CETIRIZINE HYDROCHLORIDE TABLETS, 5 MG - cetirizine hydrochloride tablet CETIRIZINE HYDROCHLORIDE TABLETS, 10 MG - cetirizine hydrochloride tablet MARKSANS PHARMA LIMITED

Allergy Relief Cetirizine Hydrochloride Tablets USP, 5 mg and 10 mg

Active ingredient (in each tablet)

For 5 mg:

Cetirizine HCI USP 5 mg

For 10 mg:

Cetirizine HCI USP 10 mg

Purpose

Antihistamine

Uses

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

- runny nose
- sneezing
- itchy, watery eyes
- 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 or to an antihistamine containing hydroxyzine.

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

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

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

If pregnant or breast-feeding

- if breast-feeding: not recommended
- if pregnant: 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

For 5 mg:

adults and	1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon		
children 6 years	severity of symptoms; do not take more than 2 tablets (10 mg) in		
and over	24 hours		
adults 65 years	1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) in		
and over	24 hours.		
children under 6 years of age	ask a doctor		
consumers with liver or kidney disease	ask a doctor		

For 10 mg:

children 6 years	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less
and over	severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- •store between 20° to 25°C (68° to 77°F)
- •do not use if foil seal under cap is broken or missing

Inactive ingredients

corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, titanium dioxide

Questions?

Call at 1-877-376-4271

PRINCIPAL DISPLAY PANEL

NDC 25000-219-03 Cetirizine Hydrochloride Tablets USP, 5 mg 30s count bottle label Original Prescription Strength
Allergy
Cetirizine Hydrochloride Tablets USP,
Antihistamine
Indoor & Outdoor
Allergies

Relief of
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy, Watery Eyes
Itchy Throat
or Nose

Active ingredient (in each tablet)

Purpose

Cetirizine HCI 5 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 or to an antihistamine containing hydroxyzine. **Ask a doctor before use if you have** liver or kidney disease. Your doctor

LOT: EXP:

should determine if you need a different dose. Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. When using this product

- drowsiness may occur avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery. **Stop use and ask**
- a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding:
- if breast-feeding: not recommended ■ if pregnant: 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**

adults and children 6 years and over: 1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) in 24 hours. adults 65 years and over: 1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) 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° to 25°C (68° to 77°F) ■ Do not use if foil seal under cap is broken or missing. Inactive ingredients lactose monohydrate, corn starch, povidone, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide

Questions? Call at 1-877-376-4271

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No. : GO/DRUGS/515

NDC 25000-219-03 Cetirizine Hydrochloride Tablets USP, 5 mg 30s count carton label



NDC 25000-219-08 Cetirizine Hydrochloride Tablets USP, 5 mg 100s count bottle label Original Prescription Strength
Allergy
Cetirizine Hydrochloride Tablets USP,
Antihistamine
Indoor & Outdoor
Allergies

Relief of
Sneezing
Runny Nose
Itchy, Watery Eyes
Itchy, Watery Eyes
Itchy Throat
or Nose

Active ingredient (in each tablet)

Purpose

Cetirizine HCI 5 mg......Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 or to an antihistamine containing hydroxyzine. **Ask a doctor before use if you have** liver or kidney disease. Your doctor

LOT: EXP:

should determine if you need a different dose. Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. When using this product

- drowsiness may occur avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery. **Stop use and ask**
- a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding:
- if breast-feeding: not recommended ■ if pregnant: 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**

adults and children 6 years and over: 1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) in 24 hours. adults 65 years and over: 1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) 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° to 25°C (68° to 77°F) ■ Do not use if foil seal under cap is broken or missing. Inactive ingredients lactose monohydrate, corn starch, povidone, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide

Questions? Call at 1-877-376-4271

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No. : GO/DRUGS/515

NDC 25000-219-08 Cetirizine Hydrochloride Tablets USP, 5 mg 100s count carton label



NDC 25000-219-14 Cetirizine Hydrochloride Tablets USP, 5 mg 1000s count bottle label NDC 25000-219-14

Compare to the active ingredient in Zyrtec® Tablets[†]

Original Prescription Strength

Allergy

Cetirizine Hydrochloride Tablets USP, **5 mg**

Antihistamine Indoor & Outdoor Allergies

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Take 1 to 2 tablets* once daily depending on the severity of your symptoms *Adults 65 and older take only one tablet per day

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



1000 Tablets



Marksans

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.

