

# **METFORMIN HYDROCHLORIDE- metformin hydrochloride tablet**

**Direct RX**

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## **METFROMIN HCL**

### **DESCRIPTION**

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### **CLINICAL PHARMACOLOGY**

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### **CLINICAL STUDIES**

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### **INDICATIONS AND USAGE**

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### **CONTRAINDICATIONS**

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### **WARNINGS**

Lactic acidosis is a rare, but serious, metabolic complication that can occur due to Metformin accumulation during treatment with Metformin Hydrochloride Tablets USP; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels ( $>5$  mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When Metformin is implicated as the cause of lactic acidosis, Metformin plasma levels  $>5$  mcg/mL are generally found.

The reported incidence of lactic acidosis in patients receiving Metformin hydrochloride is very low (approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years). In more than 20,000 patient-years exposure to Metformin in clinical trials, there were no reports of lactic acidosis. Reported cases have occurred primarily in diabetic patients with significant renal insufficiency, including both intrinsic renal disease and renal hypoperfusion, often in the setting of multiple concomitant medical/surgical problems and multiple concomitant medications. Patients with congestive heart failure requiring pharmacologic management, in particular those with unstable or acute congestive heart failure who are at risk of hypoperfusion and hypoxemia, are at increased risk of lactic acidosis. The risk of lactic acidosis increases with the degree of renal dysfunction and the patient's age. The risk of lactic acidosis may, therefore, be significantly decreased by regular monitoring of renal function in patients taking Metformin Hydrochloride Tablets USP and by use of the minimum effective dose of Metformin Hydrochloride Tablets USP. In particular, treatment of the elderly should be accompanied by careful monitoring of renal function. Metformin Hydrochloride Tablets USP treatment should not be initiated in patients  $\geq 80$  years of age unless measurement of creatinine clearance demonstrates that renal function is not reduced, as these patients are more susceptible to developing lactic acidosis. In addition, Metformin Hydrochloride Tablets USP should be promptly withheld in the presence of any condition associated with hypoxemia, dehydration, or sepsis. Because impaired hepatic function may significantly limit the ability to clear lactate, Metformin Hydrochloride Tablets USP

should generally be avoided in patients with clinical or laboratory evidence of hepatic disease. Patients should be cautioned against excessive alcohol intake, either acute or chronic, when taking Metformin Hydrochloride Tablets USP, since alcohol potentiates the effects of Metformin hydrochloride on lactate metabolism. In addition, Metformin Hydrochloride Tablets USP should be temporarily discontinued prior to any intravascular radiocontrast study and for any surgical procedure (see also PRECAUTIONS).

The onset of lactic acidosis often is subtle, and accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. There may be associated hypothermia, hypotension, and resistant bradyarrhythmias with more marked acidosis. The patient and the patient's physician must be aware of the possible importance of such symptoms and the patient should be instructed to notify the physician immediately if they occur (see also PRECAUTIONS). Metformin Hydrochloride Tablets USP should be withdrawn until the situation is clarified. Serum electrolytes, ketones, blood glucose, and if indicated, blood pH, lactate levels, and even blood Metformin levels may be useful. Once a patient is stabilized on any dose level of Metformin Hydrochloride Tablets USP, gastrointestinal symptoms, which are common during initiation of therapy, are unlikely to be drug related. Later occurrence of gastrointestinal symptoms could be due to lactic acidosis or other serious disease.

Levels of fasting venous plasma lactate above the upper limit of normal but less than 5 mmol/L in patients taking Metformin Hydrochloride Tablets USP do not necessarily indicate impending lactic acidosis and may be explainable by other mechanisms, such as poorly controlled diabetes or obesity, vigorous physical activity, or technical problems in sample handling. (See also PRECAUTIONS.) Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia).

Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with lactic acidosis who is taking Metformin Hydrochloride Tablets USP, the drug should be discontinued immediately and general supportive measures promptly instituted. Because Metformin hydrochloride is dialyzable (with a clearance of up to 170 mL/min under good hemodynamic conditions), prompt hemodialysis is recommended to correct the acidosis and remove the accumulated Metformin. Such management often results in prompt reversal of symptoms and recovery. (See also CONTRAINDICATIONS and PRECAUTIONS.)

## **PRECAUTIONS**

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## **ADVERSE REACTIONS**

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## **OVERDOSAGE**

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## **DOSAGE AND ADMINISTRATION**

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## **Patient Package Insert**

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## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Mfg For: Heritage Pharmaceuticals Inc.  
 Edison, NJ 07724  
 NDC 23155-103-05

Mfg Lot:  
 9A7M11E



**METFORMIN HCL**  
**850mg 180 Tabs**

Generic For: **GLUCOPHAGE**  
 Each tablet contains: Metformin Hydrochloride, USP  
 850mg

Lot#  
 Prod# 990-82

Discard After: 08/17

Packaged and  
 Distributed By: **DIRECT**

Alpharetta,  
 GA 30005

AE4XN

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.

**RX ONLY-KEEP OUT OF REACH OF CHILDREN**

Dosage: See package insert. Store between 68-77 degrees F

**NDC 61919-990-82**



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METFORMIN HCL 850mg  
 NDC 61919-990-82 180 Tabs  
 Lot Exp Date 08/17  
 Mfg NDC 23155-103-05

METFORMIN HCL 850mg  
 NDC 61919-990-82 180 Tabs  
 Lot Exp Date 08/17  
 Mfg NDC 23155-103-05

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 NDC 61919-990-82 180 Tabs  
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 Mfg NDC 23155-103-05

## METFORMIN HYDROCHLORIDE

metformin hydrochloride tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-990(NDC:23155-103)
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 K90 (UNII: RDH86HJV5Z)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (5 MPA.S) (UNII: R75537T0T4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
BLACKBERRY (UNII: 8A60MU3I8L)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	

### Product Characteristics

Color	white ((white to off white))	Score	no score
Shape	ROUND (( biconvex))	Size	13mm
Flavor		Imprint Code	H;103
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-990-82	180 in 1 BOTTLE; Type 0: Not a Combination Product	02/05/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090564	02/05/2016	

**Labeler** - Direct RX (079254320)**Establishment**

Name	Address	ID/FEI	Business Operations
Direct RX		079254320	repack(61919-990)

Revised: 2/2016

Direct RX