Somerset
Therapeutics Limited

TECHNICAL WRITE UP

Methocarbamol Injection USP 100 mg/mL

Description:

Methocarbamol Injection, USP is a sterile, pyrogen-free solution intended for intramuscular or intravenous administration. It is a carbamate derivative of guaifenesin, a central nervous system (CNS) depressant with sedative and musculoskeletal relaxant properties.

Methocarbamol is a white powder, sparingly soluble in water and chloroform, soluble in alcohol (only with heating) and propylene glycol, and insoluble in benzene and *n*–hexane.

The chemical name of methocarbamol is 3–(2– methoxyphenoxy)–1, 2-propanediol 1-carbamate and has the empirical formula of $C_{11}H_{15}NO_5$. Its molecular weight is 241.24.

Clinical Pharmacology:

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

Indication and usage

The injectable form of 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 this drug has not been clearly identified, but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man.

Dosage and administration

For Intravenous and Intramuscular Use Only. Total adult dosage should not exceed 30 mL (3 vials) a day for more than 3 consecutive days except in the treatment of tetanus. If the condition persists, a like course may be repeated after a drug-free interval of 48 hours.

Dosage and frequency of injection should be based on the severity of the condition being treated and therapeutic response noted.

For the relief of symptoms of moderate degree, one dose of 1 gram (one 10 mL vial) may be adequate. Ordinarily this injection need not be repeated, as the administration of the oral form will usually sustain the relief initiated by the injection. For the severest cases or in postoperative

in which oral administration is not feasible, additional doses of 1 gram may be repeated every 8 hours up to a maximum of 3 g/day for no more than 3 consecutive days.

Directions for Intravenous Use

Methocarbamol Injection may be administered undiluted directly into the vein at a maximum rate of three mL per minute. It may also be added to an intravenous drip of Sodium Chloride Injection (Sterile Isotonic Sodium Chloride Solution for Parenteral Use) or five percent Dextrose Injection (Sterile 5 percent Dextrose Solution): one vial given as a single dose should not be diluted to more than 250 mL for I.V. infusion. AFTER MIXING WITH I.V. INFUSION FLUIDS, DO NOT REFRIGERATE. Care should be exercised to avoid vascular extravasation of this hypertonic solution, which may result in thrombophlebitis. It is preferable that the patient be in a recumbent position during and for at least 10 to 15 minutes following the injection.

Directions for Intramuscular Use

When the intramuscular route is indicated, not more than five mL (one-half vial) should be injected into each gluteal region. The injections may be repeated at eight hour intervals, if necessary. When satisfactory relief of symptoms is achieved, it can usually be maintained with tablets *Not Recommended for Subcutaneous Administration.*

Special Directions for Use in Tetanus

There is clinical evidence which suggests that methocarbamol may have a beneficial effect in the control of the neuromuscular manifestations of tetanus. It does not, however, replace the usual procedure of debridement, tetanus antitoxin, penicillin, tracheotomy, attention to fluid balance, and supportive care. Methocarbamol Injection should be added to the regimen as soon as possible.

For Adults inject one or two vials directly into the tubing of the previously inserted indwelling needle. An additional 10 mL or 20 mL may be added to the infusion bottle so that a total of up to 30 mL (three vials) is given as the initial dose. This procedure should be repeated every six hours until conditions allow for the insertion of a nasogastric tube. Total daily oral doses up to 24 grams may be required as judged by patient response.

For Pediatric patients a minimum initial dose of 15 mg/kg or 500 mg/m2 is recommended. This dosage may be repeated every six hours, if required. The total dose should not exceed 1.8 g/m^2 for 3 consecutive days. The maintenance dosage may be given by injection into tubing or by I.V. infusion with an appropriate quantity of fluid.