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

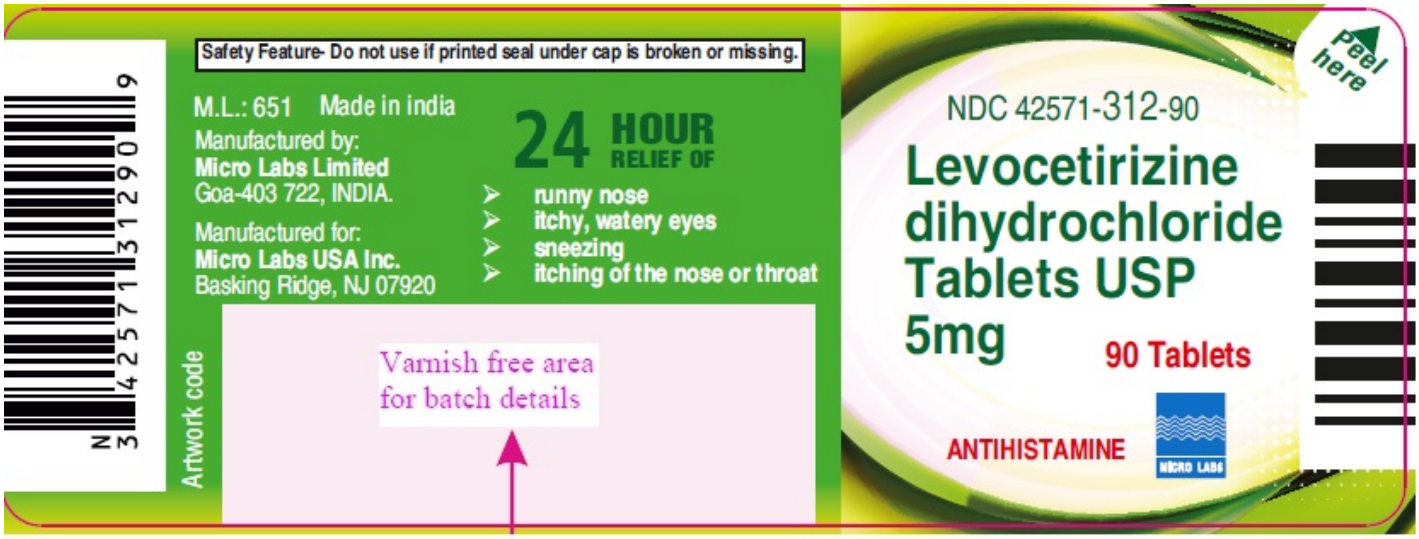
PRINCIPAL DISPLAY PANEL

MICRO LABS LIMITED

Container

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

90 Tablets MICRO LABS



REMOVABLE GLUE

Drug Facts

Active Ingredient (in each tablet) — Purpose

Levocetirizine dihydrochloride USP 5 mg.....Antihistamine

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PERMANENT GLUE STICKING AREA

