HISTAPRIN - diphenhydramine tablet
NorMed

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.

HISTAPRIN

Active Ingredient (in each caplet)

Diphenhydramine Hydrochloride 25mg

Antihistamine

Temporarily relieves these symptoms due to the common cold, hay fever, or other upper respiratory allergies:

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

Do not use with any other products containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- trouble urinating due to enlarged prostate gland
- glaucoma
- a breathing problem such as emphysema or chronic bronchiti

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

When using the product

- drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives and tranquilizers may increase the drowsiness effect
- 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

Adults and children 12 years of age and over:

- Take 1 caplet every 4 to 6 hours while symptoms persist
- do not take more than 6 caplets in 24 hours unless directed by a doctor

Children under 12 years of age: not intended for use in children under 12; ask a doctor

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HISTAPRIN

diphenhydramine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50332-0132
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink	**Score**	no score
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	T061
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0132-4	50 in 1 BOX, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	01/01/2009	

Labeler - NorMed (069560969)

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