

**DESRESFRIOL-DX SOFTGELS- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid filled OPMX LLC.**

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**Desresfriol-DX Softgels**

***Drug Facts***

<b><i>Active ingredients (in each Softgel)</i></b>	<b><i>Purpose</i></b>
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

Temporarily relieves common cold/flu symptoms:

- Nasal congestion
- Cough due to minor throat & bronchial irritation
- Sore throat
- Headache
- Minor aches & 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 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.**

**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 for children even if you do not notice any signs or symptoms.

**Directions**

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

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 special, titanium dioxide.

### **Questions?**

Call to free 619-600-5632 Monday through Friday 9AM - 5PM EST

### **Made for:**

### **RRX**

### **Exclusively distributed by:**

### **OPMX**

**Chula Vista, CA 91910**

**Phone: 619-600-5632**

### **PRINCIPAL DISPLAY PANEL**

NDC 69729-121-10

Desresfriol-DX

Acetaminophen, Dextromethorphan, Phenylephrine

Flu&Cough

Gripe y Tos

Dolor de cuerpo/Body Aches

Fiebre/Fever

Dolor de Garganta/Sore Throat

Congestion Nasal/Nasal Congestion

Tos/Cough

10 Cápsulas Blandas de Gel/Softgels

**Drug Facts** (continued)

**Drug Facts** (continued)

**Active ingredients** (in each softgel)  
 Acetaminophen 325mg, Pain reliever/fever reducer  
 Dextromethorphan HBr 15mg, Cough suppressant  
 Phenylephrine HCl 5mg, Nasal decongestant

**Purposes**  
 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.

**Uses**  
 temporarily relieves common cold/flu symptoms. • Cough due to enlarged prostate gland • Cough that occurs with minor throat & bronchial irritation • Sore throat

**Warnings**  
 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.

**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 you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or

**Keep out of reach of children.**  
 • If pregnant or breast-feeding, ask a health professional before use.

**Overdose warning:** Taking more than directed can cause serious health problems.

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

Made for:  
**RRX**  
 San Diego, CA



**Multi-Symptom Relief**

# DESRESFRIOL-DX

Acetaminophen, Dextromethorphan, Phenylephrine

**Multi-Symptom Relief**

- Dolor de Cuerpo  
Body Aches
- Fiebre  
Fever
- Dolor de Garganta  
Sore Throat
- Congestión Nasal  
Nasal Congestion
- Tos  
Cough

**10** Cápsulas Blandas de Gel Softgels

**Multi-Symptom Relief**

# DESRESFRIOL-DX

Acetaminophen, Dextromethorphan, Phenylephrine

Lot No.:  
 Exp. date

READ & KEEP  
 OUTER PACKAGE  
 FOR COMPLETE  
 PRODUCT  
 INFORMATION

Rev. 04.2023 Item # RRX1120  
 10053 18072 3

Call toll free 619-600-5632  
 Monday through Friday 9AM - 5PM EST

**Questions?**  
 FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol, titanium dioxide.

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

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

Children under 4 yrs	Do not use
Children 4 to 12 yrs & over	Ask a doctor
Adults & children 12 yrs & over	Ask a doctor

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

**Directions**  
 Adults & children 12 yrs & over: 2 softgels with water every 4 hrs. Ask a doctor.  
 Children 4 to 12 yrs & over: 1 softgel with water every 4 hrs. Ask a doctor.  
 Children under 4 yrs: Do not use.

**DESRESFRIOL-DX SOFTGELS**  
 acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride capsule, liquid

filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69729-121
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**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:69729-121-10	1 in 1 CARTON	06/30/2023	
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	06/30/2023	
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**Labeler** - OPMX LLC. (029918743)

## Establishment

Name	Address	ID/FEI	Business Operations
SOFTECH PHARMA PRIVATE LIMITED		677111277	label(69729-121) , manufacture(69729-121) , pack(69729-121)

Revised: 4/2024

OPMX LLC.