

**FOSTER AND THRIVE CHILDRENS ALLERGY RELIEF - diphenhydramine  
hcl liquid**

**Strategic Sourcing Services 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.*

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**Foster and thrive childrens Allergy Relief 549**

**ACTIVE INGREDIENT(S)**

Diphenhydramine HCl 12.5 mg

**PURPOSE**

Antihistamine

**USE(S)**

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

**WARNINGS**

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**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 THE CHILD HAS**

- glaucoma
- a breathing problem such as chronic bronchitis

**ASK A DOCTOR OR PHARMACIST BEFORE USE IF THE CHILD IS**

taking sedatives or tranquilizers

**WHEN USING THIS PRODUCT**

- sedatives and tranquilizers may increase drowsiness
- marked drowsiness may occur
- excitability may occur, especially in children

**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**

- find right dose on chart below
- mL=milliliter
- measure only with dosing cup provided
- do not use dosing cup with other products
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

<b>AGE(yr)</b>	<b>DOSE(mL)</b>
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5 mL to 10 mL

**OTHER INFORMATION**

- **each 5 mL contains:** sodium 5 mg
- dosing cup provided
- store between 20°-25°C(68°-77°F)

**INACTIVE INGREDIENTS**

carboxymethylcellulose sodium, citric acid, flavors, glycerin, purified water , saccharin sodium, sodium benzoate, sorbitol.

**QUESTIONS OR COMMENTS**

Call **833-358-6431** Monday to Friday 9:00 am to 7:00 pm EST

**PRINCIPAL DISPLAY PANEL**

NDC 70677-1012-2

COMPARE TO CHILDREN'S BENADRYL® ORAL SOLUTION ACTIVE INGREDIENT\*

Foster & Thrive TM

**Children's Allergy Relief**

**Diphenhydramine HCl oral solution,**

**12.5 mg/5ml**

**ANTIHISTAMINE**

**Dye Free**

**4-6 Hours/Dose**

**Relief of:**

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

**2+ Ages**

**CHERRY FLAVOR**

DOSING CUP INCLUDED

**8FL OZ(236 mL)**

**Drug Facts**

DO NOT USE IF SEAL UNDER CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING.

**Active ingredient (in each 5 mL)** **Purpose**  
Diphenhydramine HCl 12.5 mg.....Antihistamine

**Uses** ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • itchy, watery eyes • sneezing • 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 the child has**

- glaucoma ■ a breathing problem such as chronic bronchitis

**Ask a doctor or pharmacist before use if the child is taking** sedatives or tranquilizers

**When using this product**

- sedatives and tranquilizers may increase drowsiness
- marked drowsiness may occur
- excitability may occur, especially in children

**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).

NDC 7677-1012-2

Foster & Thrive™

**Children's Allergy Relief**

**Diphenhydramine HCl oral solution, 12.5 mg/5 mL ANTHISTANINE**

2+ Ages | 4-6 Hours/Dose | **Dye Free**

**Relief of:**

- Runny Nose • Itchy, Watery Eyes
- Sneezing • Itchy Throat or Nose

**CHERRY FLAVOR**

**8 FL OZ (236 mL)**

**Drug Facts** (continued)

- find right dose on chart below ■ mL = milliliter
- measure only with dosing cup provided
- do not use dosing cup with other products
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 doses in 24 hours

AGE (yr)	DOSE (mL)
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5 mL to 10 mL

**Other information** ■ each 5 mL contains: sodium 5 mg ■ dosing cup provided ■ store between 20°-25° C (68°-77° F)

**Inactive ingredients** carboxymethylcellulose sodium, citric acid, flavors, glycerin, purified water, saccharin sodium, sodium benzoate, sorbitol.

