

**NIGHTTIME SLEEP AID- diphenhydramine hcl tablet, film coated**  
**Strategic Sourcing Services LLC**

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**Foster and Thrive 44-367**

***Active ingredient (in each caplet)***

Diphenhydramine HCl 25 mg

***Purpose***

Nighttime sleep-aid

***Uses***

- for relief of occasional sleeplessness
- reduces time to fall asleep if you have difficulty falling asleep

***Warnings***

**Do not use**

- for children under 12 years of age
- 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
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are**

taking sedatives or tranquilizers.

**When using this product**

avoid alcoholic beverages.

**Stop use and ask a doctor if**

sleeplessness persists continuously for more than 2 weeks. Insomnia may be a symptom of a serious underlying medical illness.

**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.

### ***Directions***

- **do not take more than directed**
- adults and children 12 years and over: take 2 caplets at bedtime if needed or as directed by a doctor
- children under 12 years: do not use

### ***Other information***

- **each caplet contains:** calcium 30 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- protect from moisture
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

corn starch, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

### ***Questions or comments?***

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

### ***Principal Display Panel***

NDC 70677-1128-1

**Foster & Thrive™**

COMPARE TO SIMPLY SLEEP®  
ACTIVE INGREDIENT\*

#### **Nighttime Sleep Aid**

Diphenhydramine HCl 25 mg  
NIGHTTIME SLEEP-AID

Non-habit Forming  
Helps You Fall Asleep  
Not for treating Pain, Cold or Flu

ACTUAL SIZE

**24 CAPLETS**

**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS  
OPENED OR IF BLISTER UNIT IS TORN, BROKEN  
OR SHOWS ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by Johnson & Johnson

Corporation, owner of the registered trademark Simply Sleep®.  
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 Diphenhydramine HCl 25 mg

NDC 70677-1128-1

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no print / no varnish area  
 lot no & exp. date

B-1243-367-08  
 ORG101936708

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 www.fosterandthrive.com



Diphenhydramine HCl 25 mg .....Nighttime sleep-aid

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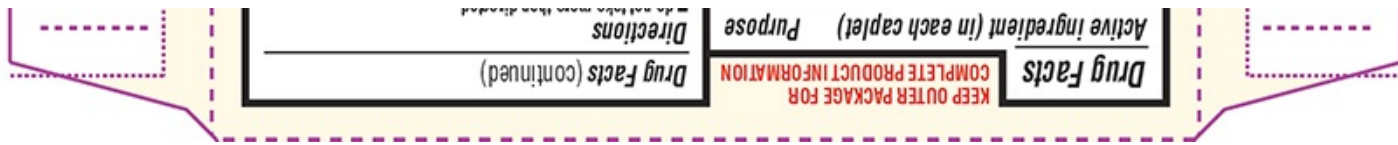
**Inactive ingredients** corn starch, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

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**Foster and Thrive 44-367**

**NIGHTTIME SLEEP AID**

diphenhydramine hcl tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1128
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	44;367
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1128-1	2 in 1 CARTON	05/18/2023	
-		12 in 1 BLISTER PACK; Type 0: Not a Combination		

Product			
<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M010	05/18/2023	

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(70677-1128)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(70677-1128) , pack(70677-1128)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(70677-1128)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(70677-1128)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(70677-1128)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(70677-1128)