LORATADINE- loratadine capsule, liquid filled CVS HEALTH CORP

686T CVS 69842 686 Loratadine Softgels 10 mg

DRUG FACTS

Active Ingredient (in each capsule)

Loratadine 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- itchy, watery eyes
- sneezing
- itching of the nose or throat

Warnings

Do not use If you have ever had an allergic reaction to this product or any of its ingredients.

Ask a doctor before use if you have liver or kidney disease. Your doctor should determine if you need a different dose.

When using this product do not take more than directed. Taking more than directed may cause drowsiness.

Stop use and ask a doctor if an allergic reaction to this product occurs, Seek medical help right away.

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.

Directions

- adults and children 6 years and over: 1 capsule daily; not more than 1 capsule in 24 hours
- children under 6 years of age: ask a doctor
- consumers with liver or kidney disease: ask a doctor

Other information

- store between 20-25°C (68-77°F)
- protect from freezing

Inactive Ingredients FD&C blue # 1, gelatin, mono and diglyceride of caprylic/capric

acid, pharmaceutical ink, polysorbate 80, povidone, purified water, sorbitol sorbitan solution

Questions or comments?

call 1-877-290-4008







LORATADINE

LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII:7AJ03B07QN) LORATADINE 10 mg Ingredients Ingredient Name Streng FD&C BLUE NO. 1 (UNII: H3R47K3TBD) Streng GELATIN (UNII: 2686QN327L) Streng POVIDOE (UNII: 602P392G8H) Streng POVIDOE (UNII: 602P392G8H) Streng SORBITOL (UNII: 5036070000 SORBITOL (UNII: 5076000R) SORBITOL (UNII: 5076000R) SORBITOL (UNII: 50760000R) Sore no score SORBITOL (UNII: 50760000R) Sore no score SORBITOL (UNII: 50760000R) Sore no score Sore NOVAL Size 3 mm Sore NOVAL Size Sore Flavor Imprint Code 2 V V Sore Nor.669842- Gel 0 10 in 1 CARTON 01/31/2017 <th c<="" th=""><th>F</th><th>roduct Info</th><th>rmation</th><th></th><th></th><th></th><th></th><th></th><th></th></th>	<th>F</th> <th>roduct Info</th> <th>rmation</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th>	F	roduct Info	rmation						
Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII:7AJ03B07QN) LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII:7AJ03B07QN) LORATADINE 10 mg Ingredients Strength Ingredient Name Strength FD&C BLUE NO. 1 (UNII: H3R47K3TBD) GELATIN (UNII: 26860N327L) POLYSORBATE 80 (UNII: E29892G8H) OVIDONE (UNII: E2989G1694E) MATER (UNII: 059G760X0R) Sore no score Shape OVAL Size 3 mm Flavor OVAL Size 3 mm Size	Pı	roduct Type		HUMAN OTC	DRUG Ite	m Code (S	iource)	NDC:	69842-686	
Ingredient Name Basis of Strength Strength LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) LORATADINE UORATADINE UORATADINE <th< th=""><th>Re</th><th>oute of Admin</th><th>istration</th><th>ORAL</th><th></th><th></th><th></th><th></th><th></th></th<>	Re	oute of Admin	istration	ORAL						
Ingredient Name Basis of Strength Strength LORATADINE (UNII: 7AJO3BO7QN) (LORATADINE - UNII:7AJO3BO7QN) LORATADINE UORATADINE UORATADINE <th< th=""><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></th<>										
