

CHILDRENS SILFEDRINE - pseudoephedrine hydrochloride liquid
Silarx Pharmaceuticals, Inc

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.

Children's Silfedrine Liquid

Active Ingredient: Pseudoephedrine hydrochloride 15 mg (in each 5 mL(teaspoonful)(TSP))

Purpose: Nasal decongestant

Uses temporarily relieves nasal congestion due to

- common cold
- hay fever
- other upper respiratory allergies
- temporarily relieves sinus congestion and pressure
- promotes nasal and/or sinus drainage

Warnings

DO NOT USE IN CHILDREN UNDER 4 YEARS OF AGE

- **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.

Ask a doctor before use if you have

- heart diseases
- high blood pressure
- thyroid disease
- diabetes

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 accompanied by fever

Keep out of reach of children. In case of overdose, get medical help or contact a poison control center right away (1800-222-1222).

Directions

- Do not exceed 4 doses in 24 hours.
- Repeat dose every 4 hours if needed.

Children 6 to 11 years of age	2 teaspoonfuls (TSP)
Children 4 to 5 years of age	1 teaspoonful(TSP)
Children under 4 years of age	DO NOT USE

Other information

store at room temperature

Inactive ingredients

citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, grape flavor, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution.

Questions

888-974-5279

Manufactured by:

Silarx Pharmaceuticals, Inc
1033 Stoneleigh Ave
Carmel, NY 10512 USA

SILARX
NDC 54838-104-40
Children's Silfedrine Liquid
Pseudoephedrine Hydrochloride
Nasal Decongestant

- Non-drowsy Formula
- GRAPE FLAVOR
- Alcohol/Sugar Free

DO NOT USE IN CHILDREN UNDER 4 YEARS OF AGE

DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING

118 mL (4 fl oz)

Drug Facts

Active ingredient (in each 5 mL (teaspoonful) (TSP)) Purpose
Pseudoephedrine hydrochloride 15 mg Nasal decongestant.

Uses temporarily relieves nasal congestion due to ■ common cold ■ hay fever ■ other upper respiratory allergies ■ temporarily relieves sinus congestion and pressure ■ promotes nasal and/or sinus drainage

Warnings
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Stop use and ask a doctor if ■ nervousness, dizziness or sleeplessness occur ■ symptoms do not improve within 7 days or are accompanied by fever

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Directions
■ Do not exceed 4 doses in 24 hours.
■ Repeat dose every 4 hours if needed.

Children 4 to 5 years of age	1 teaspoonful (TSP)
Children 6 to under 11 years of age	2 teaspoonfuls (TSP)
Children under 4 years of age	DO NOT USE

Other information store at room temperature

Inactive ingredients citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, grape flavor, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution.

Manufactured by:
Silarx Pharmaceuticals, Inc.
19 West Street
Spring Valley, NY 10977 USA

Questions ☎ 888-974-5279
Rev. 07/12

Control # & Exp. Date
354838-104-400



SILARX
NDC 54838-104-70
Children's Silfedrine Liquid
Pseudoephedrine Hydrochloride
Nasal Decongestant

- Non-drowsy Formula
- GRAPE FLAVOR
- Alcohol/Sugar Free

DO NOT USE IN CHILDREN UNDER 4 YEARS OF AGE

DO NOT USE IF PRINTED SAFETY SEAL ON THE BOTTLE IS BROKEN OR MISSING

237 mL (8 fl oz)

Drug Facts

Active ingredient (in each 5 mL (teaspoonful) (TSP)) Purpose
Pseudoephedrine hydrochloride 15 mg Nasal decongestant.

Uses temporarily relieves nasal congestion due to ■ common cold ■ hay fever ■ other upper respiratory allergies ■ temporarily relieves sinus congestion and pressure ■ promotes nasal and/or sinus drainage

Warnings
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Directions
■ Do not exceed 4 doses in 24 hours.
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Children 4 to 5 years of age	1 teaspoonful (TSP)
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Inactive ingredients citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, grape flavor, purified water, saccharin sodium, sodium benzoate, sodium citrate, sorbitol solution.

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Silarx Pharmaceuticals, Inc.
19 West Street
Spring Valley, NY 10977 USA

Questions ☎ 888-974-5279
Rev. 07/12

Control # & Exp. Date
354838-104-707



CHILDRENS SILFEDRINE

pseudoephedrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54838-104
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pseudoephedrine hydrochloride (UNII: 6 V9 V2RYJ8 N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine hydrochloride	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C red no. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
saccharin sodium dihydrate (UNII: SB8ZUX40TY)	
sodium benzoate (UNII: OJ245FE5EU)	
sodium citrate (UNII: 1Q73Q2JULR)	
sorbitol (UNII: 506T60A25R)	
water (UNII: 059QF0K00R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	GRAPE (Grape Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54838-104-40	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:54838-104-70	237 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/05/2001	

Labeler - Silarx Pharmaceuticals, Inc (161630033)

