Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis, with fasting venous plasma lactate above the upper limit of normal but less than 5 mmol/L in patients taking metformin. 

**DOSAGE AND ADMINISTRATION**

**MONITORING**

- Administer once daily with the evening meal.
- Not for treatment of type 1 diabetes or diabetic ketoacidosis.

**Important Limitations of Use**

- Diabetes mellitus.

**FULL PRESCRIBING INFORMATION: CONTENTS**

**WARNINGS AND PRECAUTIONS**

- Hypoglycemia: Use with caution in patients who are being treated with insulin or other antidiabetic drugs.
- Metabolic acidosis: Use with caution in patients who have clinical or laboratory evidence of hepatic or renal disease.
- Edema: Use with caution in patients who have evidence of edema or congestive heart failure.
- Hypersensitivity: Use with caution in patients who have a history of hypersensitivity reactions to drugs.
- Pregnancy and lactation: Use with caution in patients who are pregnant or breastfeeding.
- Children: Use with caution in patients who are children.

**ADVERSE REACTIONS**

- Gastrointestinal disorders: Nausea, vomiting, and diarrhea.
- Hypoglycemia: Headache, dizziness, and tremor.
- Other: Weight gain, edema, and rash.

**DOSE AND STRENGTHS**

- Metformin Hydrochloride Extended-Release Tablets USP, 500 mg and 1000 mg.

**INDICATIONS AND USAGE**

- Treatment of type 2 diabetes mellitus.

**CONTRAINdications**

- Hypersensitivity to metformin.

**CLINICAL STUDIES**

- In a 24-week monotherapy trial comparing metformin hydrochloride extended-release tablets to immediate-release tablets,

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**Nonclinical Toxicology**

**Race**

Genotoxicity assessments in the Ames test, gene mutation test (mouse lymphoma cells), chromosomal aberrations of carcinogenicity was observed in male or female mice.

**Gender**

The apparent volume of distribution (F) of metformin following single oral doses of 850 mg immediate release 13. NONCLINICAL TOXICOLOGY.

**Volume of Distribution**

In both single and multiple-dose studies in healthy subjects, once daily 000 mg (2x500 mg tablets) dosing provides...
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/s/

THUYANH VU
01/11/2012

JAMES T BARLOW
01/11/2012