

**ANTIFLU DES COUGH AND FLU- acetaminophen phenylephrine hcl  
chlorpheniramine maleate capsule  
Productos Farmaceuticos, S.A. de C.V.**

*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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**AntiDesCldFluCaps**

**Active Ingredients**

Acetaminophen 325 mg

Phenylephrine HCl 10 mg

Chlorpheniramine Maleate 4 mg

**Purpose**

Pain reliever/fever reducer

Nasal decongestant

Antihistamine

**Uses**

Temporarily relieves common cold and flu symptoms: ■ sore throat ■ headache ■ minor aches and pains ■ fever ■ stuffy/runny nose and sneezing

**Warnings**

**Liver warning** This product contains acetaminophen. Severe liver damage may occur if you take ■ More than 4,000 mg in 24 hours, which is the maximum daily amount ■ With other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product.

**Allergy alert:** Acetaminophen may cause severe skin or severe allergic reactions. Symptoms can include ■ skin reddening ■ blisters ■ rash ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock. If a skin or any allergic reaction occurs, stop use and seek medical attention right away.

**Sore throat warning:** Severe or persistent sore throat lasting more than 2 days or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. 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. If you are now taking a prescription Monoamine Oxidase Inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or if you have taken these products 2 weeks previously. If you do not know if your prescription drug contains an MAOI, ask a Doctor before taking this product

### ***Ask a Doctor before use if you have***

■ Liver disease ■ Heart disease ■ High blood pressure ■ Thyroid disease ■ Diabetes ■ Glaucoma ■ Breathing problem due to any given cause (asthma, chronic bronchitis or emphysema) ■ Trouble urinating due to an enlarged prostate gland

### ***Ask a Doctor before use if you are***

■ Taking sedatives or tranquilizers ■ Taking the blood thinning drug warfarin

### ***When using this product***

■ Do not exceed recommended dosage. If nervousness, dizziness, or sleeplessness occur, discontinue use and consult a Doctor. ■ Do not mix with alcohol, sedatives and tranquilizers as they may increase drowsiness ■ Driving a motor vehicle or operating machinery could be affected ■ Excitability may occur especially in children(12-18 y) ■ if symptoms do not improve within 7 days or are accompanied by fever, consult a Doctor

### ***Stop use and ask a Doctor if***

■ Pain, or nasal congestion gets worse or lasts more than 5 days (children) or 7 days (adults) ■ Fever gets worse or last more than 3 days ■ Redness or swelling is present ■ New symptoms occur

### ***Keep out of reach of children***

***If pregnant or breast-feeding, ask a health professional before use .***

### ***As with all medical products keep out of reach of children.***

In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 recommended dose **Adults and children 12 years of age and over:** take 1 capsule with water every 4 hours. ■ Do not exceed 6 capsules in 24 hours **Children under 12 years of age:** do not use

### ***Other information***

Do not store above 77°F(25°C) and in a dry place

***Inactive Ingredients***

Colloidal Silicon Dioxide, D&C Red No. 28, D&C Red No. 33, D&C Yellow No. 10, FD&C Blue No. 1, Gelatin, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Shellac, Synthetic Iron Oxide, Titanium Dioxide

***Questions and Comments?***

You may report any side effects to 1-305-677-0850 Monday through Sunday 24 hrs

**Package Label**

**Drug Facts (continued)**

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■ Liver disease ■ Heart disease ■ High blood pressure ■ Thyroid disease ■ Diabetes ■ Glaucoma ■ Breathing problem due to any given cause (asthma, chronic bronchitis or emphysema) ■ Trouble urinating due to an enlarged prostate gland.

**Drug Facts (continued)**

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■ Taking sedatives or tranquilizers ■ Taking the blood thinning drug warfarin

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**Antiflu-Des®**

Made in Mexico by / Hecho en México por:  
**PRODUCTOS FARMACÉUTICOS, S.A. DE C.V.**  
Carretera Pabellón de Hidalgo, Km 4.2  
Municipio Rincón de Romos, Aguascalientes, 20420.

Do not use if blister packaging is torn, broken or shows any signs of tampering.  
No se use si el blister se encuentra dañado, roto o presente algún tipo de manipulación.

DRUG FACTS IN SPANISH / DATOS DEL MEDICAMENTO EN ESPAÑOL

**Drug Facts (continued)**

**Directions** ■ Do not take more than recommended dose  
**Adults and children 12 years and over:** take 1 capsule with water every 4 hours. Do not exceed 6 capsules in 24 hours, or as directed by a Doctor. **Children under 12 years:** do not use

**Other information**  
Do not store above 77°F (25°C) and in a dry place

**Drug Facts (continued)**

**Inactive Ingredients** Colloidal Silicon Dioxide, Croscarmellose Sodium, D&C Red No. 28, D&C Red No. 33, D&C Yellow No. 10, FD&C Blue No. 1, Gelatin, Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Shellac, Synthetic Iron Oxide, Titanium Oxide.

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**Antiflu-Des®**

BATCH / LOTE:  
EXP / CADUCIDAD:

**Cold & Flu / Gripe y Resfriado**  
Relieves common cold and flu symptoms / Alivia la gripa y el resfriado común

- Fever
- Body aches and headaches
- Sneezing
- Stuffy/runny nose
- Fibre
- Cuerpo cortado y dolor de cabeza
- Estornudos
- Escurrimiento y congestión nasal

**12 capsules / 12 cápsulas**

Acetaminophen, Chlorpheniramine maleate, Phenylephrine HCl  
Cápsulas / Capsulas

**Antiflu-Des®**

**Drug Facts**

Active Ingredients	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Phenylephrine HCl 10 mg	Nasal decongestant
Chlorpheniramine maleate 4 mg	Antihistamine

**Uses.** Temporarily relieves common cold and flu symptoms:  
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**Drug Facts (continued)**

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**ANTIFLU DES COUGH AND FLU**

acetaminophen phenylephrine hcl chlorpheniramine maleate capsule

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82688-001
<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>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg
<b>CHLORPHENIRAMINE MALEATE</b> (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 28</b> (UNII: 767IP0Y5NH)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	gray (gray and orange)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (immediate release hard gelatin)	<b>Size</b>	24mm
<b>Flavor</b>		<b>Imprint Code</b>	ANTIDESFLU
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82688-001-12	1 in 1 CARTON	04/15/2022	
1		12 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 final	part341	04/15/2022	

**Labeler** - Productos Farmaceuticos, S.A. de C.V. (815664461)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Productos Farmaceuticos, S.A. de C.V.		815664461	manufacture(82688-001)

Revised: 4/2022

Productos Farmaceuticos, S.A. de C.V.