ALLOPAX- levocetirizine dihydrochloride 5%, loratadine 5%
PharmaGenetico LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

AlloPAX

Each Allo•PAX provides 3 grams of Levocetirizine dihydrochloride, 3 grams Loratadine USP, and 54 grams of Base. The resulting mixture is intended for transdermal use.

For Prescription Use Only

Distributed by:

PharmaGenetico LLC

San Antonio, TX 78257

Allo•PAX – Levocetirizine dihydrochloride/Loratadine 5%/5% Cream Pack

NDC: 69817-0201-1

To the pharmacist:

1. This pack contains pre-weighed Levocetirizine dihydrochloride, Loratadine, PCCA Lipoderm® base.
2. Empty PCCA Lipoderm® base into appropriate mixing container.
3. Combine the Loratadine powder with the PCCA Lipoderm® base.
   Important: make sure to tap all contents out of its container
4. Stir gently for approximately 1-2 minutes until homogenous in appearance.
5. Combine the Levocetirizine dihydrochloride powder with the PCCA Lipoderm® base / Loratadine mixture.
   Important: make sure to tap all contents out of its container
6. Stir gently for approximately 1-2 minutes until homogenous in appearance

Store formulation at controlled room temperature 15°-30° C (59°-86° F)

Dispose of this product after 30 days of being dispensed.

For external use only: Avoid contact with eyes. Keep container tightly closed. Keep out of reach of children.

It is the pharmacy's responsibility that finished product is properly labeled according to all state and federal guidelines.

RX only.

PharmaGenetico

PharmaGenetico, LLC
17806 IH10, Suite 300
San Antonio, TX 78257
E: info@pharmagenetico.com
P: 210-819-7446

Active Ingredient(s):
Loratadine USP: 3 g
Levocetirizine dihydrochloride: 3 g

Inactive Ingredient(s):
PCCA Lipoderm®: 54 g

Front Carton Label

NDC 69817-0201-1 **Allo•PAX**

For Prescription Use Only

ATTENTION PHARMACIST:

- Store formulation at room temperature, 20°-25° C (68°-77° F).
- Protect from light.
- Keep out of reach from children.
- Keep container tightly closed.
- For external use only.
- Avoid contact with eyes.
- Prepare as instructed before dispensing.

LOT: 12345678
EXP: MMM YYYY

Marketed By
PharmaGenetico LLC
San Antonio, TX 78257

PharmaGenetico

Back Carton Label

NDC 69817-0201-1 **Allo•PAX**

For Prescription Use Only

The FDA has not approved Allo•PAX to cure, treat or mitigate disease. Allo•PAX is intended for preparation in accordance with state and federal regulations and is available to patients by prescription only.

Each Pack Contains:

Levocetirizine Dihydrochloride.....3g
Loratadine USP.....3g
Base..... 54g

Rx Only

60g as Dispensed

ALLOPAX

levocetirizine dihydrochloride 5%, loratadine 5% kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69817-0201

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:69817-0201-1	1 in 1 BOX; Type 0: Not a Combination Product	06/30/2015	11/23/2016

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE, PLASTIC	3 g in 3
Part 2	1 BOTTLE, PLASTIC	3 g in 3
Part 3	1 JAR	54 g in 54

Part 1 of 3

LORATADINE

loratadine powder, for suspension

Product Information	
Route of Administration	TRANSDERMAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN)	LORATADINE	3 g in 3 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		3 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other			

Part 2 of 3

LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride powder, for suspension

Product Information	
Route of Administration	TRANSDERMAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	3 g in 3 g

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		3 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
unapproved drug other			

Part 3 of 3

CREAM BASE

cream base cream

Product Information

Route of Administration	TRANSDERMAL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
WHEAT GERM OIL (UNII: 14C97E680P)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	
LAURETH-7 (UNII: Z95S6G8201)	
XANTHAN GUM (UNII: TTV12P4NEE)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		54 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/30/2015	

Labeler - PharmaGenetico LLC (079713987)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(69817-0201)

Revised: 7/2017 PharmaGenetico LLC