

## **NASAL DECONGESTANT- oxymetazoline hcl spray**

**Promex, 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.*

-----

### **Drug Facts**

#### **Active ingredient**

Oxymetazoline HCl 0.05%

#### **Purpose**

Nasal decongestant

#### **Uses**

- temporarily relieves nasal congestion due to:
- common cold
- hay fever
- upper respiratory allergies
- sinusitis
- reduces swelling of nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose

#### **Warnings**

**Do not use this product for more than 3 days**

**Ask a doctor before use if you have**

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate

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

- **do not exceed recommended dosage**
- use only as directed. frequent or prolonged use may cause nasal congestion to recur or worsen
- temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur
- use of this container by more than one person may spread infection

**Stop use and ask a doctor if**

symptoms persist

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- To spray, squeeze bottle quickly and firmly
- Do not tilt head backward while spraying
- Wipe nozzle clean after use
- Do not exceed 2 doses in any 24 hour period
- adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours
- children under 6 years of age: ask a doctor

### **Other information**

- store at room temperature 15 - 30°C (59-86°F)
- retain carton for future reference on full labeling
- SAFETY SEAL: Do not use if seal on bottle is broken or missing

### **Inactive ingredients**

benzalkonium chloride, benzyl alcohol, edetate disodium, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

### **Carton image**

# Ampitrexyl<sup>®</sup> Nasal Spray

# Ampitrexyl<sup>®</sup> Nasal

## Decongestant Descongestionante

ProMex<sup>®</sup>

1 oz (30ml)

### Drug Facts

**Active ingredient** *Purpose*  
Oxymetazoline HCl 0.05% Nasal decongestant

**Uses** • temporarily relieves nasal congestion due to:  
• common cold • hay fever • upper respiratory allergies  
• sinusitis • reduces swelling of nasal passages; shrinks swollen membranes • temporarily restores freer breathing through the nose

### Warnings

**Do not use this product for more than 3 days**

**Ask a doctor before use if you have** • heart disease • high blood pressure • thyroid disease • diabetes • difficulty in urination due to enlargement of the prostate

**When using this product** • do not exceed recommended dosage • use only as directed; frequent or prolonged use may cause nasal congestion to recur or worsen • temporary discomfort such as burning, stinging, sneezing or an increase in nasal discharge may occur • use of this container by more than one person may spread infection

**Stop use and ask a doctor if symptoms persist**

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

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

### Directions

- to spray, squeeze bottle quickly and firmly
- do not tilt head backward while spraying
- wipe nozzle clean after use
- do not exceed 2 doses in any 24 hour period
  - adults and children 6 to under 12 years of age (with adult supervision): 2 or 3 sprays in each nostril not more often than every 10 to 12 hours
  - children under 6 years of age: ask a doctor

### Other information

- store at room temperature 15-30C (59- 86F)
- retain carton for future reference on full labeling
- SAFETY SEAL: Do not use if seal on bottle is broken or missing

### Inactive ingredients

benzalkonium chloride, benzyl alcohol, edetate disodium, polyethylene glycol, povidone, propylene glycol, sodium phosphate dibasic, sodium phosphate monobasic, water

### Información del Medicamento

**Ingrediente activo** *Propósito*  
Oximetazolina HCl 0,05% .....Descongestionante nasal

**Usos** ■ alivio temporal de la congestión nasal debido a: ■ resfriado común ■ fiebre del heno alergias respiratorias superiores ■ sinusitis ■ Reduce la hinchazón en los conductos nasales, encoge membranas inflamadas ■ restaura temporalmente la respiración más libre a través de la nariz

### Advertencias

**No utilice este producto por más de 3 días**

**Pregúntele a su médico antes de usar si usted tiene** ■ enfermedad del corazón ■ presión arterial alta ■ enfermedad tiroidea ■ diabetes ■ dificultad para orinar debido al agrandamiento de la próstata

**Al utilizar este producto** ■ no supere la dosis recomendada ■ Utilice únicamente como indicado, el uso frecuente o prolongado puede causar congestión nasal que se repita o empeore ■ molestias temporales como ardor, picazón, estornudos o un aumento en la secreción nasal puede ocurrir ■ el uso de este envase por más de una persona puede propagar infección

**Suspenda el uso y consulte a un médico si los síntomas persisten**

**Si está embarazada o en periodo de lactancia, consulte a un profesional de salud antes de usarlo.**

**Mantener fuera del alcance de los niños.** En caso de ingestión, obtenga médica ayuda o contacte un Centro de Control de intoxicación inmediatamente.

### Información del Medicamento (continuación)

#### Indicaciones

- para rociar, apriete la botella con rapidez y firmeza
- No incline la cabeza hacia atrás mientras se pulveriza
- Limpie la boquilla después de su uso
- No exceda de 2 dosis en un periodo de 24 horas
  - adultos y niños de 6 a 12 años de edad (con supervisión de un adulto): 2 o 3 pulverizaciones en cada orificio nasal no más frecuente que cada 10 a 12 horas
  - menores de 6 años de edad: consulte a un médico

#### Otra información

- Almacene a temperatura ambiente 15-30C (59 - 86F)
- Conserve la caja para futuras consultas sobre el producto
- SELLO DE SEGURIDAD: No utilice si el sello de la botella está roto o no está.

#### Ingredientes inactivos

cloruro de benzalconio, alcohol bencílico, edetato disódico, polietilenglicol, povidona, propileno glicol, sodio fosfato dibásico, fosfato monobásico de sodio, agua

Pro-Mex<sup>®</sup>

Miami, FL 33179

Questions Comments?

1 (305) 653-2700

Made in Korea / Fabricado en Corea



LOT & EXP

## NASAL DECONGESTANT

oxymetazoline hcl spray

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58988-0193

Route of Administration

NASAL

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OXYMETAZOLINE HYDROCHLORIDE</b> (UNII: K89MJ0S5VY) (OXYMETAZOLINE - UNII:8VLN5B44ZY)	OXYMETAZOLINE HYDROCHLORIDE	0.05 g in 100 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>POLYETHYLENE GLYCOLS</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM PHOSPHATE, DIBASIC</b> (UNII: GR686LBA74)	
<b>SODIUM PHOSPHATE, MONOBASIC</b> (UNII: 3980JIH2SW)	
<b>Water</b> (UNII: 059QF0KO0R)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58988-0193-5	1 in 1 BOX		
1		30 mL in 1 BOTTLE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	12/09/2013	

**Labeler** - Promex, LLC (789974388)

Revised: 12/2013

Promex, LLC