light purple/pink)	Score	no score
Shape	OVAL (Oblong)	Size	17mm
Flavor	GRAPE	Imprint Code	OPMX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-161-24	2 in 1 CARTON	01/30/2026	
1		12 in 1 BLISTER PACK; 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	01/30/2026	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
HBC HEALTHCARE PRIVATE LIMITED		854255181	manufacture(69729-161)

Revised: 1/2026

OPMX LLC