DIPHENHYDRAMINE- diphenhydramine hcl tablet, 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

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

- to make a child sleepy
- 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
- trouble urinating due to an enlarged 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 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.

Directions

- 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

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- protect from moisture
- use by expiration date on package

Inactive ingredients

corn starch, D&C red #27 aluminum lake, dicalcium phosphate, 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 to 4:00 PM ET, Monday-Friday

Principal Display Panel

Compare to Benadryl® Allergy
Ultratab® active ingredient*

Member's Mark®
QUALITY GUARANTEED

NDC 68196-929-78

diphenhydramine
diphenhydramine HCl
25 mg
antihistamine

For allergy relief of
• sneezing
• runny nose
• itchy, watery eyes
• itchy throat or nose

actual
size

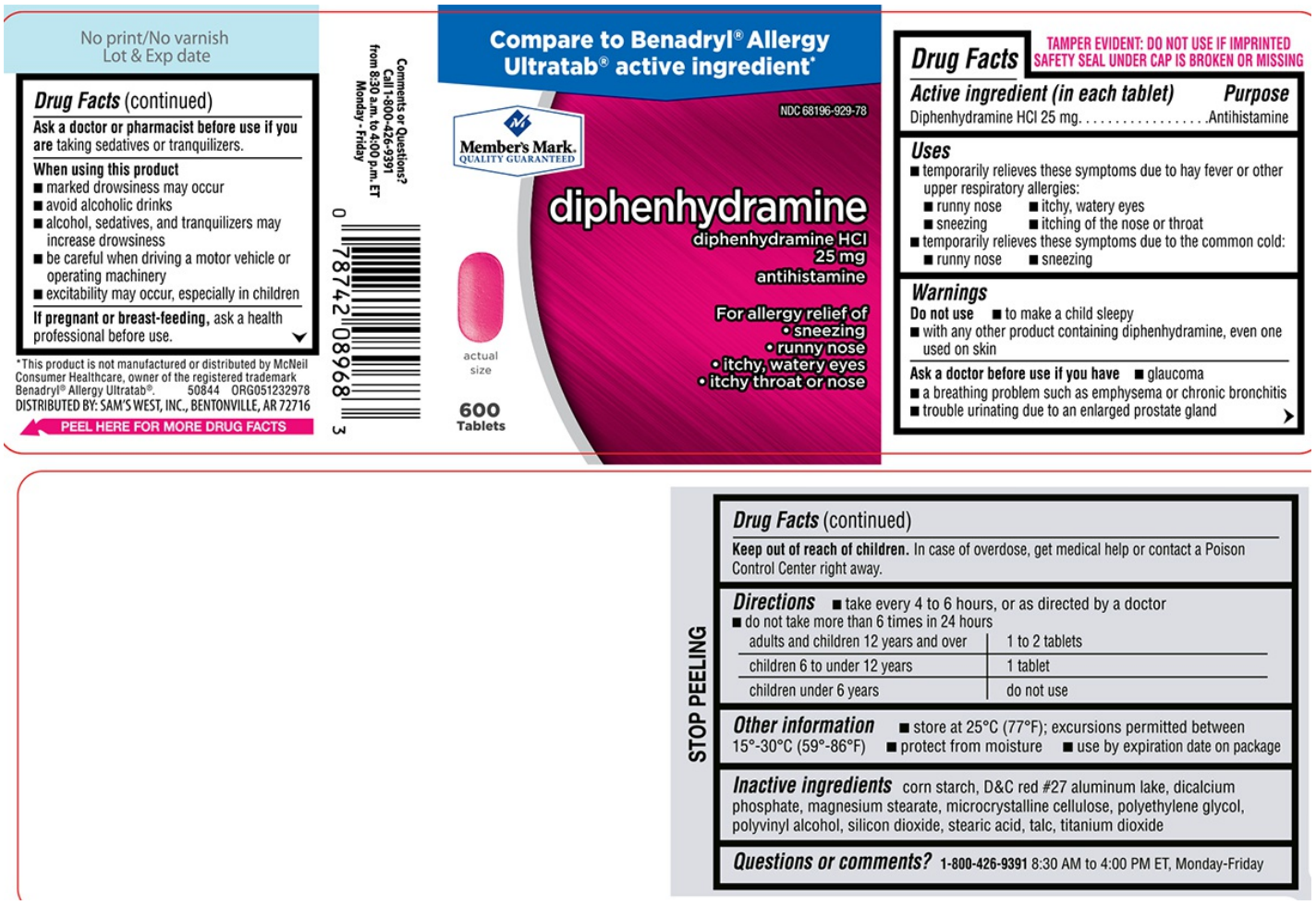
600
Tablets

Comments or Questions?
Call 1-800-426-9391
from 8:30 a.m. to 4:00 p.m. ET
Monday - Friday

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

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Benadryl® Allergy Ultratab®. 50844 ORG051232978

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



Members Mark 44-329

DIPHENHYDRAMINE

diphenhydramine hcl tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68196-929
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

Product Characteristics			
Color	PINK	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	44;329
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68196-929-78	600 in 1 BOTTLE; Type 0: Not a Combination Product	03/02/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/02/1990	

Labeler - Sam's West Inc (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	MANUFACTURE(68196-929) , PACK(68196-929)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(68196-929)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(68196-929)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68196-929)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(68196-929)

Revised: 6/2018

Sam's West Inc