

**COLDTAC SEVERE COLD MAX RELIEF- acetaminophen, dextromethorphan hydrobromide capsule, liquid filled  
OPMX LLC**

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**Coldtac Severe Cold Max Relief w/10 Softgels**

***Drug Facts***

***Active ingredients (in each Softgel)***

Acetaminophen 325mg

Dextromethorphan HBr 10mg

***Purpose***

- Pain reliever/Fever reducer
- Cough suppressant

***Uses***

Temporarily relieves common cold/flu symptoms:

- Cough due to minor throat & bronchial irritation
- Sore throat
- Headache
- Minor aches and pains
- Fever

***Warnings***

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

- More than 4 doses in 24 hrs, which is the maximum daily amount for this product.
- With other drugs containing acetaminophen.
- 3 or more alcoholic drinks daily while using this product.

**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, lasts 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 a pharmacist.
- If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

**Ask a doctor before use if you have**

- Liver disease
- Heart disease
- Diabetes
- High blood pressure
- Trouble urinating due to enlarged prostate gland
- Cough that occurs with too much phlegm (mucus)
- Persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis or emphysema.

**Ask a doctor or pharmacist before use if you are:**

Taking the blood thinning drug warfarin.

**When using this product,**

do not use more than directed.

**Stop use and ask a doctor if**

- You get nervous, dizzy or sleepless.
- Symptoms get worse or last more than 5 days (children) or 7 days (adults).
- Fever gets worse or lasts more than 3 days.
- Redness or swelling is present.
- New symptoms occur.
- Cough comes back, or occurs with rash or headache that lasts.

These could be signs of a serious condition.

**Keep out of reach of children.**

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**If pregnant or breast-feeding,**

ask a health professional before use.

**Overdose warning:**

Taking more than directed can cause serious health problems. 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**

- Take only as directed.
- Do not exceed 4 doses per 24 hours.

Adults & children 12 yrs & over	2 softgels with water every 4 hrs
Children 4 to under 12 yrs	Ask a doctor
Children under 4 yrs	Do not use

**Other information**

- Store at room temperature.

**Inactive ingredients:**

FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide.

**Questions?**

Call toll free 619-600-5632

Monday through Friday 9AM - 5PM EST

**Distributed By**

Made for:

RRX

San Diego, CA 92154

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

**Phone: 619-600-5632**

NDC 69729-808-10

**COLDTAC**

**SEVERE COLD**

**Acetaminophen 325mg / Dextromethorphan HBr 10mg**

**MAX RELIEF**

**Cold and Flu Relief:**

Para el alivio de las molestias de la Gripe:

**Headache & Sore Throat**

Dolor de Cabeza y Garganta

## **Fever Reducer**

Reduce la Fiebre

## **Cough Suppressant**

Supresor de la Tos

**10 Soft Gels**

REV 12.2025 ITEM RRX1018



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**Drug Facts (continued)**

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Dextromethorphan HBr 10mg ..... Cough suppressant

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**Ask a doctor before use if you have**  
• High blood pressure • Liver disease • Heart disease • Diabetes • High blood pressure • Trouble urinating due to enlarged prostate gland • Cough that

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**Other information** • Store at room temperature.

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NDC 69729-808-10

Acetaminophen 325mg / Dextromethorphan HBr 10mg

**MAX RELIEF**

**Cold and Flu Relief:**  
Para el alivio de las molestias de la Gripe:

- Headache & Sore Throat**  
Dolor de Cabeza y Garganta
- Fever Reducer**  
Reduce la Fiebre
- Cough Suppressant**  
Supresor de la Tos



**10 Soft Gels**

# COLDTAC SEVERE COLD

Lot No.:  
Exp. date

NO VARNISH AREA

**TAMPER EVIDENT:**  
Do not use if package is opened or if blister unit is torn, broken or shows any sign of tampering

## Información Farmacológica

### Ingredientes activos (en cada cápsula)

Acetaminofén 325 mg .....Alivia el dolor/Reduce la fiebre  
Dextrometorfano HBr 10 mg .....Supresor de la tos

### Propósito

**Usos** Alivia temporalmente los síntomas de la gripe y resfriado:  
• Tos por irritación leve de la garganta y bronquios  
• Dolor de garganta • Dolor de cabeza • Dolores leves • Fiebre

### Advertencias

**Advertencia para el hígado:** Este producto contiene acetaminofén. Puede producirse daño hepático grave si toma: • Más de 4 dosis en 24 hrs, que es la cantidad máxima diaria para este producto.  
• Con otros medicamentos que contengan acetaminofén.  
• 3 o más bebidas alcohólicas al día mientras usando este producto.

