

ACTIFED- phenylephrine hydrochloride tablet
Belmora LLC

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.

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 & 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

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



Información sobre el Medicamento
Ingrediente activo (en cada tableta) Propósito
 Fenilefrina HCl 5 mg Decongestionante nasal

Usos Alivio temporal de la congestión nasal debido al resfriado común, dolor del seno, o otros ataques de las vías respiratorias superiores. ■ la congestión y la presión sanguínea.

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

Cuando utilice este producto no acceda la dosis recomendada.

Consulte a un médico antes de usar el producto si tiene ■ enfermedad cardíaca ■ presión arterial alta ■ enfermedad de la glándula tiroides ■ diabetes ■ dificultad para orinar debido a un agrandamiento de la glándula prostática.

Déjelo usarlo y consulte a un médico si ■ se pone mareado, mareado o no puede dormir ■ si los síntomas no mejoran en 7 días o son acompañados de fiebre.

■ está embarazada o amamantando, consulte a un profesional de la salud antes de usarlo. Manténgalo fuera del alcance de los niños. En caso de emergencia, llame a su médico o comuníquese con el Centro de Control de Embarazamientos de Emergencia (1-800-235-1223).

Instrucciones
 No lo use más de lo indicado.

Adultos y niños (12 años y mayores)	Tomar 2 tabletas cada 4-6 horas. No tomar más del 2 tabletas en 24 horas.
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■ No use más de 12 años. ■ Consulte al médico.

Drug Facts

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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

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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 dizzy ■ 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 emergency, get medical help or contact a Poison Control Center right away (1-800-235-1223).

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).
 ■ keep sealed, unopened packets.
 ■ do not use any opened or torn packets.



DRUG FACTS TABLE

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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: 3WQ0SDW1A)	
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 final	part341	08/01/2023	

Labeler - Belmora LLC (112753244)

