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 HCl USP 5 mg

For 10 mg:

Cetirizine HCl 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 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

For 10 mg:

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

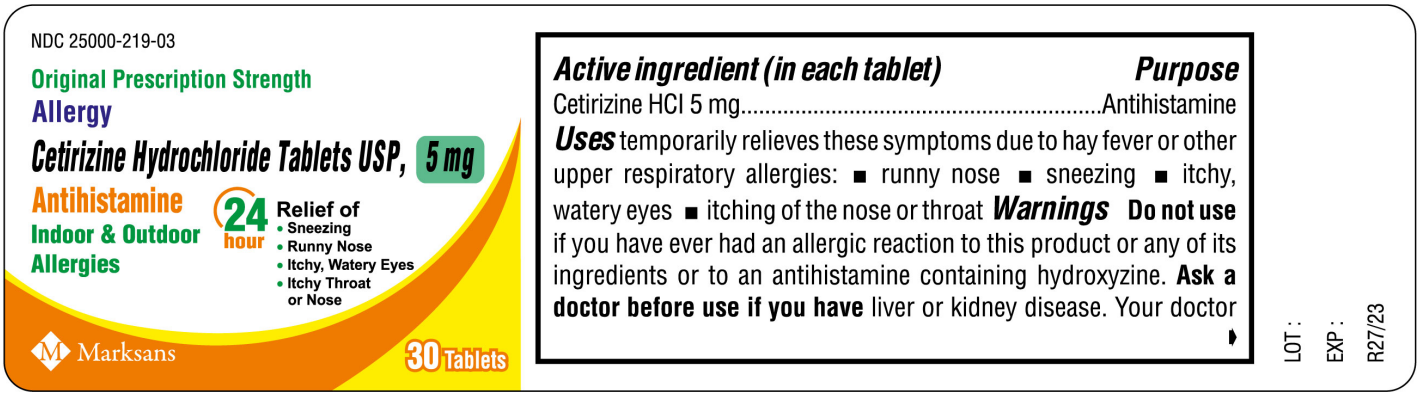
corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, titanium dioxide

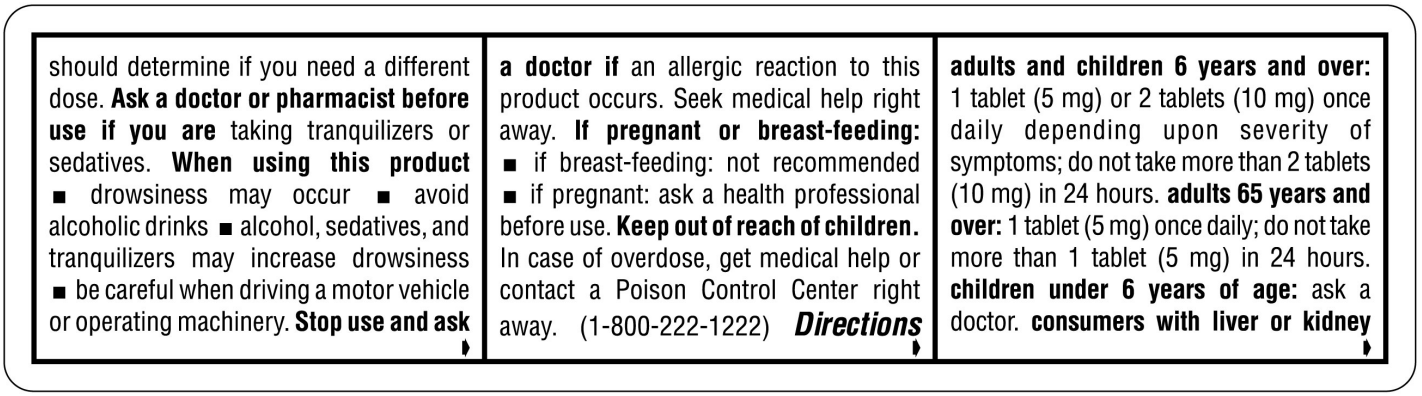
Questions?

