For Immediate Release

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American Regent Announces the Availability of Methocarbamol Injection, USP; AP rated and therapeutically equivalent to Robaxin®[1]*

Shirley, NY (January XX, 2018) – American Regent today announced the launch of Methocarbamol Injection, USP. **Methocarbamol Injection, USP is available for immediate shipment. Customers can order Methocarbamol Injection, USP through their wholesaler/distributor or by contacting our Customer Support Group at 1-800-645-1706.**

Methocarbamol Injection, USP is supplied as follows:

NDC#	Strength	Supplied As	Shelf Pack
0517-1825-10	100 mg/mL	10 mL Single Dose Vial†	10

*Robaxin® is a registered trademark owned by Wyeth LLC.

† The vial closure is not made with natural rubber latex.

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.

See the following Important Safety Information in addition to the Full Prescribing Information.

Methocarbamol Injection, USP

For Intravenous and Intramuscular Use Only

INDICATIONS 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.

IMPORTANT SAFETY INFORMATION

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.

Special Populations

Elderly
The mean elimination half-life of methocarbamol in elderly healthy volunteers was slightly prolonged compared to a younger, healthy population. The fraction of bound methocarbamol was slightly decreased in the elderly versus younger volunteers.

Renally Impaired
The clearance of methocarbamol in 8 renally-impaired patients on maintenance hemodialysis was reduced about 40% compared to 17 normal subjects, although the mean elimination half-life in these two groups was similar.

Hepatically Impaired
In 8 patients with cirrhosis secondary to alcohol abuse, the mean total clearance of methocarbamol was reduced approximately 70% compared to that obtained in 8 age-and weight-matched normal subjects. The percent of methocarbamol bound to plasma proteins was decreased.

CONTRAINDICATIONS

Methocarbamol Injection should not be administered to patients with known or suspected renal pathology, due to the presence of polyethylene glycol 300 in the vehicle.

Methocarbamol injection is contraindicated in patients hypersensitive to methocarbamol or to any of the injection components.

WARNINGS

Since methocarbamol may possess a general CNS depressant effect, patients receiving methocarbamol injection should be cautioned about combined effects with alcohol and other CNS depressants.

There have been very rare reports of fetal and congenital abnormalities following in utero exposure to methocarbamol, therefore methocarbamol injection 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.

USE IN ACTIVITIES REQUIRING MENTAL ALERTNESS

Methocarbamol may impair mental and/or physical abilities required for performance of hazardous tasks, such as operating machinery or driving a motor vehicle.

PRECAUTIONS

General

Since methocarbamol injection is hypertonic, vascular extravasation must be avoided.

Caution should be observed in using the injectable form in patients with suspected or known seizure disorders.

DRUG INTERACTIONS

Interaction with CNS drugs and alcohol causing a general CNS depressant effect.

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.

PREGNANCY *Teratogenic Effects-Pregnancy Category C*
Methocarbamol injection should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether methocarbamol or its metabolites are excreted in human milk. Caution should be exercised when methocarbamol injection is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness of methocarbamol injection in pediatric patients have not been established except in tetanus.

ADVERSE REACTIONS

The following adverse reactions have been reported coincident with the administration of methocarbamol.

Body as a whole: Anaphylactic reaction, angioneurotic edema, fever, headache
Cardiovascular system: Bradycardia, flushing, hypotension, syncope, thrombophlebitis
Digestive system: Dyspepsia, jaundice, nausea and vomiting
Hemic and lymphatic system: Leukopenia
Immune system: Hypersensitivity reactions

Nervous system: Amnesia, confusion, diplopia, dizziness or light-headedness, drowsiness, insomnia, mild muscular incoordination, nystagmus, sedation, seizures, vertigo

Administration to patients with epilepsy is not recommended.
Skin and special senses: Blurred vision, conjunctivitis, nasal congestion, metallic taste, pruritus, rash, urticaria
Other: Pain and sloughing at the site of injection

OVERDOSAGE

Overdose of methocarbamol is frequently in conjunction with alcohol or other CNS depressants. In post-marketing experience, deaths have been reported with an overdose of methocarbamol alone or in the presence of other CNS depressants, alcohol or psychotropic drugs.

Reference: 1. Approved Drug Products with Therapeutic Equivalence Evaluations. https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=207496 Accessed November 8, 2017.

For additional Safety Information, please see Full Prescribing Information.

You are encouraged to report Adverse Drug Events to American Regent Inc. at 1-800-734-9236 or to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

About American Regent

American Regent, a member of the Daiichi Sankyo Group, is a leader in the development, manufacturing and sales of generic and branded IV medications. For 50 years American Regent has been providing the medical community with generic specialty injectables manufactured in our facilities in the United States. American Regent brings to market products across a wide array of therapeutic areas.

For more information, please visit www.americanregent.com.

About Daiichi Sankyo Group

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with a Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Basking Ridge, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit: www.dsi.com.