APHENAP- diphenhydramine hydrochloride tablet
A P J Laboratories Limited

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.

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active ingredient
DIPHENHYDRAMINE HYDROCHLORIDE

purpose

Antihistamine

keep out of reach of children
In case of overdose, get medical help or contact a Poison Control Center right away(1-800-222-1222).

uses

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold, sneezing, runny nose, itchy, watery eyes, itchy throat and nose

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.

directions

Adults and children 12 years and over: take 25 to 50 mg (1 to 2 tablet) every 4 to 6 hours; not more than 12 tablets in 24 hours.

Children 6 years to 12 years of age: take 25 mg (1 tablet) every 4 to 6 hours; not more than 6 tablets in 24 hours.

Children under 6 years of age: ask a doctor

inactive ingredient

CELLULOSE, MICROCRYSTALLINE

MAGNESIUM STEARATE

METHYLPARABEN

POVIDONE K30

SILICON DIOXIDE

SODIUM STARCH GLYCOLATE TYPE A POTATO

STARCH, CORN

TALC

TITANIUM DIOXIDE

APHENAP

diphenhydramine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:46084-041
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
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	30 mg
STARCH, CORN (UNII: O8232NY3SJ)	15 mg
POVIDONE K30 (UNII: U725QWY32X)	10 mg
METHYLPARABEN (UNII: A2I8C7HI9T)	1 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	1 mg
MAGNESIUM STEARATE (UNII: 70097M6I30)	10 mg
TALC (UNII: 7SEV7J4R1U)	15 mg
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	20 mg
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	1 mg

Product Characteristics

Color	white	**Score**	no score

Shape	ROUND	**Size**	4mm
Flavor		**Imprint Code**	25mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:46084-041-15	100 in 1 BLISTER PACK		
2	NDC:46084-041-14	60 in 1 BLISTER PACK		
3	NDC:46084-041-13	30 in 1 BLISTER PACK		
4	NDC:46084-041-12	12 in 1 BLISTER PACK		
5	NDC:46084-041-11	5 in 1 BLISTER PACK		
6	NDC:46084-041-23	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/01/2013	

Labeler - A P J Laboratories Limited (677378339)

Registrant - A P J Laboratories Limited (677378339)

Establishment

Name	Address	ID/FEI	Business Operations
A P J Laboratories Limited		677378339	manufacture(46084-041)