DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule HF Acquisition Co LLC, DBA HealthFirst

DRUG FACTS

Active ingredient (in each capsule) Diphenhydramine HCl 25 mg

Purpose Antihistamine

adults and children

USES
$\ \ \ \ \ \ \ \ \ \ \ \ \ $
☐ to make a child sleepy
$\hfill \square$ with any other product containing diphenhydramine, even one used on skin
Ask a doctor before use if you have a breathing problem such as emphysema or chronic bronchitis
☐ glaucoma☐ 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 (1-800-222-1222).
DIRECTIONS
$\hfill \Box$ take every 4 to 6 hours, or as directed by a doctor
☐ do not take more than 6 doses in 24 hours

12 years of age and over 1 to 2 capsules children 6 to under 12 years of age 1 capsule children under 6 years of age do not use this product in children under 6 years of age

OTHER	INFO	RM	ΔΤ	ION	ı
O I I ILIX	1141 0		$\overline{}$	-	4

store in a dry place at 15° – 30°C (59° – 86°F)

corn starch, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, sodium lauryl sulfate

KEEP OUT OF REACH OF CHILDREN. DO NOT USE IF PRODUCT APPEARS TO BE TAMPERED WITH OR IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING. DO NOT USE IF RED CAPSULE BAND IS BROKEN OR MISSING.

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

QUESTIONS OR COMMENTS
1-800-616-2471
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
ORAL
Diphenhydramine HCl 25 mg
take every 4 to 6 hours, or as directed by a doctor
do not take more than 6 doses in 24 hours
\square temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: \square runny nose \square sneezing \square itchy, watery eyes \square itching of the nose or throat



(01) 00351662162811 (17) 300101 (21) 127321891620 (10) 123456



See manufacturer's package insert Distributed by HF Acquisition Co., LLC Mukilteo, WA 98275

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51662-1628(NDC:0904-7237)		
Route of Administration	ORAL				

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
,,	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients			
Ingredient Name	Strength		
GELATIN (UNII: 2G86QN327L)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
STARCH, CORN (UNII: O8232NY3SJ)			
D&C RED NO. 28 (UNII: 767IP0Y5NH)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			

Product Characteristics				
Color	pink (Half pink and half clear with white powder inside and sealed with red band)	Score	no score	
Shape	CAPSULE	Size	14mm	
Flavor		Imprint Code	CPC;835	
Contains				

F	Packaging				
#	tem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:51662- 1628-1	2 in 1 CARTON; Type 0: Not a Combination Product	04/14/2022		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	04/14/2022		

Labeler - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Registrant - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Establishment				
Name	Address	ID/FEI	Business Operations	
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1628)	