**Questions or comments?** Call 833-318-6431 Monday to Friday 9:00 am to 7:00 pm EST

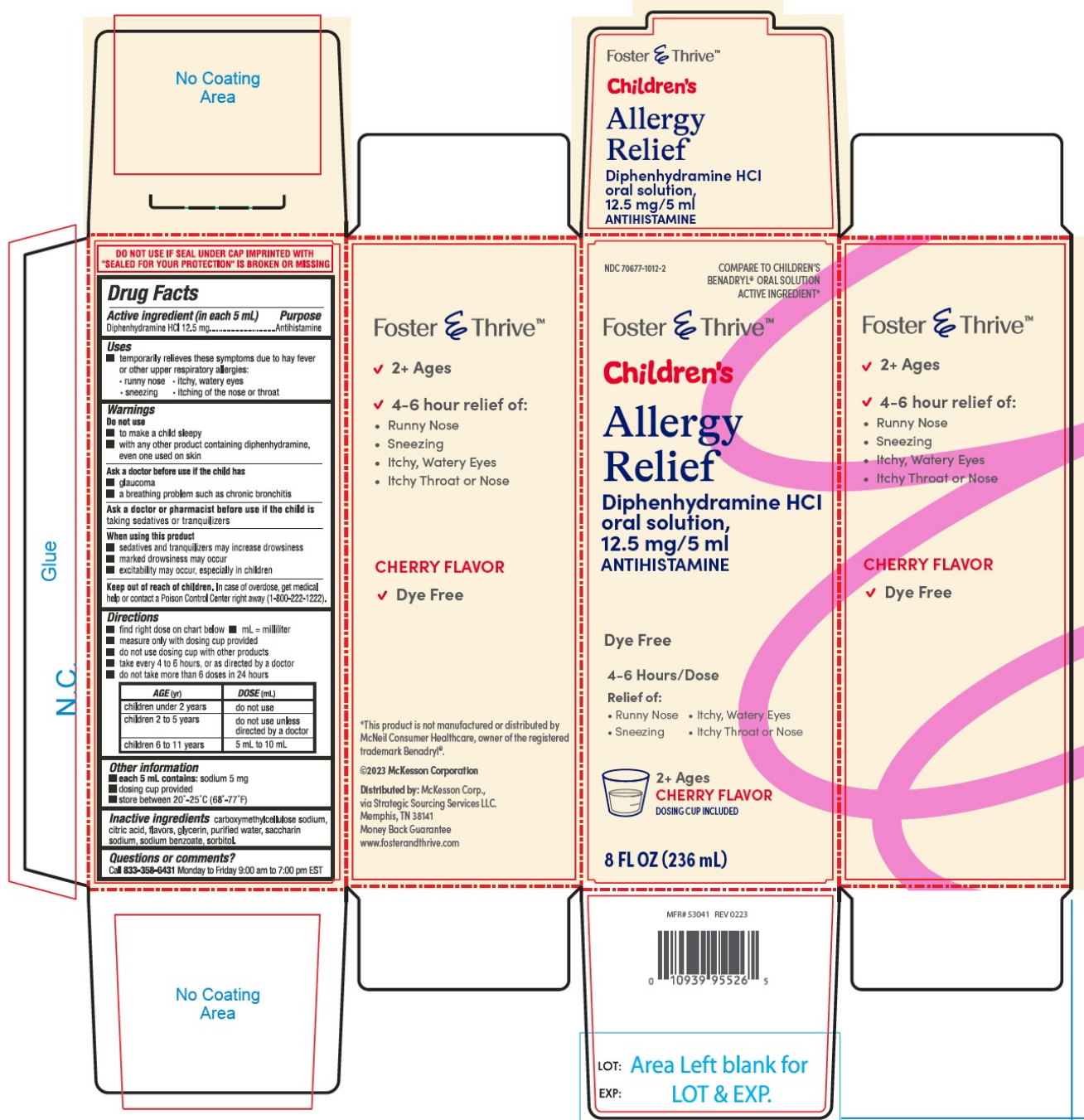
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NDC 70677-1012-1