Drug Facts

Active ingredient (in each tablet)

Purpose

Cetirizine HCI 5 mg......Antihistamine

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

- runny nose
- sneezing
- itchy, watery eyes
- 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 or to an antihistamine containing hydroxyzine.

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

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

Drug Facts (Continued)

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery.

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

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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

adults and children 6 years and over	1 tablet (5 mg) or 2 tablets (10 mg) once daily depending upon severity of symptoms; do not take more than 2 tablets (10 mg) in 24 hours	
adults 65 years and over	1 tablet (5 mg) once daily; do not take more than 1 tablet (5 mg) in 24 hours.	

children under 6 years of age consumers with liver or kidney disease	ask a doctor	Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA	
	der cap is broken or missing.	Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.	
Inactive ingredients lactose monohydrate, corn starch, povidone, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide Questions? Call at 1-877-376-4271		Mfg. Lic. No. : GO/DRUGS/515	
Call at 1-877-376-4271 †This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, distributor of Zyrtec® Tablets.			

NDC 25000-220-03 Cetirizine Hydrochloride Tablets USP, 10 mg 30s count bottle label



Active ingredient (in each tablet)

Purpose

Cetirizine HCl 10 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 or to an antihistamine containing hydroxyzine. **Ask a doctor before use if you have** liver or kidney disease. Your doctor

LOT: EXP: R19/21

should determine if you need a different dose. Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. When using this product drowsiness may occur avoid alcoholic drinks alcohol, sedatives, and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery. Stop use and ask

- a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding:
- if breast-feeding: not recommended
 if pregnant: 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**

more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms. Adults 65 years and over: ask a doctor. Children under 6 years of age: ask a doctor. Consumers with liver or kidney disease: ask a doctor. Other information store between

Adults and children 6 years and over:

one 10 mg tablet once daily; do not take

20° to 25°C (68° to 77°F) ■ Do not use if foil seal under cap is broken or missing. Inactive ingredients lactose monohydrate, corn starch, povidone, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide

Questions? Call at 1-877-376-4271

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735. USA

Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No.: GO/DRUGS/515

NDC 25000-220-03 Cetirizine Hydrochloride Tablets USP, 10 mg 30s count carton label



NDC 25000-220-08 Cetirizine Hydrochloride Tablets USP, 10 mg 100s count bottle label



Active ingredient (in each tablet)

Purpose

Cetirizine HCI 10 mg......Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itchy, watery eyes ■ 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 or to an antihistamine containing hydroxyzine. **Ask a doctor before use if you have** liver or kidney disease. Your doctor

LOT: EXP: R19/21

should determine if you need a different dose. Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives. When using this product drowsiness may occur avoid alcoholic drinks alcohol, sedatives, and tranquilizers may increase drowsiness be careful when driving a motor vehicle or operating machinery. Stop use and ask

a doctor if an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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**

Adults and children 6 years and over: one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms. Adults 65 years and over: ask a doctor. Children under 6 years of age: ask a doctor. Consumers with liver or kidney disease: ask a doctor. Other information store between

20° to 25°C (68° to 77°F) ■ Do not use if foil seal under cap is broken or missing. Inactive ingredients lactose monohydrate, corn starch, povidone, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide Questions? Call at 1-877-376-4271

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735. USA

Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No.: GO/DRUGS/515

NDC 25000-220-08 Cetirizine Hydrochloride Tablets USP, 10 mg 100s count carton label



