

**TESALON TESAPERLAS SEVERE COLD MAX RELIEF- dextromethorphan hbr,
guaifenesin capsule, liquid filled
OPMX LLC**

TESALON Tesaperlas Severe Cold Max Relief

Drug Facts

Active ingredients

Active Ingredients (in each softgel)

Active Ingredients (in each softgel)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg

Purpose

Cough suppressant
Expectorant

Uses

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

Warnings

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 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

Inactive Ingredients:

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)

Tesalon®

Tesaperlas

Adults

Expectorant & Cough Suppressant

Expectorante & Supresor de la Tos

Controls cough

Controla la tos

Thins & loosens mucus

Adelgaza y expulsa las flemas

SOFTGELS

Dextromethorphan HBr 20 mg / Guaifenesin 400 mg

20 Softgels Box

Read & keep package for complete product information

TAMPER EVIDENT; DO NOT USE IS PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN,

BROKEN OR SHOWS ANY SIGN OF TAMPERING

Glue - No Coating

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



Exclusively distributed by:
PMA
Cruza Vista, CA 91910
Phone: 619-600-5632

Made for:
Tesalon
Adults

VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA
Call: (619) 600-5632 (Mon-Fri 9am-5pm CST)

Questions or comments?
Folic, yellow #111, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, xylitol, xylitol, vitamin d10000

Inactive ingredients:
■ Avoid excessive heat and humidity
■ Store at room temperature between 20-25°C (68-77°F)

Other information:
Under 12 years of age
Children
12 years of age & over
Do not use

Directions:
■ Do not take more than 7 days.
■ Do not use for more than directed. See Overdose warning.
■ Cough suppressant
■ Expectant

Drug Facts (continued)

Drug Facts

Active ingredients (in each softgel)
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg

Purpose
Cough suppressant

Warnings:
■ Helps loosen phlegm (mucus)
■ Helps thin bronchial secretions to make coughs more productive

Do not use:
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■ 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 for more than 7 days, recurs, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

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.

REV 09_2024
ITEM # RRX1144
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Tesaperlas

Adults

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

Expectorant & Cough Suppressant



Tesaperlas

Adults

Dextromethorphan HBr 20 mg / Guaifenesin 400 mg

Expectorant & Cough Suppressant

Expectorante & Supresor de la Tos

- Controls cough
Controla la tos
- Thins & loosens mucus
Adelgaza y expulsa las flemas



SOFTGELS

Dextromethorphan HBr 20 mg / Guaifenesin 400 mg 20 Softgels Box



Tesaperlas

Adults

Dextromethorphan HBr 20 mg Guaifenesin 400 mg

Expectorante & Supresor de la Tos

TESALON TESAPERLAS SEVERE COLD MAX RELIEF			
dextromethorphan hbr, guaifenesin capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-788

Route of Administration ORAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POVIDONE (UNII: FZ989GH94E)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0KO0R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	781
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-788-20	1 in 1 CARTON	09/27/2024	
1		20 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	09/27/2024	

Labeler - OPMX LLC (029918743)

Establishment

Name	Address	ID/FEI	Business Operations
Medgel Private Limited		677385498	manufacture(69729-788)

Revised: 9/2024

OPMX LLC