DRX CHOICE CHILDRENS ALLERGY CHEWS- diphenhydramine hcl tablet, chewable
RARITAN PHARMACEUTICALS 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.

DRx Choice children's allergy chews

Active ingredient (in each tablet)

Diphenhydramine HCl 12.5 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

Warnings

Do not use

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

Ask your 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 at 1-800-222-1222

Directions

- chew one tablet completely at the onset of symptoms. Do not swallow tablets whole.
- Find right dose on chart below
- 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 (chewable tablets)**
children under 2 years of age	do not use
children 2 to under 5 years of age	do not use unless directed by a doctor
children 6 to under 12 years of age	1 to 2 tablets
adults and children 12 years of age and over	2 to 4 tablets

Other information

- store below at room temperature. Avoid high humidity. Protect from light.

Inactive ingredients

citric acid, crospovidone, D&C Red No.30, dextrose, FD&C Blue No 1, flavors, magnesium stearate, maltodextrin, potassium citrate, silica, sodium polystyrene sulfonate, starch, sucralose

Questions or comments ?

1-866-467-2748

Principal Display Panel

NDC 68163-012-48

Compare to active ingredient in Children's Benadryl® Allergy Chewable Tablets

DRx Choice

children's allergy chews
diphenhydramine HCl, 12.5 mg/ antihistamine

For Relief of:

- Sneezing
- Runny nose
- Itchy throat or Nose
- Itchy, watery eyes

48 Chewable Tablets

Grape Flavor

4-6 HOURS/DOSE

TAMPER EVIDENT: DO NOT USE IF CARTON 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 Consumer INC, owner of the registered trademark Children's Benadryl® Allergy Chewable Tablets.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick,

NJ 08816

IMPORTANT: Keep this carton for future reference on full labelling

DRX CHOICE CHILDRENS ALLERGY CHEWS

diphenhydramine hcl tablet, chewable

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68163-012
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

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPOVIDONE (120 .MU.M) (UNII: 68401960MK)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM POLYSTYRENE SULFONATE (UNII: 1699G8679Z)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	PURPLE	**Score**	2 pieces
Shape	ROUND	**Size**	16mm
Flavor	GRAPE	**Imprint Code**	RP012
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-012-48	4 in 1 CARTON	07/04/2022	
1		12 in 1 BLISTER PACK; 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	07/04/2022	

Labeler - RARITAN PHARMACEUTICALS INC (127602287)

Revised: 9/2023 RARITAN PHARMACEUTICALS INC