NDC 25000-220-14 Cetirizine Hydrochloride Tablets USP, 10 mg 1000s count bottle label NDC 25000-220-14

Compare to the active ingredient in Zyrtec® Tablets[†]

Original Prescription Strength

Allergy

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine
Indoor & Outdoor
Allergies

THIS PACKAGE FOR HOUSEHOLDS
WITHOUT YOUNG CHILDREN

24 hour

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



1000 Tablets

LOT :

Marksans

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE. Dra

Drug Facts

Active ingredient (in each tablet)

Purpose

Cetirizine HCI 10 mg......Antihistamine

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

- runny nose
- sneezing
- itchy, watery eyes
- 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 or to an antihistamine containing hydroxyzine.

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

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives.

Drug Facts (Continued)

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- \blacksquare alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery.

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

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: 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

Adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.	
Adults 65 years and over	ask a doctor	•

Drug Facts (Continued)

Drug Facts (Continued)

Children under 6 years of age Consumers with liver or kidney disease	ask a doctor	Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA	
Inactive ingredients la	der cap is broken or missing. actose monohydrate, corn starch, povidone,	Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India.	
Questions? Call at 1-877-376-4271	omellose, polyethylene glycol, titanium dioxide	Mfg. Lic. No. : G0/DRUGS/515	
†This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division, distributor of Zyrtec® Tablets.			

NDC 25000-220-78 Cetirizine Hydrochloride Tablets USP, 10 mg 7s count carton label

Allergy

Cetirizine Hydrochloride Tablets USP, 10 mg

NDC 25000-220-78

Compare to the active ingredient in Zyrtec® Tablets†

Original Prescription Strength

Allergy

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Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine Indoor & Outdoor Allergies

PACKAGE NOT

CHILD-RESISTANT

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose



M Marksans

7 Tablets

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale,

Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No. : GO/DRUGS/515

NY 11735, USA

(weekdays 9 AM to 5 PM) Questions or comments? Call 1-877-376-4271

glycol, povidone, titanium dioxide actose monohydrate, magnesium stearate, polyethylene Inactive ingredients corn starch, hypromellose,

> ■ Store between 20° to 25°C (68° to 77°F) Other information

Consumers with liver or kidney disease	ask a doctor
Children under 6 years of age	sak a doctor
Adults 65 years and over	sak a doctor
and over	A 5 mg product may be appropriate for less severe symptoms.

children 6 years | more than one 10 mg tablet in 24 hours. one 10 mg tablet once daily; do not take Adults and

Directions

medical help or contact a Poison Control Center right away. keep out of reach of children. In case of overdose, get it pregnant: ask a health professional before use. ■ if breast-feeding: not recommended

Drug Facts (Continued)

It pregnant or breast-feeding:

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

- be careful when driving a motor vehicle or operating **GLOWSINGSS**
 - slcohol, sedatives and tranquilizers may increase ■ drowsiness may occur ■ avoid alcoholic drinks When using this product

tranquilizers or sedatives.

Ask a doctor or pharmacist before use if you are taking

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

containing hydroxyzine.

product or any of its ingredients, or to an antihistamine Do not use if you have ever had an allergic reaction to this Warnings

■ itching of the nose or throat ■ itchy, watery eyes ôuizəəus **■** ■ runny nose

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

Active ingredient (in each tablet) Purpose

Drug Facts IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE. REFER CARTON FOR COMPLETE INFORMATION

'This product is not manufactured or distributed by Johnson & Johnson Consumer WcNeil Consumer Healthcare Division owner of Zyrtec® Tablets.

Lot #:

Varnish/Print Omit area

NDC 25000-220-81 Cetirizine Hydrochloride Tablets USP, 10 mg 14s count carton label

Cetirizine Hydrochloride Tablets USP, <mark>10 mg</mark>

VD19IIA

[†] This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division owner of Zyrtec® Tablets.

