ALLERGY RELIEF- diphenhydramine hcl 25 mg tablet Pioneer Life Sciences, LLC

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 Hcl 25mg

Purpose

Antihistamine

Uses:

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

runny nose sneezing itchy, watery eyes 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 Doctor:

Ask a doctor before use if you have - glaucoma - troble urinating due to an enlarged prostate gland - a breathing problem such as emphysema or chronic bronchitis

ASK DOCTOR/PHARMACIST:

Ask a doctor or pharmacist before use if you aretaking 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

PREGNANCY

If pregnant or breast-feeding, ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

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

DIRECTIONS

if needed, repeat dose every 4 to 6 hours do not take more than 6 times in 24 hours adults and children 12 years of age or older - 1 to 2 caplets children 6 to under 12 years - 1 caplet children under 6 years of age - do not use.

OTHER INFORMATION

each tablets contains: calcium 24 mg - store between 20-25°C (68-77°F). Avoid high humidity. Protect from moisture and light

INACTIVE INGREDIENTS

Dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, OPADRY II

QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9AM–5PM EST or www.pioneerlifesciences.com

PRINCIPAL DISPLAY PANEL



Label

ALLERGY RELIEF diphenhydramine hcl 25 mg tablet Product Information Product Type HUMAN OTC DRUG Route of Administration ORAL

		Moiety Ingredient Name	0		Basis of	Strength	Strengt
DIPHENHYDRAMINE I UNII:8GTS82S83M)	HYDRO C	-	e 2D6JAD40) (DIPHENHYD	RAMINE -		MINE	25 mg
Inactive Ingredie	nts						
		Ingre	dient Name				Strength
LECITHIN, SO YBEAN							
CELLULOSE, MICRO							
CROSCARMELLOSE							
ANHYDRO US DIBASI			NII: L11K75P92J)				
SILICON DIO XIDE (U							
MAGNESIUM STEARA							
POLYVINYL ALCOH		PECIFIED (UNII: 532)	3291990)				
TALC (UNII: 7SEV7J4R1U)							
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)							
D&C RED NO.27 ALU	JMINUM	LAKE (UNII: ZK64F7	XSTX)				
Product Characte	eristics						
Color		pink	Score	Score		no score	
Shape		OVAL	Size			11mm	
Flavor		Imprint Code		S4		S4	
Contains							
Packaging							
Packaging # Item Code		Package De	scription	Marke	ting Start Da	te Marke	ting End Dat
	1 in 1 CA	0	scription	Marke 06/29/2	0	te Marke	ting End Date
# Item Code		ARTON	scription a Combination Product		0	te Marke	ting End Dat
# Item Code 1 NDC:72090-021-26		ARTON			0	te Marke	ting End Dat
Item Code NDC:72090-021-26		ARTON			0	te Marke	ting End Date
# Item Code 1 NDC:72090-021-26		ARTON			0	te Marker	ting End Date
# Item Code 1 NDC:72090-021-26 1		ARTON	a Combination Product		0	te Marke	ting End Dat
# Item Code 1 NDC:72090-021-26 1		ARTON			0	te Marker	ting End Dat
# Item Code NDC:72090-021-26 1	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marken	ting End Dat
# Item Code 1 NDC:72090-021-26 1	24 in 1 B	ARTON SOTTLE; Type 0: Not	a Combination Product		0	te Marker	ting End Dat
 Item Code NDC:72090-021-26 interface 	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marken	ting End Dat
 Item Code NDC:72090-021-26 i <lii< li=""> i i i i</lii<>	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marke	ting End Dat
# Item Code 1 NDC:72090-021-26 1	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marken	ting End Dat
# Item Code 1 NDC:72090-021-26 1	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marke	ting End Dat
 Item Code NDC:72090-021-26 interface in	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Market	6 80044 64647 3
 Item Code NDC:72090-021-26 i <lii< li=""> i i i i</lii<>	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marken	ting End Dat ۲ (24949) ۲ (24949) 1
Item Code NDC:72090-021-26 I	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Market	6 80044 64647 3
 Item Code NDC:72090-021-26 i <lii< li=""> i i i i</lii<>	24 in 1 B	ARTON OTTLE; Type 0: Not	a Combination Product		0	te Marken Hunne Hauren Hunne Ha	6 80044 64647 3

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/29/2020	

Labeler - Pioneer Life Sciences, LLC (014092742)

Revised: 7/2020

Pioneer Life Sciences, LLC