LORATADINE (UNII: 7AJ03B07QN) (LORATADINE - UNII:7AJ03B07QN) LORATADINE 10 mg INDECENTIONE (UNII: 7AJ03B07QN) (LORATADINE - UNII:7AJ03B07QN) LORATADINE Streng INDECENTIONE (UNII: 13R47K3TBD) Streng Streng GELATIN (UNII: 2G86QN327L) Streng Streng POVIDORE (UNII: 602P392G8H) Streng Streng VSORBATE 80 (UNII: 602P392G8H) Streng Streng SOURDONE (UNII: 5090F0K0R) Streng Streng SORBITOL (UNII: 5090F0K0R) Streng Streng Sore OVAL Size 3mm Flavor OVAL Size 3mm Flavor OVAL Size 3mm In In CARTON In 1 CARTON O1/31/2017 In 1 CARTON In SubStER PACK: Type 0: Not a Combination Product Size Size In In BUISTE	A	ctive Ingred	ient/Activ	ve Moiety						
Ingredients Streng Ingredient Name Streng FD&C BLUE NO. 1 (UNII: H3R47K3TBD) GELATIN (UNII: 2086QN327L) POLYSORBATE 80 (UNII: 602P392G8H) POLYSORBATE 80 (UNII: 602P392G8H) POLYSORBATE 80 (UNII: 602P392G8H) Sorget Colspan="2">Sorget Colspan="2">Sorget Colspan="2">Sorget Colspan="2">Sorget Colspan="2">Sorget Colspan="2">Sorget Colspan="2">Ingredient Score Product Characteristics Color blue Score no score Shape OVAL Size 3mm Flavor Imprint Code 21 Contains Packaging # tem Code Package Description Marketing Start Date Marketing Date 1 in 1 CARTON 01/31/2017 Cordica NDC:69842- 666-07 1 in 1 CARTON 01/31/2017 2 NDC:69842- 666-607 0 in 1 BLISTER PACK; Type 0: Not a Combination Product <th colsp<="" th=""><th></th><th></th><th>Ing</th><th>redient Nam</th><th>е</th><th></th><th>Basis of S</th><th>Strengtl</th><th>h Strengtl</th></th>	<th></th> <th></th> <th>Ing</th> <th>redient Nam</th> <th>е</th> <th></th> <th>Basis of S</th> <th>Strengtl</th> <th>h Strengtl</th>			Ing	redient Nam	е		Basis of S	Strengtl	h Strengtl
Ingredient Name Streng FD&C BLUE NO. 1 (UNII: H3R47K3TBD) GELATIN (UNII: 2G86QN327L) POUTSORBATE 80 (UNII: 602P392G8H) POUTSORBATE 80 (UNII: 602P392G8H) POUTSORBATE 80 (UNII: 602P392G8H) POVIDONE (UNII: 509GP0400R) SORBITOL (UNII: 509GF0400R) SORBITOL (UNII: 509GF0402SR) Color blue Score no score SoBape OVAL Size 3mm Flavor Imprint Code 2 POL:69842- 686-07 1 in 1 CARTON Ol/31/2017 IDI in 1 BLISTER PACK; Type 0: Not a Combination Product Ol/31/2017 IDI in 1 BLISTER PACK; Type 0: Not a Combination Product Ol/31/2017 Solution Ol/31/2017 IDI in 1 BLISTER PACK; Type 0: Not a	LC	RATADINE (UNI	I: 7AJO3BO7C)n) (loratadine	- UNII:7AJO3BO7Q	N)	LORATADINE		10 mg	
Fb&C BLUE NO. 1 (UNII: H3R47K3TBD) Image: State S	In	active Ingre	edients							
GELATIN (UNII: 2080QN327L) Image: Second secon	FF	SC BLUE NO. 1	I (IINII: H3R4	-	ent Name				Strength	
POLYSORBATE 80 (UNII: 60ZP39ZG8H) POVIDONE (UNII: F2989GH94E) WATER (UNII: 059QF0K00R) SORBITOL (UNII: 506T60A25R) CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q218C85) CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q218C85) POULC CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q18C8) POULC CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLIC/CAPRYLI				, (3100)						
Povidone (UNII: FZ 989GH94E) WATER (UNII: 059QF0K00R) SORBITOL (UNII: 50GF0A2SR) CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85) Product Characteristics Color blue Score no score Shape 0VAL Size no score 3mm Imprint Code 3mm Imprint Code 3mm Product Contains 1 in 1 CARTON 01/31/2017 01/31/2017 Marketing Date 1 in 1 CARTON 01/31/2017 01/31/2017 Marketing Code 1 in 1 CARTON 01/31/2017 01/31/2017 NDC:69842- 686-30 3 in 1 CARTON 01/31/2017 01/31/2017 01/31/2017 NDC:69842- 686-30 3 in 1 CARTON 01/31/2017 01/31/2017 01/31/2017 01/31/2017 NDC:69842- 686-30 6 in 1 CARTON 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 01/31/2017 0				2307 (284)						
