

**CORRECT DOSE CHILDRENS ALLERGY RELIEF- diphenhydramine hydrochloride liquid
BFS Pharma, 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.

Drug Facts

Active ingredient (in each 5 mL)*

Diphenhydramine HCl 12.5 mg

*5 mL = one pre-filled spoon

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat

Warnings

Do not use

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- 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 overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- refer to chart below
- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

| | |
|--|---|
| Children under 2 years of age | do not use |
| Children 2 to 5 years of age | do not use unless directed by a doctor |
| Children 6 to 11 years of age | 1 to 2 pre-filled spoons (12.5 mg to 25 mg) |
| Adults and children 12 years of age and over | 2 to 4 pre-filled spoons (25 mg to 50 mg) |

Other information

- each pre-filled spoon contains: **sodium 14 mg**
- store between 20-25°C (68-77°F).
- Protect from light. Store in outer carton until contents used.
- **SAFETY SEALED: This product is protected by sealed pouches. Do not use if individual pouches are torn or damaged**

Inactive ingredients

anhydrous citric acid, D&C red #33, FD&C red #40, flavors, glycerin, monoammonium glycyrrhizinate, poloxamer 407, purified water, sodium benzoate, sodium chloride, sodium citrate, sucrose

Questions or comments?

1-877-545-3635

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Children's Benadryl[®] Allergy Perfect Measure

PRINCIPAL DISPLAY PANEL

NDC 76103-004-10

Correct Dose

Children's Allergy Relief[®]

Diphenhydramine HCl
Oral Solution Antihistamine

Correct Dose HELPS RELIEVE

- Sneezing
- Runny Nose
- Itchy Eyes & Throat
- Watery Eyes

CHERRY FLAVOR

Alcohol Free

10 PRE-FILLED SINGLE USE SPOONS**

0.17 FL OZ (5 mL) EACH
****12.5 mg Diphenhydramine HCl each**

CORRECT DOSE CHILDRENS ALLERGY RELIEF
 diphenhydramine hydrochloride liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76.103-004 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------------------|-----------------|
| Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M) | Diphenhydramine Hydrochloride | 12.5 mg in 5 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| anhydrous citric acid (UNII: XF417D3PSL) | |
| D&C red NO. 33 (UNII: 9DBA0SBB0L) | |

| | |
|--|--|
| FD&C red NO. 40 (UNII: WZB9127XOA) | |
| glycerin (UNII: PDC6A3C0OX) | |
| glycyrrhizin, ammoniated (UNII: 3VRD35U26C) | |
| poloxamer 407 (UNII: TUF2IVW3M2) | |
| water (UNII: 059QF0KOOR) | |
| sodium benzoate (UNII: OJ245FE5EU) | |
| sodium chloride (UNII: 451W47IQ8X) | |
| sodium citrate (UNII: 1Q73Q2JULR) | |
| sucrose (UNII: C151H8M554) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | RED | Score | |
| Shape | | Size | |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:76103-004-10 | 10 in 1 CARTON | | |
| 1 | | 5 mL in 1 POUCH | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part341 | 06/15/2011 | |

Labeler - BFS Pharma, Inc. (967271458)