COMPARE TO CHILDREN'S BENADRYL® ORAL SOLUTION ACTIVE INGREDIENT\*

Foster & Thrive™

**Children's Allergy Relief**

**Diphenhydramine HCl oral solution,**

**12.5 mg/5ml**

**ANTIHISTAMINE**

**Dye Free**

**4-6 Hours/Dose**

**Relief of:**

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

**2+Ages**

**CHERRY FLAVOR**

DOSING CUP INCLUDED

**4FL OZ(118 mL)**

NDC 70677-012-1

# Foster Thrive<sup>®</sup> **Children's** **Allergy Relief**

Diphenhydramine HCl  
oral solution,  
12.5 mg/5 ml  
ANTIHISTAMINE

2+ Ages | 4-6 Hours/Dose | Dye Free

Relief of:

- Runny Nose
- Itchy, Watery Eyes
- Sneezing
- Itchy Throat or Nose

**CHERRY FLAVOR**

**4 FL OZ (118 mL)**

**DO NOT USE IF SEAL UNDER CAP INTERRUPTED WITHIN 15 MINUTES OF YOUR PERFECT USE. SHAKE OR MIXING.**

### Drug Facts

**Active ingredient (in each 5 mL)**

Diphenhydramine HCl 12.5 mg Antihistamine

**Uses** ■ Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: • runny nose • itchy, watery eyes • sneezing • 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 the child has ■ glucose-6-phosphate dehydrogenase (G6PD) deficiency
- a breathing problem such as chronic bronchitis
- Ask a doctor or pharmacist before use if the child is taking sedatives or tranquilizers
- When using this product ■ sedatives and tranquilizers may increase drowsiness
- impaired consciousness may occur ■ excitability may occur, especially in children
- Keep out of reach of children. If 3 years of age or older, get medical help or contact a Poison Control Center right away. (1-800-422-1224).

**Directions** ■ Invert right case on cap below ■ mL = milliliter

- Take every 4 to 6 hours, or as directed by a doctor
- Do not take more than 6 doses in 24 hours
- Do not use dosing cup with other products
- Do not take more than 6 doses in 24 hours

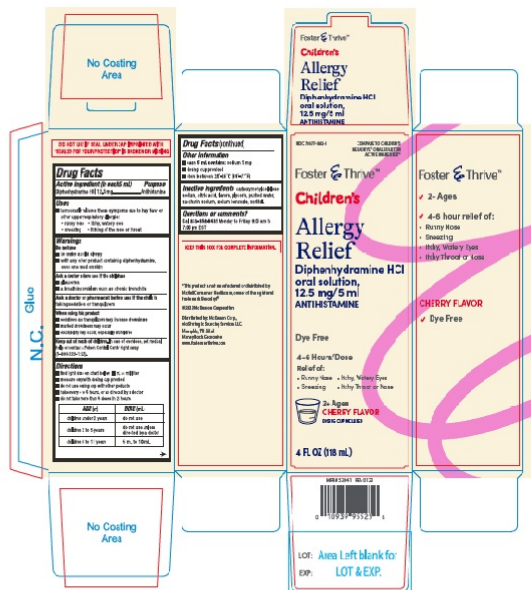
AGE (yr)	DOSE (mL)
children under 2 years	do not use
children 2 to 5 years	do not use unless directed by a doctor
children 6 to 11 years	5 mL to 17 mL

**KEEP BOX FOR COMPLETE INFORMATION**

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# FOSTER AND THRIVE CHILDRENS ALLERGY RELIEF

diphenhydramine hcl liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1012
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 5 mL
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### Inactive Ingredients

Ingredient Name	Strength
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1012-1	1 in 1 CARTON	04/12/2023	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70677-1012-2	1 in 1 CARTON	04/12/2023	
2		236 mL in 1 BOTTLE; 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	04/12/2023	

**Labeler** - Strategic Sourcing Services LLC (116956644)

### Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(70677-1012)