LEVOCETIRIZINE DIHYDROCHLORIDE - levocetirizine dihydrochloride tablet Micro Labs Limited

Drug Facts

Active ingredient (in each tablet)

Levocetirizine dihydrochloride USP 5 mg

Purpose

Antihistamine

Uses

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

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

WARNINGS

Do not use

- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

Ask a doctor before use if you have

• ever had trouble urinating or emptying your bladder

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

- you have trouble urinating or emptying your bladder
- 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).

DO NOT USE

- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

ASK A DOCTOR OR PHARMACIST BEFORE USE IF

KEEP OUT OF REACH OF CHILDREN

DIRECTIONS

adults 65 years of age and older	ask a doctor
adults and children 12-64 years of age	 take 1 tablet (5 mg) once daily in the evening do not take more than1 tablet (5 mg) in 24 hours ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6-11 years of age	 take ½ tablet (2.5 mg) once daily in the evening do not take more than ½ tablet (2.5 mg) in 24 hours
children under 6 years of age	• do not use
consumers with kidney disease	• do not use

STORAGE

- store between 20° and 25°C (68° and 77°F)
- safety sealed: do not use if carton was opened or torn

Inactive ingredients

hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, silicon dioxide, and titanium dioxide

Questions or comments?

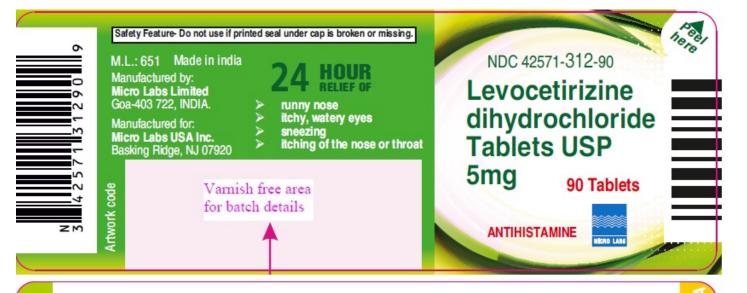
call 1-855-839-8195

PRINCIPAL DISPLAY PANEL

MICRO LABS LIMITED Container

NDC- 42571-312-90 Levocetirizine dihydrochloride Tablets USP 5mg Antihistamine

90 Tablets MICRO LABS



Drug Facts Active Ingredient (in each tablet)

Purpose

Levocetirizine dihydrochloride USP 5 mg.....Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other respiratory allergies: - runny nose - itchy, watery eyes - sneezing - itching of the nose or throat Warnings Do not use - if you have kidney disease - if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine Ask a doctor before use if you have - ever had trouble urinating or emptying your bladder 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 - you have trouble urinating or emptying your bladder - an allergic reaction to this product occurs. Seek medical help right away. If pregnant or breast-feeding: - if breast-feeding: not recommended

PERMANENT GLUE STICKING

PERMANENT GLUE

EMOVABLE GLUE

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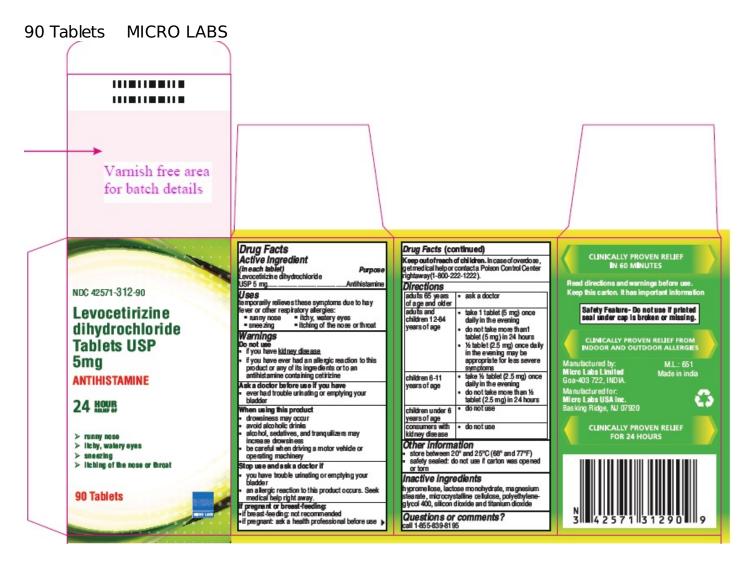
■ if pregnant: ask a health professional before use Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). *Directions* adults 65 years of age and older ask a doctor adults and children 12-64 years of age = take 1 tablet (5 mg) once daily in the evening = do not take more than1 tablet (5 mg) in 24 hours = ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms children 6-11 years of age = take ½ tablet (2.5 mg) once daily in the evening = do not take more than ½ tablet

(2.5 mg) in 24 hours children under 6 years of age do not use **consumers with kidney disease** do not use **Other information** store between 20° and 25°C (68° and 77°F) safety sealed: do not use if carton was opened or torn **Inactive ingredients** hypromellose, lactose monohydrate, magnesium st e a r at e, m i c r o c r y st all i n e c ellulos e, polyethyleneglycol 400, silicon dioxide and titanium dioxide **Questions or comments?** call 1-855-839-8195

