

# HISTIACIL COUGH- dextromethorphan hydrobromide and guaifenesin capsule OPMX LLC

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**Histiacil Cough**

## **Drug Facts**

<b>ACTIVE INGREDIENTS (in each softgel)</b>	<b>PURPOSE</b>
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	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 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 doses 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

FD&C yellow #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)

Exclusively distributed by:

OPMX

Chula Vista, CA 91910

## PRINCIPAL DISPLAY PANEL - 20 Softgel Blister Pack Box

NDC 69729-000-00

Histiacil NF

Dextromethorphan HBr

Guaifenesin

Cough

Expectorant & Cough Suppressant

- Controls cough
- Thins & loosens mucus

- Easy to swallow

20 Softgels Box

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



VERSION EN ESPAÑOL EN EL INTERIOR DE LA CAJA

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Questions or comments? Call: (619) 600-5632 (Mon-Fri 9am-5pm EST)

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

Drug Facts (continued): Under 12 years of age Do not use

Directions: Do not take more than 6 doses in 24 hours. Do not take more than 7 days. See Overdose warning.

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.

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.

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.

Uses: Helps loosen phlegm (mucus) helps thin bronchial secretions to make coughs more productive.

Drug Facts: ACTIVE INGREDIENTS (in each softgel) Dextromethorphan HBr 20 mg, Guaifenesin 400 mg. PURPOSE: Cough suppressant, Expectorant.

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

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



REV. 01/2022 ITEM # RRX112  
10053 18049 5

Lot No.:  
Exp. Date:

Read & keep outer package for complete product information

NO VARNISH AREA

# Histiacil<sup>NF</sup> Expectorante & Supresor de la Tos

Dextromethorphan HBr Guaifenesin

# Histiacil<sup>NF</sup>

Dextromethorphan HBr Guaifenesin

## Expectorante & Supresor de la Tos

Expectorant & Cough Suppressant

## Cough

- Controls cough Controla la tos
- Thins & loosens mucus Adelgaza y expulsa las flemas
- Easy to swallow Fácil de ingerir



20 Softgels Box



NO VARNISH AREA

NO VARNISH AREA

NDC 6825-000-00

# Histiacil<sup>NF</sup> Expectorant & Cough Suppressant

Dextromethorphan HBr Guaifenesin

## HISTIACIL COUGH

dextromethorphan hydrobromide and guaifenesin capsule

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-108
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

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

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	781
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-108-20	2 in 1 BOX	03/01/2022	
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	03/01/2022	

**Labeler** - OPMX LLC (029918743)

**Registrant** - Strive Pharmaceuticals Inc. (474844049)

Revised: 4/2024

OPMX LLC