

**GUAIFENESIN, DEXTROMETHORPHAN HBR- guaifenesin, dextromethorphan  
hbr capsule, liquid filled  
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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**TENALIF**

**(DEXTROMETHORPHAN HBR 20MG, GUAIFENESIN 400MG SOFTGEL)**

Drug facts

Active ingredients (in each softgel)	Purpose
Dextromethorphan HBr 20 mg	Cough Suppressant
Guaifenesin 400 mg	Expectorant

**Uses**

helps loosen phlegm (mucus)  
helps thin bronchial secretions to make coughs more productive

**Do not use**

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**

cough that occurs with too much phlegm (mucus)  
cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Stop use and ask a doctor if**

cough lasts for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

**If pregnant or breast-feeding**

ask a health professional before use  
Keep out of reach of children.

**Overdose warning**

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

## **Directions**

Do not take more than directed - **See Overdose warning**

Do not use for more than 7 days.

Do not take more than 6 softgels in 24 hours

Adults and children 12 years of age & over:

Take 1 softgel every 4 hours with a full glass of water while symptoms persist

Children under 12 years of age:

Do not use

## **Other information**

Store at room temperature between 20-25°C (68-77°F)

Avoid excessive heat and humidity

D&C yellow No. 10, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, titanium dioxide.

## **Questions or comments?**

Call: (619) 600-5632 (Mon-Fri 9am-5pm EST)

VERSIÓN EN ESPAÑOL EN EL INTERIOR DE LA CAJA

Tenalif - Adults

Tesaperlas

Expectorant & Cough Suppressant

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING**

Tenalif

Adults

Tesaperlas

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Expectorant & Cough Suppressant

Made for:

RRX

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

Phones: 619-600-5632

**TAMPER EVIDENT:**

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

**PRINCIPAL DISPLAY PANEL**

NDC 69729-783-02

Tenalif® - Adults

Tesaperlas

Expectorante & Supresor de la Tos

Expectorant & Cough Suppressant

Controls cough

Controla la tos

Thins & loosens mucus

Adelgaza y expulsa las flemas

**SOFTGELS**

Dextromethorphan HBr 20 mg / Guaifenesin 400 mg

20 Softgels Box

Tenalif

Adults

Tesaperlas

Expectorante & Supresor de la Tos

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

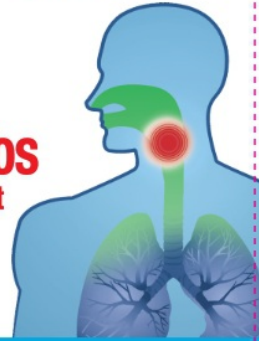
NDC 69729-783-02

Tenalif

Adults

Tesaperlas

Expectorante & Supresor de la Tos  
Expectorant & Cough Suppressant



- Controls cough *Controla la tos*
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SOFTGELS

Dextromethorphan HBr 20 mg / Guaifenesin 400 mg

20 Softgels Box

NO VARNISH AREA

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Tenalif

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VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA



Tesaperlas

Expectorant & Cough Suppressant  
Dextromethorphan HBr 20 mg Guaifenesin 400 mg



Made for:

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

Exclusively distributed by:

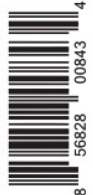
TAMPER EVIDENT:  
Do not use if package is opened or if blister unit is torn, broken or shows any sign of tampering

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGN OF TAMPERING

NO VARNISH AREA

Read & keep outer package for complete product information

ITEM # RRX1071 REV: 09-2022



8

NO VARNISH AREA

Lot No.:

Exp. Date:

### Información del Fármaco

#### Ingredientes Activos (en cada cápsula)

Dextrometorfan HBr 20 mg ..... Supresor de la tos  
Guafenesina 400 mg ..... Expectorante

#### Propósito

#### Usos:

- Ayuda a aflojar la flema (moco)
- Ayuda a diluir las secreciones bronquiales para que la tos sea más productiva

#### Advertencias:

##### No utilizar:

- si está tomando ahora un inhibidor de la monoaminoxidasa (IMAO) de prescripción médica (ciertos medicamentos para la depresión, afecciones psiquiátricas o emocionales, o la enfermedad de Parkinson), o durante 2 semanas después de dejar el medicamento IMAO.
- si no sabe si su medicamento recetado contiene un IMAO, pregunte a un médico o farmacéutico antes de tomar este producto.

##### Consulte a un médico antes de usarlo si tiene:

- tos que se produce con demasiada flema (mucosidad)
- tos persistente o crónica como la que se produce con el tabaquismo, el asma, la bronquitis crónica o el enfisema.

##### Suspenda su uso y consulte a un médico si:

- La tos dura más de 7 días, se repite o va acompañada de fiebre, sarpullido o dolor de cabeza persistente. Estos podrían ser signos de una enfermedad grave.

Si está embarazada o en periodo de lactancia: consulte a un profesional de la salud antes de utilizarla.

Mantener fuera del alcance de los niños

### Información del Fármaco (continuación)

**Advertencia de sobredosis:** En caso de sobredosis, busque ayuda médica o póngase en contacto con un Centro de Control de Intoxicaciones de inmediato. La atención médica inmediata es fundamental tanto para los adultos como para los niños, incluso si no se observa ningún signo o síntoma.

#### Indicaciones:

- No tomar más de lo indicado - Ver Advertencia de sobredosis
- No usar durante más de 7 días.
- No tomar más de 6 cápsulas blandas en 24 horas.

Adultos y niños mayores de 12 años	Tomar 1 cápsula blanda cada 4 horas con un vaso lleno de agua mientras persistan los síntomas
Niños menores de 12 años	No utilizar

#### Otras informaciones:

- Almacenar a temperatura ambiente entre 20-25°C (68-77°F)
- Evitar el calor y la humedad excesivos

#### Ingredientes Inactivos:

FD&C amarillo #10, gelatina, glicerina, polietilenglicol, povidona, propilenglicol, agua purificada, solución de sorbitol y dióxido de titanio

#### ¿Preguntas o comentarios?

Lláme: (619) 600-5632 (de lunes a viernes de 9 a 17 horas EST)

A PRUEBA DE MANIPULACIONES: NO UTILIZAR SI EL ENVASE ESTÁ ABIERTO O SI EL BLÍSTER ESTÁ RASGADO, ROTO O PRESENTA ALGÚN SIGNO DE MANIPULACIÓN

**GUAIFENESIN, DEXTROMETHORPHAN HBR**

guaifenesin, dextromethorphan hbr capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-783
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL SOLUTION</b> (UNII: 8KW3E207O2)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	yellow (LIGHT YELLOW)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	781
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69729-783-02	2 in 1 CARTON	02/18/2019	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	02/18/2019	

**Labeler** - OPMX LLC (029918743)

**Establishment**

Name	Address	ID/FEI	Business Operations
MEDGEL PRIVATE LIMITED		677385498	manufacture(69729-783)

Revised: 10/2022

OPMX LLC