REMOVABLE GLUE

Container-Carton

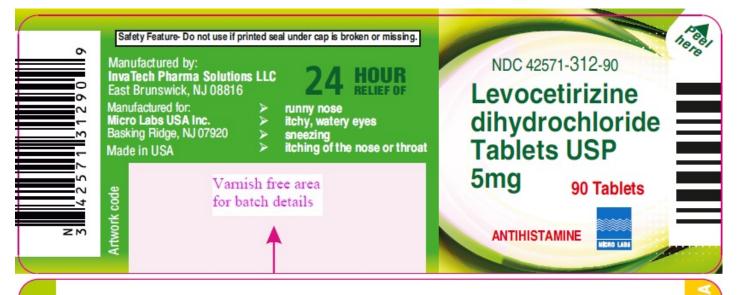
NDC- 42571-312-90 Levocetirizine dihydrochloride Tablets USP 5mg Antihistamine



INVATECH PHARMA SOLUTIONS LLC Container

NDC- 42571-312-90 Levocetirizine dihydrochloride Tablets USP 5mg Antihistamine

90 Tablets MICRO LABS



Drug Facts Active Ingredient (in each tablet)

Purpose

Levocetirizine dihydrochloride

REMOVABLE GLUE

PERMANENT GLUE

USP 5 mg.....Antihistamine Uses temporarily relieves these symptoms due to hay fever or other respiratory allergies: • runny nose • itchy, watery eyes • sneezing • itching of the nose or throat Warnings Do not use • if you have kidney disease • if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine Ask a doctor before use if you have - ever had trouble urinating or emptying your bladder 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 - you have trouble urinating or emptying your bladder - 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 65 years of age and older ask a doctor adults and children 12-64 years of age = take 1 tablet (5 mg) once daily in the evening = do not take more than1 tablet (5 mg) in 24 hours = ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms children 6-11 years of age = take ½ tablet (2.5 mg) once daily in the evening = do not take more than ½ tablet (2.5 mg) in 24 hours children under 6 years of age do not use **consumers with kidney disease** do not use **Other information** store between 20° and 25°C (68° and 77°F) safety sealed: do not use if carton was opened or torn **Inactive ingredients** hypromellose, lactose monohydrate, magnesium stearate, microcrystallinecellulose, polyethyleneglycol 400, silicon dioxide and titanium dioxide **Questions or comments?** call 1-855-839-8195 MANENT GLUE STICKING

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Container-Carton

NDC- 42571-312-90 Levocetirizine dihydrochloride Tablets USP 5mg Antihistamine

90 Tablets MICRO LABS



LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:4257	NDC:42571-312	
Route of Administration	ORAL					
Active Ingredient/Active	Moiety					
Ingred		Basis of Strength		Strength		
EVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA)LEVOCETIRIZINELEVOCETIRIZINE - UNII:605EA9RT2O)DIHYDROCHLORIDE		E	5 mg			
Inactive Ingredients						
	Ingredient Name			Sti	rength	
SILICON DIOXIDE (UNII: ETJ7Z6XB	U4)					
CELLULOSE, MICROCRYSTALLIN	E (UNII: OP1R32D61U)					
MAGNESIUM STEARATE (UNII: 700)97M6I30)					
HYPROMELLOSE 2910 (5 MPA.S)	(UNII: R75537T0T4)					
TITANIUM DIOXIDE (UNII: 15FIX9V	2JP)					

		LYCOL 400 (UNII: B697894SGQ)			
LA	CTOSE MONOH	IYDRATE (UNII: EWQ57Q8I5X)			
Pı	roduct Char	acteristics			
Color		white (White to off-white)	Score	2 pieces	
Shape		OVAL	Size	8mm	
Flavor			Imprint Code	LI	
Co	ontains				
_					
Pa	ackaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:42571- 312-53	2500 in 1 POUCH; Type 0: Not a Combination Product	02/01/2019		
2	NDC:42571- 312-90	1 in 1 CARTON	02/01/2019		
2		90 in 1 BOTTLE; Type 0: Not a Combination Product			
3	NDC:42571- 312-11	100 in 1 CARTON	02/01/2019		
3	NDC:42571- 312-32	10 in 1 BLISTER PACK; Type 0: Not a Combination Product			
4	NDC:42571- 312-18	1 in 1 CARTON	02/01/2019		
4		10 in 1 BOTTLE; Type 0: Not a Combination Product			
M	larketing	Information			
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	IDA	ANDA211551	02/01/2019		

Labeler - Micro Labs Limited (862174955)

Establishment				
Name	Address	ID/FEI	Business Operations	
InvaTech Pharma Solutions LLC		078602180	manufacture(42571-312)	

Establishment						
Name	Address	ID/FEI	Business Operations			
Micro Labs Limited		915793658	manufacture(42571-312)			

Revised: 2/2025

Micro Labs Limited