For the use of a registered medical practitioner or a hospital or a laboratory

AMERICAN

Blucan Injection

℞

Methylene blue Injection USP 1.0%

Composition:
Each ml Contains:

Methylene blue USP	10 mg
Water for Injection IP	q.s.

DESCRIPTION
Methylene Blue Injection, USP is a sterile solution of Methylene Blue. Each ml contains Methylene Blue, USP, 10 mg in Water for Injection q.s. pH adjusted with suitable buffering agent.

CLINICAL PHARMACOLOGY
Methylene Blue will produce two opposite actions on hemoglobin. Low concentrations will convert methemoglobin to hemoglobin. High concentrations convert the ferrous iron of reduced hemoglobin to ferric iron which results in the formation of methemoglobin.
Methylene blue is metabolized in the body to leukomethylene blue which is excreted primarily in the urine. Some unchanged drug is also excreted in the urine.

INDICATIONS AND USAGE
Drug-induced methemoglobinemia.

CONTRAINDICATION
Methylene blue can cause fetal harm when administered to a pregnant woman. An association exists between the use of methylene blue in amniocentesis and atresia of the ileum and jejunum, ileal occlusions and other adverse effects in the neonate. Methylene blue is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.
Intraspinal and subcutaneous injections are contraindicated.
Methylene blue is contraindicated in patients with a known hypersensitivity to the drug.

WARNINGS
Methylene Blue should not be given by subcutaneous or intrathecal injection.
Methylene blue is a potent monoamine oxidase inhibitor: Methylene blue has been demonstrated to be a potent monoamine oxidase inhibitor (MAOI) and may cause potentially fatal serotonin toxicity (serotonin syndrome) when combined with serotonin reuptake inhibitors (SRIs). Serotonin toxicity is characterized by development of neuromuscular hyperactivity (tremor, clonus, myoclonus and hyperreflexia, and, in the advanced stage, pyramidal rigidity); autonomic hyperactivity (diaphoresis, fever, tachycardia, tachypnea, and mydraisis); and altered mental status (agitation, excitement, and in the advanced stage, confusion). If methylene blue is judged to be indicated, SRIs must be ceased, prior to treatment/procedure/surgery.

PRECAUTIONS
Drug Interactions: Methylene blue may interact with any drug that acts as a serotonin reuptake inhibitor (SRI) including, amongst others, selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), norepinephrine-dopamine reuptake inhibitors (NDRIs), triptans and ergot alkaloids; such combinations may have the consequence of potentially fatal serotonin toxicity (serotonin syndrome). Methylene blue should not be co-administered with any drug that acts as an SRI.
Use in Pregnancy: Pregnancy Category X: Epidemiologic evidence exists that Methylene blue is a teratogen. An association exists between the use of methylene blue in amniocentesis and atresia of the ileum and jejunum, ileal occlusions and other adverse effects in the neonate. Methylene blue Injection should not be administered to pregnant women during amniocentesis due to the risk of teratogenicity and other newborn adverse effects.
Glucose-6-Phosphate Dehydrogenase Deficiency (G6PD): Methylene blue should be avoided in patients with G6PD deficiency due to the risk of paradoxical methemoglobinemia and hemolysis.
Renal Failure: Methylene blue should be used with caution in patients with severe renal impairment (see CLINICAL PHARMACOLOGY).
Methylene Blue must be injected intravenously very slowly over a period of several minutes to prevent local high concentration of the compound from producing additional methemoglobin.
Do not exceed recommended dosage.

ADVERSE REACTIONS
Large intravenous doses of Methylene Blue produce nausea, abdominal and precordial pain, dizziness, headache, profuse sweating, mental confusion and the formation of methemoglobin.

DOSAGE AND ADMINISTRATION
0.1 to 0.2 ml per kg body weight (0.045 to 0.09 ml per pound body weight). Inject Methylene Blue intravenously very slowly over a period of several minutes.
Methylene blue must be injected intravenously very slowly over a period of several minutes to prevent local high concentration of the compound from producing additional methemoglobin. Do not exceed recommended dosage.
Parenteral drug products should be inspected visually for particulate matter and discoloration, whenever solution and container permit.

Storage : Store protected from light at a temperature not exceeding 30°C.
Improper storage may deteriorate the product.

Presentation 1 x 10 ml Ampoule

Manufactured by:

AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

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