Questions or comments? Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

povidone, titanium dioxide monohydrate, magnesium stearate, polyethylene glycol, Inactive ingredients corn starch, hypromellose, lactose

> Do not use if blister unit is torn or broken Store between 20° to 25°C (68° to 77°F) Other information

Consumers with liver or kidney disease	ask a doctor
Children under 6 years of age	азк а doctor
Adults 65 years and over	азк а doctor
and over	A 5 mg product may be appropriate for less severe symptoms.

one 10 mg tablet once daily; do not take

Directions

Adults and

Keep out of reach of children. In case of overdose, get medical help or confact a Poison Control Center right away. (1-800-222-1222) if breast-feeding: not recommended if pregnant: ask a health professional before use. If pregnant or breast-feeding:

Drug Facts (Continued)

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

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- be careful when driving a motor vehicle or operating
 - alcohol, sedatives and tranquilizers may increase drowsiness may occur
 avoid alcoholic drinks When using this product

tranquilizers or sedatives.

Ask a doctor or pharmacist before use if you are taking

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

containing hydroxyzine.

product or any of its ingredients, or to an antihistamine Do not use if you have ever had an allergic reaction to this Warnings

■ itching of the nose or throat Buizəəus ■ ■ runny nose

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

Cetirizine HCI 10 mg.

Purpose

Active ingredient (in each tablet)

Drug Facts

ВЕГЕВ САВТОИ ГОВ СОМРLЕТЕ INFORMATION MPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.

Manufactured for: Time-Cap Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa - 403722, India. Mfg. Lic. No.: GO/DRUGS/515

NDC 25000-220-81

Compare to the active ingredient in Zyrtec® Tablets[†]

Original Prescription Strength

Allergy

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine Indoor & Outdoor Allergies

Relief of

- Sneezing
- Runny Nose
- Itchy, Watery Eyes
- Itchy Throat or Nose

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14 Tablets







CETIRIZINE HYDROCHLORIDE TABLETS, 5 MG

cetirizine hydrochloride tablet

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:25000-219

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	CETIRIZ INE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (white to off white)	Score	no score
Shape	RECTANGLE (Rounded-off rectangular shaped)	Size	7mm
Flavor		Imprint Code	J219
Contains			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:25000-219- 03	1 in 1 CARTON	01/13/2022			
1		30 in 1 BOTTLE; Type 0: Not a Combination Product				
	NDC 25000 210					

2	08 NDC:52000-518-	1 in 1 CARTON	01/13/2022	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000-219- 14	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2022	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078933	01/13/2022		

CETIRIZINE HYDROCHLORIDE TABLETS, 10 MG

cetirizine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-220	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
CETIRIZINE HYDROCHLORIDE (UNII: 640047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZ INE HYDROCHLORIDE	10 mg		

Inactive Ingredients				
Ingredient Name	Strength			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
STARCH, CORN (UNII: O8232NY3SJ)				
POVIDONE K30 (UNII: U725QWY32X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				

Product Characteristics				
Color	WHITE (white to off white)	Score	no score	
Shape	RECTANGLE (Rounded-off rectangular shaped)	Size	9mm	
Flavor		Imprint Code	J220	
Contains				

Packaging			
# Hom Codo	Backago Bossrintian	Marketing Start	Marketing End

#	item Code	Раскаде резсприон	Date	Date
1	NDC:25000- 220-03	1 in 1 CARTON	01/13/2022	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:25000- 220-08	1 in 1 CARTON	01/13/2022	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:25000- 220-14	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2022	
4	NDC:25000- 220-78	1 in 1 CARTON	04/17/2023	
4		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:25000- 220-81	1 in 1 CARTON	07/21/2023	
5		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA078933	01/13/2022		

Labeler - MARKSANS PHARMA LIMITED (925822975)

Establishment					
Name	Address	ID/FEI	Business Operations		
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-219, 25000-220)		

Revised: 8/2023 MARKSANS PHARMA LIMITED