water (UNII: 059QF0K00R) in 1 CARTON 01/31/2017 in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 i in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 i in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 i in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 i in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 i in 1 CARTON NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 i in 1 CARTON										
SOBEITOL (UNII: 506T60A25R) CAPRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85) Product Characteristics Color blue Score no score Shape 0VAL Size 3mm Flavor 0VAL Size 3mm Flavor 01/31/2017 Marketing Start Marketing Date Marketing Date Marketing Date Marketing Date Marketing Date 1 in 1 CARTON 01/31/2017 NDC:69842- 3 in 1 CARTON 01/31/2017 NDC:69842- 686-07 NDC:69842- 3 in 1 CARTON 01/31/2017 NDC:69842- 686-07 NDC:69842- 7 NDC:69842- 7 NDC				,						
APRYLIC/CAPRIC MONO/DIGLYCERIDES (UNII: U72Q2I8C85) Product Characteristics no score oVAL Score no score Shape OVAL Size 3mm Flavor 21 Contains OVAL Size Size Smm Flavor 21 Contains OVAL Size Smm 21 Flavor OVAL Size Size <th cols<="" td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th>	<td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>									
Product Characteristics no score Shape OVAL Size no score Shape OVAL Size 3mm Flavor Imprint Code 21 Contains Package Description Marketing Date Marketing Date NDC:69842- 686-07 1 in 1 CARTON 01/31/2017 Marketing Date NDC:69842- 686-03 3 in 1 CARTON Not a Combination Product 01/31/2017 Imprint Code NDC:69842- 686-03 3 in 1 CARTON Not a Combination Product 01/31/2017 Imprint Code NDC:69842- 686-03 3 in 1 CARTON Not a Combination Product 01/31/2017 Imprint Code NDC:69842- 686-03 3 in 1 CARTON Not a Combination Product 01/31/2017 Imprint Code NDC:69842- 686-03 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 Imprint Code Imprint Code NDC:69842- 686-03 10 in 1 BLISTER PACK; Type 0: Not a Combination 01/31/2017 Imprint Code Imprint Code NDC:69842- 686-03 10 in 1 BLISTER PACK; Type 0: Not a Combination 01/31/2017 Imprint Code Imprint Code NDC:69842- 686-03 10 in 1 BLISTER PACK; Type 0: N										
Flavor Imprint Code 21 Flavor 21 Contains Package Description Marketing Start Date Marketing Date 1 NDC:69842- 686-07 1 in 1 CARTON 01/31/2017 Marketing Date 1 NDC:69842- 686-07 1 in 1 CARTON 01/31/2017 Imprint Code 2 NDC:69842- 686-30 3 in 1 CARTON 01/31/2017 Imprint Code 3 NDC:69842- 686-30 3 in 1 CARTON 01/31/2017 Imprint Code 3 NDC:69842- 686-60 6 in 1 CARTON 01/31/2017 Imprint Code 3 NDC:69842- 686-60 6 in 1 CARTON 01/31/2017 Imprint Code		roduct Char								
Image: Second State Sta		olor	acteristic	blue				no score	2	
Item Code Package Description Marketing Start Date Marketing Start Date NDC:69842- 686-07 1 in 1 CARTON 01/31/2017 1 I NDC:69842- 686-07 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 1 I NDC:69842- 686-30 3 in 1 CARTON 01/31/2017 1 1 I NDC:69842- 686-30 3 in 1 CARTON 01/31/2017 1 1 I NDC:69842- 686-30 6 in 1 CARTON 01/31/2017 1 1 I NDC:69842- 686-60 10 in 1 BLISTER PACK; Type 0: Not a Combination Product 01/31/2017 1 1		olor	acteristic	blue					2	
#Item CodePackage DescriptionMarketing Start DateMarketing Date1NDC:69842- 686-071 in 1 CARTON01/31/201701/31/2017110 in 1 BLISTER PACK; Type 0: Not a Combination Product10 in 1 BLISTER PACK; Type 0: Not a Combination 01/31/201701/31/20172NDC:69842- 686-303 in 1 CARTON01/31/201701/31/20173NDC:69842- 686-606 in 1 CARTON01/31/201701/31/20173NDC:69842- 686-606 in 1 CARTON01/31/201701/31/2017	Sł Fla	olor nape avor	acteristic	blue	Size			3mm	2	