PERMANENT GLUE

▪ 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 ▶

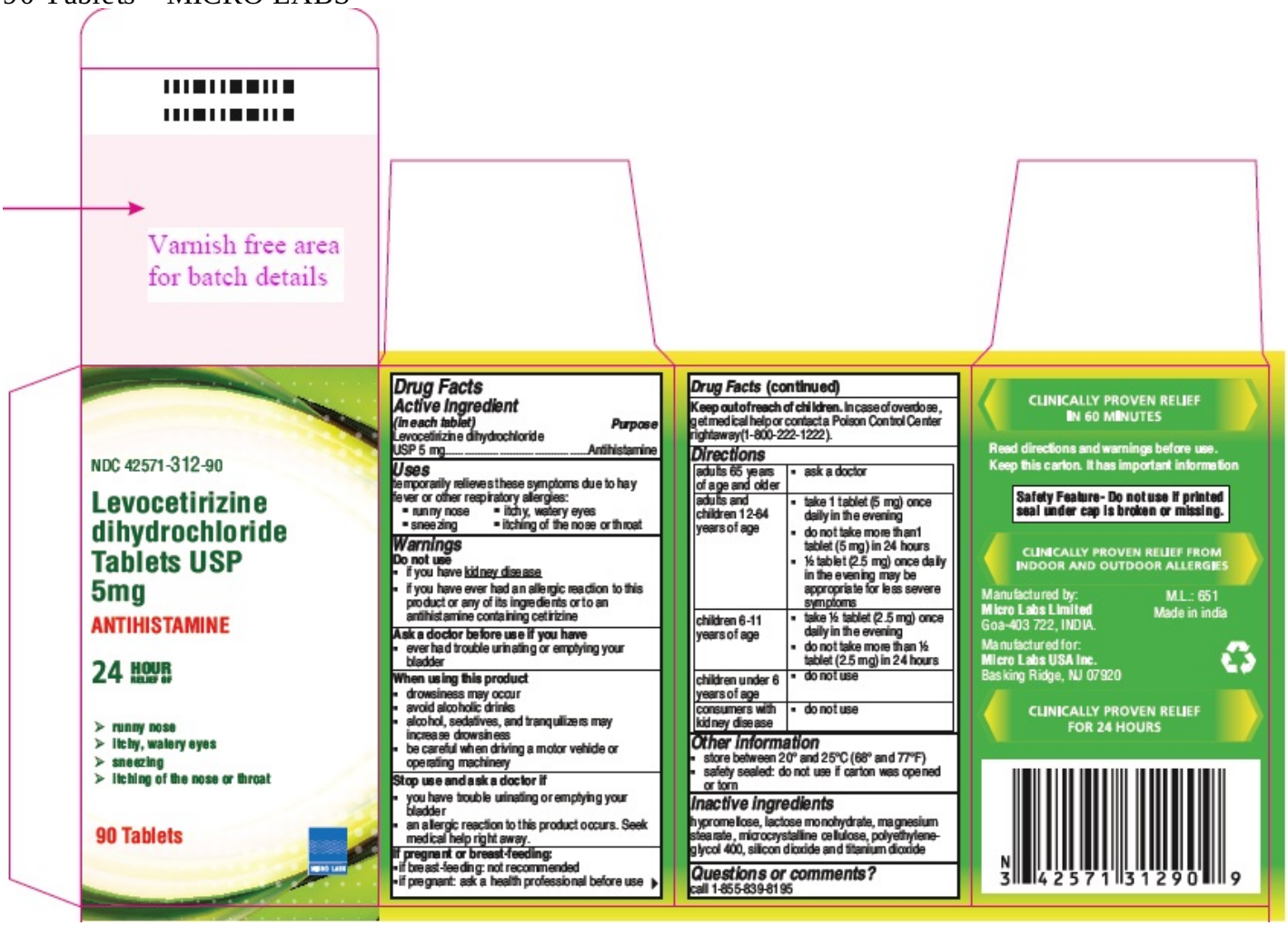
(2.5 mg) in 24 hours children under 6 years of age ▪ do not use **consumers with kidney disease** ▪ do not use ***Other information*** ▪ store between 20° and 25°C (68° and 77°F) ▪ safety sealed: do not use if carton was opened or torn ***Inactive ingredients*** hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, 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

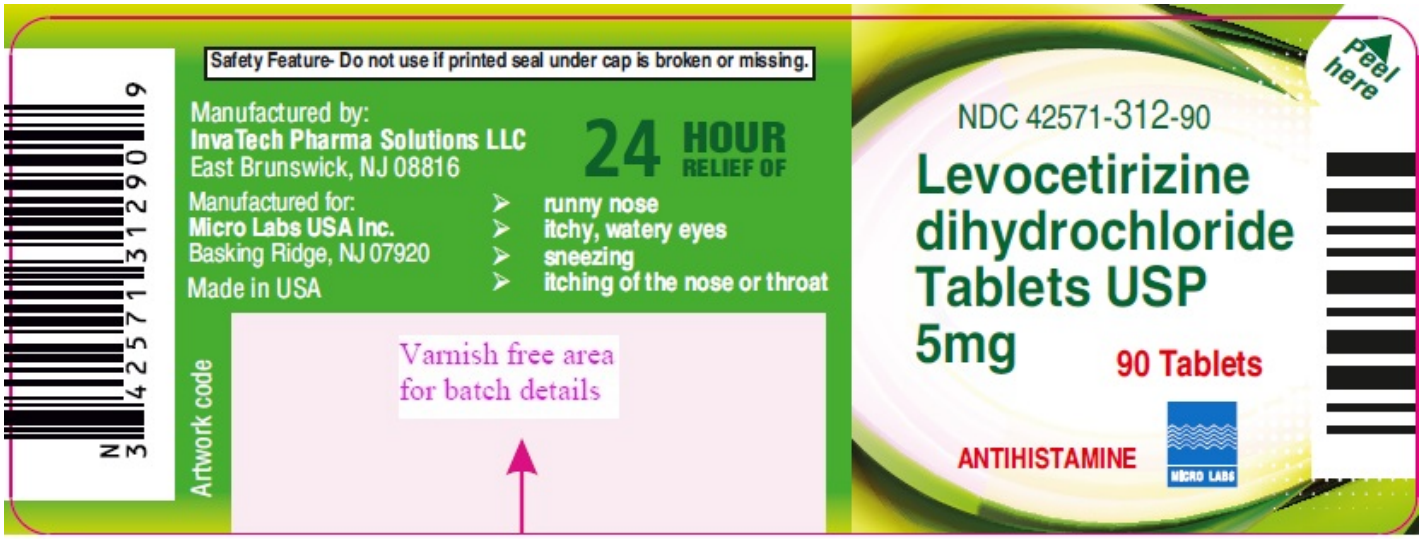
90 Tablets MICRO LABS



INVATECH PHARMA SOLUTIONS LLC
Container

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

90 Tablets MICRO LABS



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PERMANENT GLUE STICKING AREA