Call at 1-877-376-4271

PRINCIPAL DISPLAY PANEL

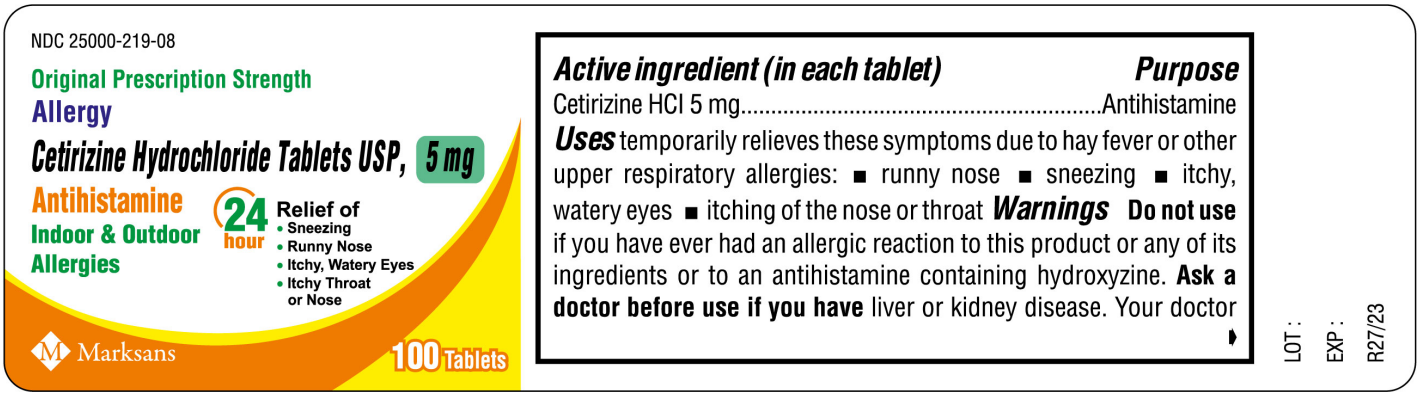
NDC 25000-219-03
Cetirizine Hydrochloride Tablets USP, 5 mg
30s count bottle label

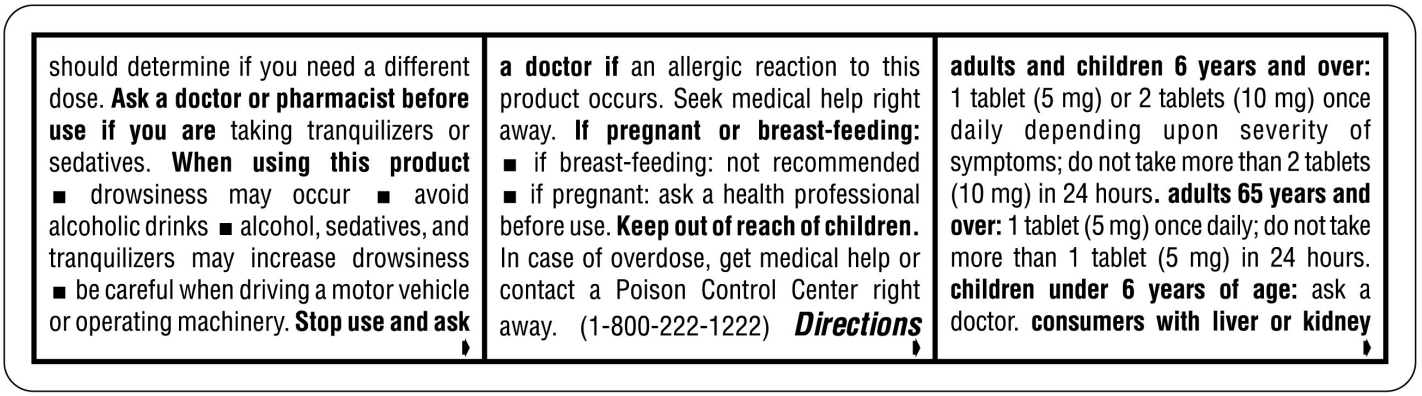




NDC 25000-219-03
Cetirizine Hydrochloride Tablets USP, 5 mg
30s count carton label

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





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

24 hour

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

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

Actual Size

Marksans

1000 Tablets

LOT :

EXP :

R27/23

N 3 25000 21914 7

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.

Drug Facts

Active ingredient (in each tablet) — ***Purpose***

Cetirizine HCl 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 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.