#Item CodePackage DescriptionDateDate1NDC:69842- 686-071 in 1 CARTON01/31/201701/31/2017110 in 1 BLISTER PACK; Type 0: Not a Combination Product01/31/201701/31/20172NDC:69842- 686-303 in 1 CARTON01/31/201701/31/20173NDC:69842- 686-606 in 1 CARTON01/31/201701/31/20173NDC:69842- 686-606 in 1 CARTON01/31/201701/31/2017	Sł Fla	olor nape avor	acteristic	blue	Size			3mm	2	
1686-071 III 1 CARTON01/31/2017110 in 1 BLISTER PACK; Type 0: Not a Combination Product01/31/20172NDC:69842- 686-303 in 1 CARTON01/31/2017210 in 1 BLISTER PACK; Type 0: Not a Combination Product01/31/20173NDC:69842- 686-606 in 1 CARTON01/31/2017310 in 1 BLISTER PACK; Type 0: Not a Combination 10 in 1 BLISTER PACK; Type 0: Not a Combination01/31/2017	Sł Fla	olor nape avor ontains	acteristic	blue	Size			3mm 21		
ProductProductOldNDC:69842- 686-303 in 1 CARTON01/31/2017Image: Comparison of the state of the	Sh Fla Co	olor hape avor ontains ackaging		blue OVAL	Size Imprint Code	Marl		3mm 21	rketing End	
2686-303 IN I CARTON01/31/2017210 in 1 BLISTER PACK; Type 0: Not a Combination Product10 in 1 CARTON10/31/20173NDC:69842- 686-606 in 1 CARTON01/31/2017310 in 1 BLISTER PACK; Type 0: Not a Combination10/31/2017	Sh Fli Co Pi	olor hape avor ontains ackaging Item Code NDC:69842-		blue OVAL	Size Imprint Code		Date	3mm 21	rketing End	
Product Oldstate 3 NDC:69842- 686-60 6 in 1 CARTON 01/31/2017 3 10 in 1 BLISTER PACK; Type 0: Not a Combination 01/31/2017	Sh Fla Co Pa #	olor hape avor ontains ackaging Item Code NDC:69842-	1 in 1 CART 10 in 1 BLIS	blue OVAL Package Des	Size Imprint Code	01/31/2	Date	3mm 21	rketing End	
3 686-60 01/31/2017 3 10 in 1 BLISTER PACK; Type 0: Not a Combination	SH Fl: Cc Pi # 1	olor hape avor ontains ackaging Item Code NDC:69842- 686-07	1 in 1 CART 10 in 1 BLIS Product 3 in 1 CART	blue OVAL Package Des ON STER PACK; Type ON	Size Imprint Code Scription 0: Not a Combinat	ion 01/31/2	Date 2017	3mm 21	rketing End	
	Sh Fli Cc Pi # 1	olor hape avor ontains ackaging Item Code NDC:69842- 686-07 NDC:69842- 686-30	1 in 1 CART 10 in 1 BLIS Product 3 in 1 CART 10 in 1 BLIS	blue OVAL Package Des ON STER PACK; Type ON	Size Imprint Code Scription 0: Not a Combinat	ion 01/31/2	Date 2017	3mm 21	rketing End	
	Sh Fla Co Pa # 1 1 2	A vor A	1 in 1 CART 10 in 1 BLIS Product 3 in 1 CART 10 in 1 BLIS Product 6 in 1 CART	blue OVAL Package Des ON STER PACK; Type ON STER PACK; Type ON	Size Imprint Code Scription 0: Not a Combinat 0: Not a Combinat	ion 01/31/2 01/31/2 01/31/2 01/31/2	Date 2017 2017	3mm 21	rketing End	
	Sh Fli Cc Pi # 1 1 2 3	A vor A	1 in 1 CART 10 in 1 BLIS Product 3 in 1 CART 10 in 1 BLIS Product 6 in 1 CART 10 in 1 BLIS	blue OVAL Package Des ON STER PACK; Type ON STER PACK; Type ON	Size Imprint Code Scription 0: Not a Combinat 0: Not a Combinat	ion 01/31/2 01/31/2 01/31/2 01/31/2	Date 2017 2017	3mm 21	rketing End	

Category	Citation	Date	Date
ANDA	ANDA206214	01/31/2017	

Labeler - CVS HEALTH CORP (062312574)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment										
Name	Address	ID/FEI	Business Operations							
MARKSANS PHARMA LIMITED		925822975	manufacture(69842-686)							

Revised: 11/2022

CVS HEALTH CORP