METOPROLOL tartrate

NEOBLOC®

50mg Tablet
100mg Tablet

BETA ADRENOCEPTOR BLOCKER

FORMULATION:
Each tablet contains 50mg or 100mg METOPROLOL tartrate, USP

DESCRIPTION:
METOPROLOL tartrate (NEOBLOC®) 50mg is a round, biconvex, white tablet coded with GXI MT5 on one side, plain on the other side.
METOPROLOL tartrate (NEOBLOC®) 100mg is a round, biconvex, white tablet coded with GXI MT1 on one side, plain on the other side.
NEOBLOC® is a brand of METOPROLOL tartrate, a beta-adrenergic receptor blocking agent which acts preferentially on ß1-receptors.

This ß1-blocking activity of METOPROLOL tartrate (NEOBLOC®) is manifested by a reduction in heart rate and cardiac output, and control of blood pressure both at rest and during exercise.

MECHANISM OF ACTION:
Metoprolol is readily and completely absorbed from the gastrointestinal tract but is subject to considerable first-pass metabolism, with a bioavailability of about 50%. Peak plasma concentrations vary widely and occur about 1.5 to 2 hours after a single oral dose. It is moderately lipid-soluble. Metoprolol is widely distributed; it crosses the blood brain barrier and the placenta, and is distributed into breast milk. It is about 12% bound to plasma protein. It is extensively metabolized in the liver, mainly by the cytochrome P450 isoenzyme CYP2D6. The metabolites are excreted in the urine with only small amounts of unchanged metoprolol. The half-life of metoprolol in fast hydroxylators is stated to be 3 to 4 hours, whereas in poor hydroxylators it is about 7 hours.

INDICATIONS:
It is used in the management of hypertension, angina pectoris, cardiac arrhythmias, myocardial infarction, and heart failure. It is also used in the management of hyperthyroidism and in the prophylactic treatment of migraine.

DOSAGE AND ADMINISTRATION:
The dose is dependent on the individual requirement and should be adjusted according to the response of the patient. Although the dose should be individualized, the usual initial oral adult dose is 50mg twice a day or 100mg once a day.

Dosage may be increased at one-week interval to as high as 400mg a day according to the patient's response until optimum hypotensive effect is attained. The usual oral maintenance dose is 100mg to 400mg daily. In some patients, once daily administration of 200mg METOPROLOL tartrate (NEOBLOC®) tablet is usually effective for maintenance dose.

METOPROLOL tartrate (NEOBLOC®) tablet may be combined with other anti-hypertensive agent and/or diuretic combination for therapeutic advantage.

CONTRAINDICATIONS AND PRECAUTIONS:
METOPROLOL tartrate (NEOBLOC®) is contraindicated in heart block, greater than first degree Atrioventricular (AV) block II and III degree, cardiogenic shock, overt cardiac failure and sinus bradycardia. Abrupt withdrawal of the drug should be avoided and it should not be used by patients who have bronchospastic disease unless the patients does not respond to, or cannot tolerate other anti-hypertensive drug. In such cases, the lowest possible dose should be used and a ß2- agonist should be administered concomitantly.

METOPROLOL tartrate may prolong hypoglycemic effect of insulin and should therefore be used with caution in diabetic patients especially those with labile diabetes. METOPROLOL tartrate therapy must be reported to the anesthetist prior to general anaesthesia. Administration during the first trimester of pregnancy is not recommended.

SIDE EFFECTS:
The most common side effects are disturbances in gastrointestinal and sleep pattern headache, dizziness and weakness. They are however mild, transient and well-tolerated. A reduction in dosage will, in most cases, eliminate these side effects.

OVERDOSE AND TREATMENT:
Symptoms: The symptoms of overdosage may include bradycadia and bradyarrhythmia, hypotension, cardiac insufficiency, cardiac conduction disturbances and bronchospasm.
Management: Care should be provided at a facility that can provide appropriate supporting measures, monitoring, and supervision.
If justified, gastric lavage and /or activated charcoal can be administered.
Atropine, adreno stimulating drugs or pacemaker to treat bradycardia and conduction disorders.
Hypotension, acute cardiac failure, and shock to be treated with suitable volume expansion, injection of glucagon (if necessary, followed by an intravenous infusion of glucagon), intravenous administration of adrenostimulating drugs such as dobutamine, with α_1 receptor agonistic drugs added in presence of vasodilation. Intravenous use of Ca^{2+} can also be considered.
Bronchospasm can usually be reversed by bronchodilators.

WARNING:
Do not take other medicines, especially non-prescription sympathomimetics, unless discussed with physician.

STORAGE RECOMMENDATION:
Store at temperatures not exceeding 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription (List B).

For suspected adverse drug reaction, report to the FDA:
www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY:
50mg Blister Pack x 10's (Box of 100's, 500's)- DR-XY27497
100mg Blister Pack x10's (Box of 100's, 500's)- DR-XY27498

DATE OF FIRST AUTHORIZATION:
50mg – October 3, 2008
100mg – October 3, 2008

DATE OF REVISION OF PACKAGE INSERT:
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NEOBLOC® is a registered mark of GX INTERNATIONAL, INC.

Manufactured by:
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Antipolo City
For:
GX INTERNATIONAL, INC.
RMG Corporate Center
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