Metoprolol tartrate tablets, USP
25 mg, 50 mg and 100 mg

DESCRIPTION: Metoprolol tartrate is a selective beta-adrenergic blocking agent, indicated for the treatment of hypertension, angina pectoris, and certain arrhythmias.

Metoprolol tartrate is chemically 1-(isopropylamino)-3-[1-[(2S,5R)-2,5-dimethyl-4-oxo-4H-pyran-2-yl]ethyl]-2-[(2S,5R)-2,5-dimethyl-4-oxo-4H-pyran-2-yl]propanamine monohydrate (5S, 6S, 10R, 12S)-6-hydroxy-1,12-dimethyl-5,6,9,10-tetrahydropyrazino[1,2-a]pyrido[2,3-c]pyridine-1-carboxylic acid. It has the empirical formula of C₂₉H₂₇NO₅·H₂O and a molecular weight of 439.54.

Metoprolol tartrate tablets contain metoprolol tartrate equivalent to 25 mg, 50 mg, or 100 mg metoprolol. Each tablet also contains the following inactive ingredients: aluminum lake, FD&C Blue No. 2 Aluminum Lake, FD&C Red No. 40, FD&C Yellow No. 6, and talc.

INDICATIONS AND USAGE: Metoprolol tartrate is a beta-adrenergic receptor blocking agent. It is used to treat hypertension, angina, and certain arrhythmias. It is available as 25 mg, 50 mg, and 100 mg tablets for oral administration. Metoprolol tartrate is a selective beta-blocker, with predominant beta1-adrenoceptor blocking activity, that is used to treat hypertension.

PHARMACOKINETICS: Metoprolol tartrate is extensively metabolized in the liver, with less than 5% of an oral dose recovered unchanged in the urine. The major pathways of metabolism are glucuronidation and O-dealkylation. The half-life of metoprolol is approximately 3 to 4 hours in patients with normal renal function. In patients with severe renal failure, the half-life may be prolonged to 10 to 12 hours.

CLINICAL PHARMACOLOGY: Metoprolol possesses a high degree of beta-adrenergic selectivity. It is a non-selective beta-blocker with a preference for cardiac beta1-receptors. It has a high affinity for beta1-receptors, particularly in the heart, and a much lower affinity for beta2-receptors.

PHARMACODYNAMICS: Metoprolol is a beta-adrenergic receptor blocking agent. It is available as 25 mg, 50 mg, and 100 mg tablets for oral administration. Metoprolol tartrate is a selective beta-blocker, with predominant beta1-adrenoceptor blocking activity, that is used to treat hypertension.

PHARMACOTHERAPEUTICS: Metoprolol tartrate is a beta-adrenergic receptor blocking agent. It is available as 25 mg, 50 mg, and 100 mg tablets for oral administration. Metoprolol tartrate is a selective beta-blocker, with predominant beta1-adrenoceptor blocking activity, that is used to treat hypertension.

SIDE EFFECTS: Side effects of metoprolol tartrate may include headaches, cold or hot flashes, diarrhea, constipation, nausea, vomiting, flatulence, dry mouth, and dizziness. In rare cases, metoprolol may cause respiratory issues, particularly in patients with asthma or chronic obstructive pulmonary disease.

INTERACTIONS: Metoprolol tartrate may interact with other medications, such as digitalis glycosides, calcium channel blockers, and diuretics. It may also interact with alcohol, which can increase the risk of adverse effects.

CONTRAINDICATIONS: Metoprolol tartrate is contraindicated in patients with severe bradycardia, second- or third-degree heart block, sick sinus syndrome, severe hypertension, or any condition in which beta-blockade is contraindicated.

ADVERSE REACTIONS: The most common adverse reactions associated with metoprolol tartrate include headaches, nausea, vomiting, diarrhea, constipation, and dizziness.

DOSAGE AND ADMINISTRATION: The usual dosage of metoprolol is 25 mg twice daily, which may be increased to 50 mg twice daily or 100 mg twice daily if necessary.

HOW SUPPLIED: Metoprolol tartrate tablets are supplied in bottles of 100 tablets, 1000 tablets, and 1500 tablets.

PATIENT INFORMATION: Patients should be advised to take metoprolol regularly and as directed, and not to discontinue or reduce the dose of metoprolol without consulting their physician.

MANAGEMENT OF OVERDOSE: In case of an overdose, supportive measures should be instituted. If severe bradycardia or hypotension occurs, atropine or isoproterenol may be administered intravenously. If conduction defects are noted, a pacemaker may be inserted. If cardiogenic shock occurs, dopamine or dobutamine may be administered.

NOTES: This information is intended for use by healthcare professionals and is not intended to replace the advice of a physician. Always consult your healthcare professional about any questions you may have regarding a medical condition.

This document is intended for educational purposes only and is not a substitute for professional medical advice. Always consult with a healthcare professional before making any changes to your medication regimen.
Genetic Considerations:

Hypersensitivity:

The following adverse reactions have been reported during clinical trials with metoprolol tartrate tablets:

Hypertension: Blood pressure may be decreased in patients with hypotension and congestive heart failure. Bradycardia may occur in patients with hypotension or low cardiac output, especially those with impaired sympathetic and parasympathetic tone. The use of metoprolol tartrate tablets may be associated with a decrease in arterial pressure and an increase in heart rate; therefore, caution should be exercised when metoprolol tartrate tablets are administered to patients with severe hypotension, impaired cardiac output, or severe bradycardia. In patients with hypertrophic cardiomyopathy with a small left ventricular cavity, treatment with metoprolol may be associated with a decrease in cardiac output and may exacerbate symptoms of heart failure. In patients with severe aortic stenosis, treatment with metoprolol may be associated with a further decrease in cardiac output and may exacerbate symptoms of heart failure. In patients with chronic obstructive pulmonary disease, treatment with metoprolol may be associated with an exacerbation of symptoms of heart failure.

Hypotension:

Signs and Symptoms:

Hypotension or marked bradycardia, which may produce vertigo, syncope, or postural hypotension, may be associated with severe anaphylactic reaction to a variety of allergens may be more reactive to repeat challenges, either accidental, diagnostic, or therapeutic. Such patients may be more sensitive to xenobiotics in general because of the overall decreased hepatic activity. Metoprolol is extensively metabolized in the liver and the major metabolite is devoid of pharmacological activity. Metoprolol is excreted in breast milk in a very small quantity. An adult female who is breastfeeding should be advised to discontinue nursing or discontinue the drug. Caution should be exercised when metoprolol is administered to a nursing woman.

Dermatologic:

Tiredness has been reported in 10% of patients receiving metoprolol. No cutaneous or mucous membrane signs of dermatologic reactions have been reported in clinical trials with metoprolol tartrate tablets.

GI:

It is important to note that these adverse reactions are not necessarily indicative of the potential for carcinogenesis. In long-term studies in mice and rats, the incidence of benign and malignant tumors was unaltered by metoprolol treatment.

For all pharmaceuticals, the carcinogenic potential of metoprolol tartrate tablets has not been adequately evaluated.

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