PERMANENT GLUE

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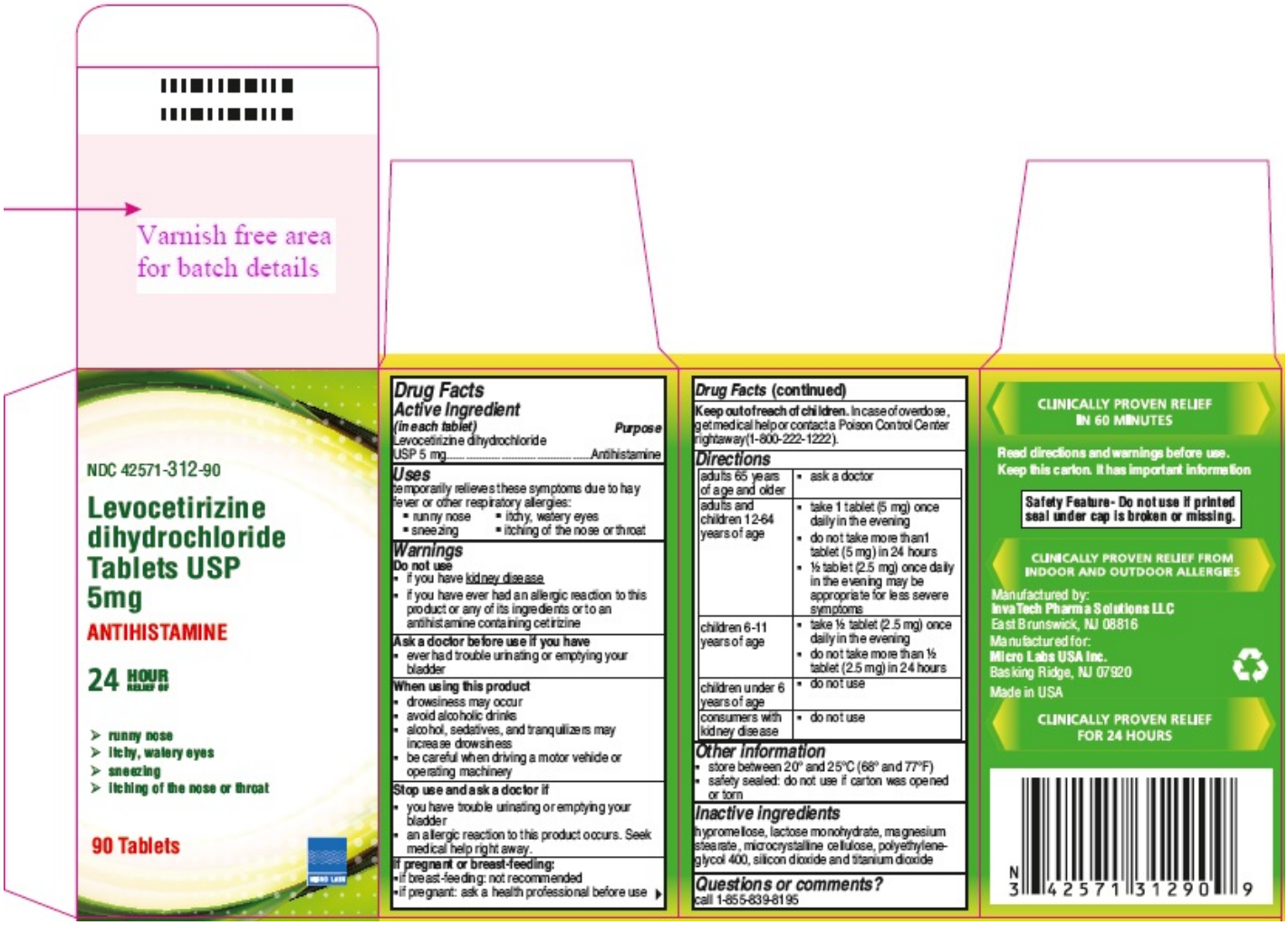

LEVOCETIRIZINE DIHYDROCHLORIDE

levocetirizine dihydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:42571-312
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

Product Characteristics			
Color	white (White to off-white)	**Score**	2 pieces
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	LI
Contains			

Packaging

#	Item 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	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: 11/2019 Micro Labs Limited