

METFORMIN HCL- metformin hcl tablet, film coated
TIME CAP LABORATORIES, INC

TCL METFORMIN TABLETS 500MG - 850 MG & 1000 MG

HOW SUPPLIED

METFORMIN HYDROCHLORIDE TABLETS, USP 500 MG ARE WHITE TO OFF-WHITE COLORED, FILM COATED, ROUND SHAPED WITH BEVELED EDGES ON BOTH SIDES AND DEBOSSSED WITH "134" ON ONE SIDE AND PLAIN ON THE OTHER SIDE. BOTTLES OF 100 AND 500.

HOW SUPPLIED

METFORMIN HYDROCHLORIDE TABLETS, USP 850 MG ARE WHITE TO OFF-WHITE COLORED, FILM COATED, ROUND SHAPED WITH BEVELED EDGES ON BOTH SIDES AND DEBOSSSED WITH "131" ON ONE SIDE AND PLAIN ON THE OTHER SIDE. BOTTLES OF 100 AND 500.

HOW SUPPLIED

METFORMIN HYDROCHLORIDE TABLETS, USP 1000 MG ARE WHITE TO OFF-WHITE COLORED, FILM COATED, OVAL SHAPED WITH BEVELED EDGES ON BOTH SIDES AND DEBOSSSED WITH "132" ON ONE SIDE AND PLAIN ON THE OTHER SIDE. BOTTLES OF 100 AND 500.

100 ct 620R 1000 MG

NDC 49483-620-01



**METFORMIN
HYDROCHLORIDE
TABLETS, USP**

1000 mg

Pharmacist: Dispense with
Patient Information Sheet

Rx only 100 Tablets

Each tablet contains:
Metformin Hydrochloride, USP 1000 mg

DOSAGE AND USE
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F),
excursions permitted between 15° - 30°C
(59° - 86°F) [See USP Controlled Room
Temperature].
Dispense in a light-resistant container as
defined in the USP.

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-403 722, India 620R 0717




49483-620-016

Varnish Omit
Serialization Area

100 CT 621R

NDC 49483-621-01



**METFORMIN
HYDROCHLORIDE
TABLETS, USP**

850 mg

Pharmacist: Dispense with
Patient Information Sheet

Rx only 100 Tablets


Each tablet contains:
Metformin Hydrochloride, USP 850 mg

DOSAGE AND USE
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F),
excursions permitted between 15° - 30°C
(59° - 86°F) [See USP Controlled Room
Temperature].
Dispense in a light-resistant container as
defined in the USP.

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

Manufactured by: Marksans Pharma Ltd.
Plot No. L-82, L-83, Verma Indl. Estate,
Verna, Goa-403 722, India 621R 0717



49483-621-013

Varnish Omit
Serialization Area

NDC 49483-622-01

 **Time-Cap Labs, Inc.**

**METFORMIN
HYDROCHLORIDE
TABLETS, USP**

500 mg

Pharmacist: Dispense with
Patient Information Sheet

Rx only 100 Tablets

Each tablet contains:
Metformin Hydrochloride, USP 500 mg

DOSAGE AND USE
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° – 30°C (59° – 86°F) (See USP Controlled Room Temperature).
Dispense in a light-resistant container as defined in the USP.

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 622R 0717



49483-622-01 0

Varnish Omit
Serialization Area

METFORMIN HCL

metformin hcl tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49483-620
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	1000 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (WHITE TO OFF-WHITE)	Score	2 pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	132
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-620-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2016	
2	NDC:49483-620-81	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2017	
3	NDC:49483-620-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2016	
4	NDC:49483-620-10	1000 in 1 PACKAGE; Type 0: Not a Combination Product	06/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090888	11/14/2016	

METFORMIN HCL

metformin hcl tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49483-621
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	850 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND	Size	13mm
Flavor		Imprint Code	131
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-621-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2016	
2	NDC:49483-621-81	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2017	
3	NDC:49483-621-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2016	
4	NDC:49483-621-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090888	11/14/2016	

METFORMIN HCL

metformin hcl tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49483-622
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METFORMIN HYDROCHLORIDE (UNII: 786Z46389E) (METFORMIN - UNII:9100L32L2N)	METFORMIN HYDROCHLORIDE	500 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	134
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-622-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2016	
2	NDC:49483-622-81	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2017	
3	NDC:49483-622-50	500 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/16/2016	
4	NDC:49483-622-10	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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ANDA	ANDA090888	11/14/2016	
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Labeler - TIME CAP LABORATORIES, INC (037052099)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-620, 49483-621, 49483-622)

Revised: 12/2019

TIME CAP LABORATORIES, INC