Drug Facts (Continued)

Drug Facts (Continued)

children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information
- store between 20º to 25ºC (68º to 77ºF)
- **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

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

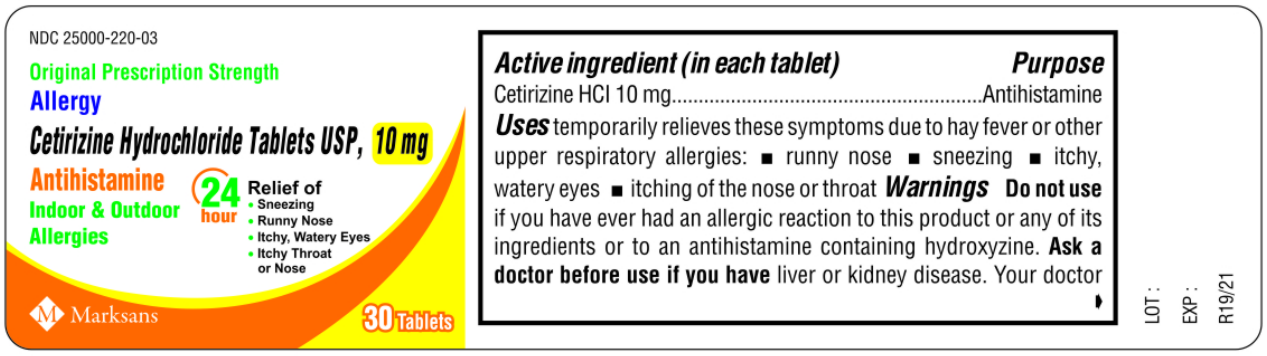
Manufactured for:
Time-Cap Labs, Inc.
7 Michael Avenue, Farmingdale,
NY 11735, USA

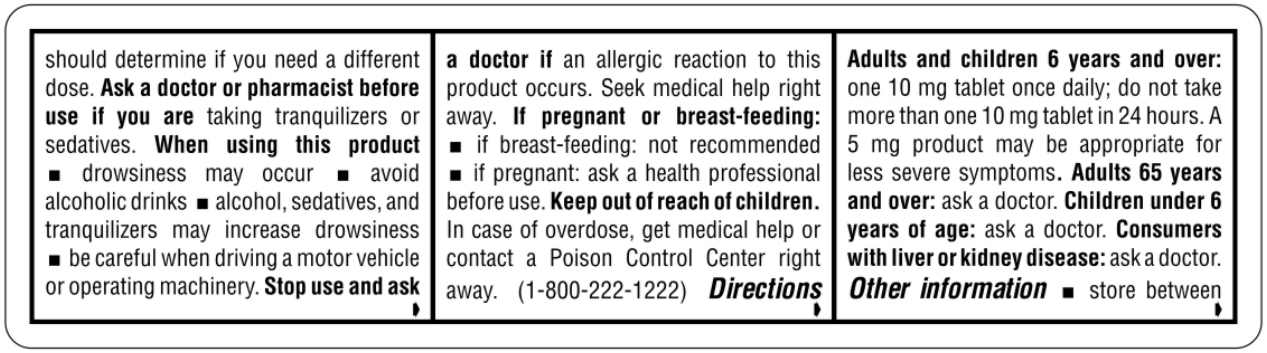
Manufactured by:
Marksans Pharma Ltd.
Plot No. L-82, L-83,
Verna Indl. Estate,
Verna, Goa - 403722, India.