**Alerta de alergia:** El acetaminofén puede causar reacciones cutáneas graves. Los síntomas pueden incluir: • Enrojecimiento de la piel  
• Ampollas • Erupción cutánea • Si se produce una reacción cutánea, interrumpa su uso y busque ayuda médica de inmediato.

**Advertencia sobre el dolor de garganta:** Si el dolor de garganta es intenso, dura más de 2 días, va acompañado o seguido de fiebre, dolor de cabeza, erupción cutánea, náuseas o vómitos, consulte inmediatamente a un médico.

**No utilizar** • Con ningún otro medicamento que contenga acetaminofén (con o sin receta).  
• Si no está seguro de si un medicamento contiene acetaminofén, pregunte a su médico o farmacéutico.  
• Si está tomando un inhibidor de la monoaminoxidasa (IMAO) de venta con receta (ciertos medicamentos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson), o durante 2 semanas después de dejar de tomar el medicamento IMAO.  
• Si no sabe si su medicamento recetado contiene un IMAO, pregunte a su médico o farmacéutico antes de tomar este producto.

**Consulte a su médico si sufre de** • Enfermedad hepática  
• Enfermedad cardíaca • Diabetes • Hipertensión arterial • Dificultad para orinar debido al agrandamiento de la próstata • Tos con demasiada flema (mucosidad) • Tos persistente o crónica como ocurre con el tabaquismo, el asma, la bronquitis crónica o el enfisema.

**Consulte a su médico o farmacéuta antes de tomar este medicamento si:** Está tomando el medicamento anticoagulante warfarina.

**Cuando use este medicamento,** no use más de lo indicado.

**Deje de utilizarlo y consulte a un médico si** • Se siente nervioso, mareado o con insomnio. • Los síntomas empeoran o duran más de 5 días (niños) o 7 días (adultos). • La fiebre empeora o dura más de 3 días.  
• Aparece enrojecimiento o hinchazón. • Aparecen nuevos síntomas.  
• Reaparece la tos, o aparece una erupción cutánea o dolor de cabeza de larga duración. Pueden ser signos de una enfermedad grave.

**Manténgase fuera del alcance de los niños.**

**Si está embarazada o en período de lactancia,** consulte a su médico antes de utilizarlo.

**Advertencia de sobredosis:** Tomar más de lo indicado puede causar graves problemas de salud. En caso de sobredosis, busque ayuda médica o póngase en contacto con un Centro de Toxicología inmediatamente. La pronta atención médica es fundamental tanto para los adultos como para los niños, incluso si no nota ningún signo o sintoma.

**Indicaciones** • Tome sólo lo indicado. • No exceda 4 dosis en 24 hrs.

Adultos y niños mayores de 12 años	2 cápsulas con agua cada 4 horas
Niños de 4 a 12 años	Consultar al médico
Niños menores de 4 años	No tomar

**Información adicional** • Conservar a temperatura ambiente.

**Ingredientes inactivos:** FD&C Rojo n° 40, FD&C Amarillo n° 6, gelatina, glicerina, polietilenglicol, povidona, propilenglicol, agua purificada, sorbitol, dióxido de titanio.

### ¿Preguntas?

Llame al 619-600-5632 de Lun-Vie 9 am - 5 pm EST

## COLDTAC SEVERE COLD MAX RELIEF

acetaminohpen, dextromethorphan hydrobromide capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-808
<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	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

**POVIDONE** (UNII: FZ989GH94E)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	AP01
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-808-10	1 in 1 CARTON	01/29/2026	
1		10 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	M012	01/29/2026	

**Labeler** - OPMX LLC (029918743)

### Establishment

Name	Address	ID/FEI	Business Operations
Rebase Lifescience Private Limited		861502593	manufacture(69729-808)

Revised: 1/2026

OPMX LLC