

SILPHEN - diphenhydramine hydrochloride syrup

Silarx Pharmaceutical, 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.

Silphen Cough Syrup

Active Ingredient: Diphenhydramine hydrochloride 12.5 mg (in each 5 mL(teaspoonful)(TSP))

Purpose: Antitussive

Uses

temporarily relieves coughs due to cold or bronchial irritation

Warnings

Do not use with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough is accompanied by excessive phlegm (mucus)
- breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor

if symptoms last for more than 1 week or recurred or accompanied by fever, rash, headache

Ask a doctor or pharmacist before use

if you are taking tranquilizers or sedatives

When using this product

- you may get drowsy
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding

- ask a health professional before use.

Keep out of reach of children.

- In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not take more than six doses

Adults and children over 12 years	2 teaspoonfuls (TSP) every 4 hours
children under 12 years	DO NOT USE

Other information

- Store below 20°-25°C (68°-77°F)
- Protect from freezing.

Inactive ingredients:

Alcohol 5%, ammonium chloride, citric acid, D&C red no. 33, FD&C red no. 40, menthol, methylparaben, propylene glycol, propylparaben, sodium citrate, strawberry flavor, sucrose, water

Questions: 888-974-5279

Manufactured by:

Sliarx Pharmaceutical, Inc
1033 Stoneleigh Ave.
Carmel, NY 10512 USA.

SILARX
NDC 54838-154-40
SILPHEN
COUGH SYRUP
Diphenhydramine Hydrochloride
COUGH SUPPRESSANT
Contains 5% Alcohol
DO NOT USE IN CHILDREN UNDER 12 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
Diphenhydramine hydrochloride 12.5 mg Antitussive
Uses temporarily relieves coughs due to cold or bronchial irritation
Warnings
Do not use with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema
■ cough is accompanied by excessive phlegm (mucus)
■ breathing problem such as emphysema or chronic bronchitis
■ glaucoma ■ trouble urinating due to an enlarged prostate gland
Stop use and ask a doctor if symptoms last for more than 1 week or recur or accompanied by fever, rash, headache.
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives
When using this product ■ you may get drowsy ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children
If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center right away.
Directions do not take more than six doses.
Adults and children over 12 years 2 teaspoonfuls (TSP) every 4 hours
Children under 12 years **DO NOT USE**
Other information ■ Store at room temperature 20°-25°C (68°-77°F). ■ Protect from freezing.
Inactive ingredients alcohol 5%, ammonium chloride, citric acid, D&C red no. 33, FD&C red no. 40, menthol, methylparaben, propylene glycol, propylparaben, sodium citrate, strawberry flavor, sucrose, water
Questions 888-974-5279
Manufactured by: Sliarx Pharmaceuticals, Inc. Rev. 07/13
1033 Stoneleigh Ave., Carmel, NY 10512
Control # & Exp. Date 354838-154-405

SILPHEN

diphenhydramine hydrochloride syrup

Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:54838-154
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Diphenhydramine hydrochloride (Diphenhydramine)	Diphenhydramine hydrochloride	12.5 mg in 5 mL
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Inactive Ingredients

Ingredient Name	Strength
Alcohol	
ammonium chloride	
anhydrous citric acid	
D&C red no. 33	
FD&C red no. 40	
menthol	
methylparaben	
propylene glycol	
propylparaben	
sodium citrate	
sucrose	
water	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY (Strawberry Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54838-154-40	118 mL in 1 BOTTLE, PLASTIC		
2	NDC:54838-154-70	237 mL in 1 BOTTLE, PLASTIC		
3	NDC:54838-154-80	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/03/1993	

Labeler - Silarx Pharmaceutical, Inc (161630033)

Revised: 6/2014

Silarx Pharmaceutical, Inc