

**ALLER-BEN- diphenhydramine hcl tablet, film coated**  
**Sam's West 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.*

-----

**Members Mark 44-329 Aller-Ben**

***Active ingredient (in each tablet)***

Diphenhydramine HCl 25 mg

***Purpose***

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
- temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

***Warnings***

**Do not use**

- with any other product containing diphenhydramine, even one used on skin

**Ask a doctor before use if you have**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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**

- marked drowsiness may occur

- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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.

**Directions**

- **do not take more than directed**
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

adults and children 12 years and over	1 to 2 tablets
children 6 to under 12 years	1 tablet
children under 6 years	do not use

**Other information**

- **each tablet contains:** calcium 30 mg
- protect from moisture
- use by expiration date on package
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Inactive ingredients**

corn starch, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

**Questions or comments?**

**1-800-426-9391** 8:30 AM-4:00 PM ET, Monday-Friday

**Principal display panel**

**Compare to Benadryl® Allergy Ultratab® active ingredient\***

NDC 68196-829-78

**Member's Mark™**

**Aller-Ben™**

Diphenhydramine HCl 25 mg  
Antihistamine

**Allergy**

For Allergy Relief of

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

actual size

**600 Tablets**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS  
BROKEN OR MISSING**

Comments or Questions?

Call 1-800-426-9390

from 8:30a.m. to 4:00p.m. ET

Monday-Friday

\*This product is not manufactured or distributed by Johnson & Johnson Corporation,  
owner of the registered trademark Benadryl® Allergy Ultratab®.

50844 REV1220A32978

DISTRIBUTED BY: SAM'S WEST, INC., BENTONVILLE, AR 72716

**STOP PEELING**

**Questions or comments?** 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

**Inactive ingredients** com starch, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

**Other information** ■ use by expiration date on package ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Directions** ■ do not take more than directed ■ take every 4 to 6 hours, or as directed by a doctor ■ do not take more than 6 times in 24 hours ■ adults and children 12 years and over 1 to 2 tablets ■ children 6 to under 12 years 1 tablet ■ children under 6 years do not use

**Drug Facts (continued)**

Varnish Area/No print  
Lot no. & Exp. Date

**Drug Facts (continued)**

**When using this product**

- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- use caution 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.

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl® Allergy Ultratab®, 50844 REV1220A32978 DISTRIBUTED BY: SAM'S WEST, INC., BENTONVILLE, AR 72716

**PEEL HERE FOR MORE DRUG FACTS**

**Compare to Benadryl® Allergy Ultratab® active ingredient\***

NDC 68196-829-78

**Member's Mark™**

**Aller-Ben™**  
Diphenhydramine HCl 25 mg  
Antihistamine  
**Allergy**

For Allergy Relief of

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

actual size

**600 Tablets**

Comments or Questions? Call 1-800-426-9391 from 8:30 am to 4:00 pm ET Monday - Friday

1 939688 05151 8

**Drug Facts** TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

**Active ingredient (in each tablet)** **Purpose**

Diphenhydramine HCl 25 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
- temporarily relieves these symptoms due to the common cold:
- runny nose ■ sneezing

**Warnings**

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

**Ask a doctor before use if you have** ■ glaucoma

- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

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

**Members Mark 44-329**

<b>ALLER-BEN</b>			
diphenhydramine hcl tablet, film coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68196-829
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
STARCH, CORN (UNII: O8232NY3SJ)			
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
MAGNESIUM STEARATE (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>	pink	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	44;329
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-829-78	600 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/18/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/18/2020	

### Labeler - Sam's West Inc (051957769)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(68196-829)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(68196-829) , pack(68196-829)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	pack(68196-829)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(68196-829)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(68196-829)

Revised: 7/2021

Sam's West Inc