Methomol™

Methocarbamol USP

Composition

Methomol™ 500: Each film coated tablet contains Methocarbamol USP 500 mg.
Methomol™ 750: Each film coated tablet contains Methocarbamol USP 750 mg.

Pharmacology

The mechanism of action of Methocarbamol in humans has not been established but may be due to general Central Nervous System (CNS) depression. It has no direct action on the contractile mechanism of striated muscle, the motor end plate or the nerve fiber.

Indication

Methocarbamol is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of methocarbamol has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

Dosage & Administration

Route of Administration: Oral
Recommended dosing:
Methomol™ 500 mg – Adults:
Initial dosage: 3 tablets q.i.d.
Maintenance dosage: 2 tablets q.i.d.
Methomol™ 750 mg – Adults:
Initial dosage: 2 tablets q.i.d.
Maintenance dosage: 1 tablet q.4h. or 2 tablets t.i.d.
Six grams a day are recommended for the first 48 to 72 hours of treatment (for severe conditions 8 grams a day may be administered). Thereafter, the dosage can usually be reduced to approximately 4 grams a day.

Contraindications

Methocarbamol is contraindicated in patients hypersensitive to **Methomol**™ or to any of the tablet components.

Warnings & Precautions

Patients should be cautioned that Methocarbamol may cause drowsiness or dizziness, which may impair their ability to operate motor vehicles or machinery because Methocarbamol may possess a general CNS-depressants effect. Patients should be cautioned about combined effects with alcohol and other CNS depressants. Safe use of Methocarbamol has not been established with regard to possible adverse effects upon fetal development. There have been reports of fetal and congenital abnormalities following in utero exposure to methocarbamol. Therefore, Methocarbamol should not be used in women who are or may become pregnant and particularly during early pregnancy unless in the judgment of the physician the potential benefits outweigh the possible hazards.

Side-effects

Adverse reactions reported coincident with the administration of methocarbamol include:
Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache
Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis
Digestive system: Dyspepsia, jaundice (including cholestatic jaundice), nausea and vomiting
Hemic and lymphatic system: Leukopenia
Immune system: Hypersensitivity reactions
Nervous system: Amnesia, confusion, Diplopia, dizziness or lightheadedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures (including grand mal), vertigo
Skin and special senses: Blurred vision, conjunctivitis, nasal congestion, metallic taste, pruritus, rash, urticaria.

Drug interactions

Methocarbamol may inhibit the effect of Pyridostigmine Bromide. Therefore, Methocarbamol should be used with caution in patients with myasthenia gravis receiving anticholinesterase agents.
Drug/Laboratory Test Interactions: Methocarbamol may cause a color interference in certain screening tests for 5-hydroxyindoleacetic acid (5-HIAA) using nitrosonaphthol reagent and in screening tests for urinary vanillylmandelic acid (VMA) using the Gitlow method. Carcinogenesis, Mutagenesis, Impairment of Fertility Long-term studies to evaluate the carcinogenic potential of Methocarbamol have not been performed. No studies have been conducted to assess the effect of Methocarbamol on mutagenesis or its potential to impair fertility.

Use in specific populations

Pregnancy: Pregnancy Category C.
Animal reproduction studies have not been conducted with Methocarbamol. It is also not known whether Methocarbamol can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Methocarbamol should be given to a pregnant woman only if clearly needed.
Nursing Mothers: Methocarbamol and/or its metabolites are excreted in the milk of dogs; however, it is not known whether Methocarbamol or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Methocarbamol is administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Methocarbamol in pediatric patients below the age of 16 have not been established.

Storage

Protect from light, store below 30° C. Keep the medicine out of the reach of children.

How Supplied

Methomol™ 500: Each box contains 30 tablets in Alu-PVDC Blister pack.
Methomol™ 750: Each box contains 30 tablets in Alu-PVDC Blister pack.

Manufactured by –
SQUARE
PHARMACEUTICALS PLC.
Kaliakoir, Gazipur, Bangladesh