Mfg. Lic. No. : GO/DRUGS/515

NDC 25000-220-03
Cetirizine Hydrochloride Tablets USP, 10 mg

30s count bottle label

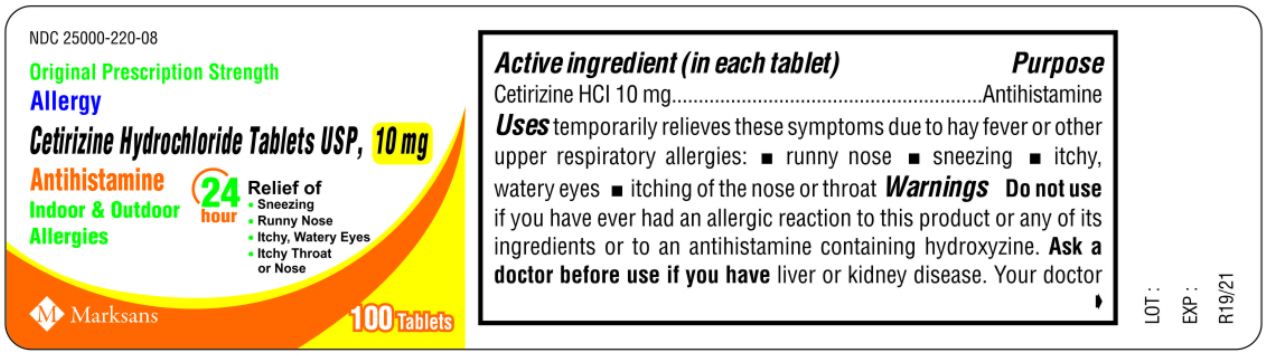


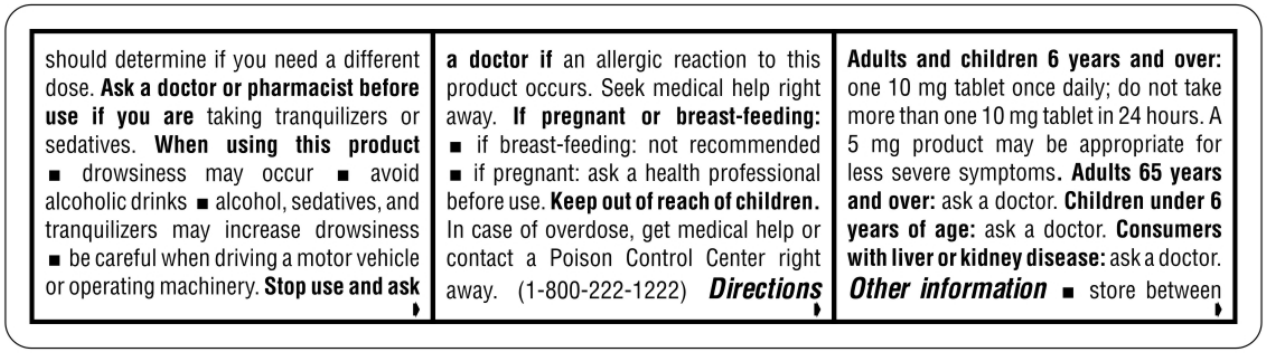


NDC 25000-220-03
Cetirizine Hydrochloride Tablets USP, 10 mg

30s count carton label

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





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

24 hour

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

THIS PACKAGE FOR HOUSEHOLDS WITHOUT YOUNG CHILDREN

Marksans

1000 Tablets

LOT :

EXP :

R38/23

N 3 25000 22014 3

IMPORTANT: READ ALL PRODUCT INFORMATION BEFORE USE.

Drug Facts

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 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	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	ask a doctor
Consumers with liver or kidney disease	ask a doctor

Other information
- store between 20º to 25ºC (68º to 77ºF)
- **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

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

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 25000-220-78
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

Cetirizine Hydrochloride Tablets USP, 10 mg

Antihistamine

Indoor & Outdoor Allergies

24 hour

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

PACKAGE NOT CHILD-RESISTANT

Actual Size

Marksans

7 Tablets

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

Varnish/Print Omit area

Lot #:

Exp. Date:

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

R28/23

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

Drug Facts

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 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:

Drug Facts (Continued)

- 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

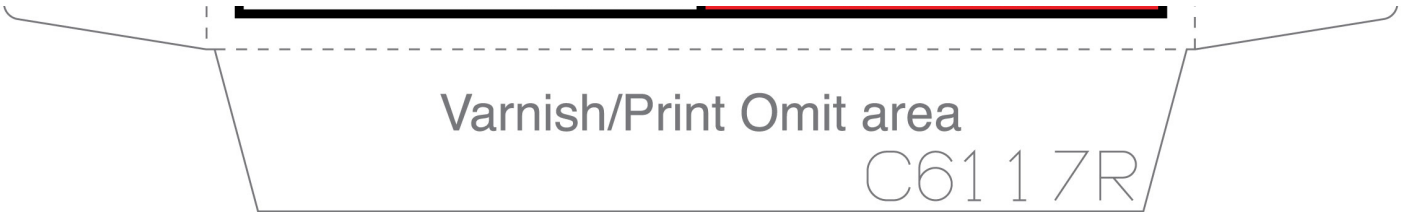
- Store between 20° to 25°C (68° to 77°F)
- **Do not use if blister unit is torn or broken.**

Inactive ingredients

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

Questions or comments?

Call **1-877-376-4271** (weekdays 9 AM to 5 PM)



NDC 25000-220-81
Cetirizine Hydrochloride Tablets USP, 10 mg

14s count carton label

Allergy

Cetirizine Hydrochloride Tablets USP, 10 mg

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

Drug Facts

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 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.

Drug Facts (Continued)

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 blister unit is torn or broken.**

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

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

3 25000 22081 5

Lot No.:
Exp Date:

Varnish Omit Area

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

R18/23

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

24 hour

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

PACKAGE NOT CHILD-RESISTANT

Actual Size

Marksans

14 Tablets

CETIRIZINE HYDROCHLORIDE TABLETS, 5 MG

cetirizine hydrochloride tablet

Product Information

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
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE 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: 3WQ0SDW1A)	
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			

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		

2	NDC:25000-219-08	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: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE 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: 3WQ0SDW1A)	
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

#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	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