

ACTIFED- phenylephrine hydrochloride tablet
Belmora LLC

ACTIFED

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 5mg

Purpose

Nasal decongestant

Uses

Temporarily relieves • nasal congestion due to the common cold, hay fever or other upper respiratory allergies • sinus congestion and pressure

Warnings

Do not use • If you are now taking a prescription monoamineoxidase 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.

When using this product do not exceed recommended dosage

Ask a doctor before use if you have • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless • symptoms do not improve within 7 days or are accompanied by fever

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

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

• **do not use more than directed**

Adults & Children: (12 years &	Take 2 tablets every 4-6 hours. Do not take more than 12
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older)	tablets in 24 hours.
Children under 12 years:	Ask a doctor

Other Information

- store at room temperature 59°-86° F (15°-30° C).
- tamper evident sealed packets.
- do not use any opened or torn packets

Inactive ingredients

croscarmellose sodium, FD&C red #40, FD&C yellow #6, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, propylene glycol, silicon dioxide, titanium dioxide

Questions or comments?

Call 1-888-779-2877 M-F 9AM-5PM EST
 Belmora LLC 3033 Wilson Blvd. Suite 700 Arlington, VA 22201

Quick Nasal Decongestant Relief! Non-Drowsy/Sugar Free

KEEP THE BOX FOR COMPLETE PRODUCT INFORMATION

Packaging

The image displays the packaging for ACTIFED/FENILEFRINA. The front of the box features the product name in large, bold letters, a diagram of a human nose, and the text "Alivio Descongestionante Nasal Rápido Sin somnolencia/Sin azúcar Quick Nasal Decongestant Relief Non-Drowsy/Sugar Free". The side of the box shows "50 TABLETS/50 PAQUETES DOBLES" and "Fenilefrina HCl 5 mg - Phenylephrine HCl 5mg". The back of the box contains the following information:

Información sobre el Medicamento

Ingrediente activo (en cada tableta) Propósito
 Fenilefrina HCl 5 mg Descongestionante nasal

Usos Alivio temporal de la congestión nasal debido al resfriado común, fiebre del heno u otros alergias de las vías respiratorias superiores.

Advertencias
 No lo use si está tomando actualmente un inhibidor de la monoaminoxidasa (MAOI) recetado (para tratar la depresión, las condiciones psiquiátricas o emocionales, o la enfermedad de Parkinson), o dentro 2 semanas después de suspender un medicamento MAOI. Si lo está o si su medicamento recetado contiene un MAOI, consulte a su médico o farmacéutico antes de tomar este producto.

Precauciones
 Consulte a su médico antes de usar el producto si tiene hipertensión, problemas cardíacos, presión arterial alta, enfermedad tiroidea, diabetes o dificultad para orinar debido a un agrandamiento de la glándula prostática.

Interacciones
 No lo use más de lo indicado.
 Alérgico y otros: Tome 2 tabletas cada 4-6 horas. No tomar más de 12 tabletas en 24 horas.
 Niños menores de 12 años: Consulte al médico.

Información adicional
 Alérgico a temperatura ambiente de 59-86°F (15-30°C).
 Manténgalo fuera del alcance de los niños. En caso de emergencia, llame al número de emergencia o consulte con un Centro de Control de Intoxicaciones de inmediato (1-800-222-1222).

Ingredientes inactivos
 croscarmellose sódica, FD&C rojo no. 40, FD&C amarillo no. 6, hipromelosa, lactosa, estearato de magnesio, celulosa microcristalina, celulosa, propilenglicol, dióxido de silicio, dióxido de titanio.

¿Preguntas o comentarios?
 Llame al 1-888-779-2877 DE LUNES A VIERNES DE 9AM A 5PM HORAS DEL ESTE.

**ACTIFED/
 FENILEFRINA**

**Alivio Descongestionante Nasal Rápido
 Sin somnolencia/Sin azúcar
 Quick Nasal Decongestant Relief!
 Non-Drowsy/Sugar Free**

Fenilefrina HCl 5 mg - Phenylephrine HCl 5mg

Drug Facts

Active Ingredient (in each tablet) Purpose
 Phenylephrine HCl 5mg Nasal decongestant

Uses Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies in sinus congestion and pressure.

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.

Directions
 Do not use more than directed.
 Adults & Children: Take 2 tablets every 4-6 hours.
 Children under 12 years: Ask a doctor.

Other information
 Store at room temperature 59-86°F (15-30°C).
 Keep out of reach of children. In case of emergency, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Inactive ingredients
 croscarmellose sódica, FD&C rojo no. 40, FD&C amarillo no. 6, hipromelosa, lactosa, estearato de magnesio, celulosa microcristalina, celulosa, propilenglicol, silicio dióxido, titanio dióxido.

Questions or comments?
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DRUG FACTS TABLE

Drug Facts

Active ingredient (in each tablet)	Purpose
Phenylephrine HCl 5mg	Nasal decongestant

Uses Temporarily relieves ■ nasal congestion due to the common cold, hay fever or other upper respiratory allergies ■ sinus congestion and pressure

Warnings
 Do not use ■ If you are now taking a prescription monoamineoxidase 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.

When using this product do not exceed recommended dosage

Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if ■ you get nervous, dizzy, or sleepless ■ symptoms do not improve within 7 days or are accompanied by fever
 If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions
 ■ do not use more than directed

Adults & Children: (12 years & older)	Take 2 tablets every 4-6 hours. Do not take more than 12 tablets in 24 hours.
Children under 12 years:	Ask a doctor

Other Information
 ■ store at room temperature 59°-86° F (15°-30° C).
 ■ tamper evident sealed packets.
 ■ do not use any opened or torn packets

Inactive ingredients
 croscarmellose sodium, FD&C red #40, FD&C yellow #6, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, propylene glycol, silicon dioxide, titanium dioxide

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ACTIFED
 phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-119
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	271
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-119-01	50 in 1 BOX	08/01/2023	
1		1 in 1 POUCH; 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	08/01/2023	

Labeler - Belmora LLC (112753244)