TOPCARE CHILDRENS ALLERGY RELIEF- loratadine tablet, chewable Topco Associates LLC

Topco Associates LLC. Children's Allergy Relief Drug Facts

Active ingredient (in each tablet)

Loratadine 5 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 (1-800-222-1222).

Directions

• chew or crush tablets completely before swallowing

adults and children 6 years and over	chew 2 tablets daily; not more than 2 tablets in 24 hours
children 2 to under 6 years of age	chew 1 tablet daily; not more than 1 tablet in 24 hours
children under 2 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- phenylketonurics: contains phenylalanine 1.4 mg per tablet
- do not use if blister unit is broken or torn
- store between 20° to 25°C (68° to 77°F)

Inactive ingredients

artificial grape flavor, aspartame, colloidal silicon dioxide, D&C red #27 aluminum lake, FD&C blue #2 aluminum lake, magnesium stearate, mannitol, microcrystalline cellulose, sodium starch glycolate, stearic acid

Questions or comments?

1-888-423-0139

Principal Display Panel

TopCare_® health

COMPARE TO CHILDREN'S CLARITIN® ACTIVE INGREDIENT

children's

NON-DROWSY*

Allergy Relief

LORATADINE CHEWABLE TABLETS, 5 mg • ANTIHISTAMINE

INDOOR & OUTDOOR ALLERGIES

24 HOUR

RELIEF OF:

- Sneezing
- Runny Nose

- Itchy, Watery Eyes
- Itchy Throat or Nose
- 2 Years & older
- GRAPE FLAVOR
- 30 CHEWABLE TABLETS
- *When taken as directed. See Drug Facts Panel.
- actual size



**This product is rot manufactured or distributed by Bayer HealthCare LLC, distributor of Children's Clarifin®.



away (1 -900-222-1222).

DIS TRIBUTED BY TOP CO AS SOCIATES LLC ELKGROVE VILLAGE, IL 6 0007





©TOPCO PERA 0521 QUES TIONS ? 1-888-423-01 39 bpcare@topco.com www.bpcarebrand.com



oratadine tablet,		S ALLERGY RE	LIEF					
Product Infor	mation							
Product Type		HUMAN OTC DRUG	ltem Co	Code (Source) NDC:36800-363			800-363	
Route of Admini	istration	ORAL						
Active Ingred	ient/Active	Moiety						
Ingredient Name Basis of Stre					ength	Strength		
LORATADINE (UNII:	-	(LORATADINE - UNII:7AJO	3BO7QN)				5 mg	
Inactive Ingre	dients							
Ingredient Name						S	Strength	
ASPARTAME (UNII:	RTAME (UNII: Z0H242BBR1)							
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)								
D&C RED NO. 27 (UNII: 2LRS185U6K)								
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)								
MAGNESIUM STEARATE (UNII: 70097M6I30)								
MANNITOL (UNII: 3	OWL53L36A)							
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)								
STEARIC ACID (UN	III: 4ELV7Z65AP))						
Product Chara	acteristics							
Color	PURPLE	(light)	Score			no score		
Shape	ROUND	-	Size			8mm		
Flavor	GRAPE		Imprint Co	nt Code		L3Y8		
Contains								
Packaging								
# Item Code	Pa	ckage Description		Mark	eting Start Date		eting End Date	
1 NDC:36800-363- 39	30 in 1 CARTO	N	0	9/20/20				
1	1 in 1 BLISTER Product	PACK; Type 0: Not a Cor	nbination					
2 NDC:36800-363- 49	40 in 1 CARTO	40 in 1 CARTON		6/20/2	023			
2	1 in 1 BLISTER Product	PACK; Type 0: Not a Cor	nbination					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ANDA	ANDA210033	09/20/2019				

Labeler - Topco Associates LLC (006935977)

Revised: 6/2023

Topco Associates LLC