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.

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 LABEL	Item Code (Source)	NDC:46084-041	
Route of Administration	ORAL	DEA Sche dule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDRO CHLO RIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CELLULOSE, MICRO CRYSTALLINE	30 mg			
STARCH, CORN	15 mg			
PO VIDO NE K30	10 mg			
METHYLPARABEN	1 mg			
TITANIUM DIO XIDE	1 mg			
MAGNESIUM STEARATE	10 mg			
TALC	15 mg			
SODIUM STARCH GLYCOLATE TYPE A POTATO	20 mg			
SILICON DIO XIDE	1 mg			

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	4mm	

Flavor	Imprint Code	25mg
Contains		

P	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			

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)	

Revised: 2/2013 A P J Laboratories Limited