NASAL DECONGESTANT- pseudoephedrine hcl tablet Proficient Rx LP

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.

Equaline 44-112

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 mg

Purpose

Nasal Congestant

Use(s)

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily restores freer breathing through the nose

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 2 weeks after stoppin the MAOI drug. If you do not know if your prescription drug contains and MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- diabetes
- high blood pressure
- heart disease
- thyroid disease
- trouble urinating due to an enlarged prostate gland

When using this product

do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with 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

adults and children	take 2 tablets every 4 to 6 hours;
12 years and older	do not take more than 8 tablets in
	24 hours
children ages 6 to 12 years	take 1 tablet every 4 to 6 hours;
·	do not take more than 4 tablets in
	24 hours
children under 6 years	do not use

Other information

• store at room temperature 15°-30°C (59°-86°F)

Inactive ingredients

• calcium sulfate, carnauba wax, croscarmellose sodium, FD&C red #40 lake, FD&C yellow #6 lake, gelatin, kaolin, lactose, magnesium silicate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, silica, stearic acid, sugar and titanium dioxide

Questions or comments?

1-800-645-2158

Principal Display Panel

Rugby®

compare to Sudafed®

Decongestant active ingredient*

NDC 63187-344-24

Nasal Decongestant

pseudoephedrine HCl 30 mg

Temporarily relieves:

• nasal congestion due to cold & allergies withoout drowsiness

24 tablets, 30 mg each

TAMPER EVIDENT: SAFETY SEALED: DO NOT USE IF BLISTER SEAL IS BROKEN

Rev 04/13

R-29

DISTRIBUTED BY: Rugby Laboratories 31778 Enterprise Drive Livonia, MI 48150 www.rugbylaboratories.com

Repackaged by:
Proficient Rx LP
Thousand Oaks, CA 91320





NDC 63187-344-24

Lot #:00000 Exp. 00/00/00 SN# MASTER

Pseudoephedrine HCl 30mg (Nasal Decongestant) #24 Tablets Lot #:00000 SN#MASTER NDC 63187-344-24 Exp:00/00/00

Pseudoephedrine HCl 30mg (Nasal Decongestant) #24 Tablets Lot #:00000 SN#MASTER NDC 63187-344-24 Exp:00/00/00

Pseudoephedrine HCI 30mg (Nasal Decongestant) #24 Tablets Lot #:00000 SN#MASTER NDC 63187-344-24 Exp:00/00/00

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Pseudoephedrine HCI 30mg (Nasal Decongestant)

#24 Tablets

Each tablet contains: Pseudoephedrine Hydrochloride 30mg Nasal Decongestant

Red, round, unscored tablet with "1004" as imprint code

Product ID: RP034424

Dist. By: Rugby Laboratories 31778 Enterprise Drive Livonia, MI 48150

Store at room temperature 15°-30°C (59°-86°F)

Keep medication out of the reach of children

NASAL DECONGESTANT

pseudoephedrine hcl tablet

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:63187-344(NDC:0536-3607)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

PSEUDO EPHEDRINE HYDRO CHLO RIDE (UNII: 6 V9 V2RYJ8 N) (PSEUDO EPHEDRINE
- UNII:7CUC9 DDI9F)

PSEUDO EPHEDRINE
HYDRO CHLO RIDE

30 mg

Inactive Ingredients			
Ingredient Name	Strength		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)			

TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
CALCIUM SULFATE, UNSPECIFIED FORM (UNII: WAT0 DDB505)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
KAOLIN (UNII: 24H4NWX5CO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
SHELLAC (UNII: 46 N10 7B71O)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
12-HYDRO XYSTEARIC ACID (UNII: 933ANU3H2S)	
ACER SACCHARUM POLLEN (UNII: V38QUQ7861)	

Product Characteristics			
Color	RED	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	1004
Contains			

	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:63187-344-24	1 in 1 CARTON	03/03/2014	
l	1	24 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	10/29/2012	

Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	RELABEL(63187-344)	

Revised: 1/2021 Proficient Rx LP