Relatro™ 25

Dantrolene Sodium USP 25 mg

Composition

Relatro™ Capsule: Each capsule contains Dantrolene Sodium USP 25 mg.

Pharmacology

Dantrolene produces relaxation by affecting the contractile response of the skeletal muscle. In skeletal muscle, Dantrolene dissociates the excitation-contraction coupling, probably by interfering with the release of Ca++ from the sarcoplasmic reticulum.

Indication

In Chronic Spasticity: Dantrolene is indicated in controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders (e.g., spinal cord injury, stroke, cerebral palsy or multiple sclerosis). It is of particular benefit to the patients whose functional rehabilitation has been retarded by the sequelae of spasticity. Dantrolene is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

A decision to continue the administration of Dantrolene on a long-term basis is justified if introduction of the drug into the patient's regimen:

- produces a significant reduction in painful and/or disabling spasticity such as clonus, or
- permits a significant reduction in the intensity and/or degree of nursing care required, or
- Relieves the patient of any annoying manifestation of spasticity considered important by the patient himself.

In Malignant Hyperthermia: Oral Dantrolene is also indicated preoperatively to prevent or attenuate the development of signs of malignant hyperthermia in known, or strongly suspect, malignant hyperthermia susceptible patients who require anesthesia and/or surgery.

Dosage and Administration

For Use in Chronic Spasticity: It is important that the dosage be titrated and individualized for maximum effect. The lowest dose compatible with optimal response is recommended. Each dosage level should be maintained for seven days to determine the patient's response. If no further benefit is observed at the next higher dose, dosage should be decreased to the previous lower dose.

Adults: 25 mg once daily for seven days, then 25 mg t.i.d. for seven days, 50 mg t.i.d. for seven days, 100 mg t.i.d.

Pediatric Patients: 0.5 mg/kg once daily for seven days, then 0.5 mg/kg t.i.d. for seven days, 1 mg/kg t.i.d. for seven days, 2 mg/kg t.i.d.

For Malignant Hyperthermia: Preoperatively: 4 to 8 mg/kg/day of oral Dantrolene in 3 or 4 divided doses for one or two days prior to surgery, with the last dose being given approximately 3 to 4 hours before scheduled surgery with a minimum of water. Post Crisis Follow-up: Oral Dantrolene should also be administered following a malignant hyperthermia crisis, in doses of 4 to 8 mg/kg per day in four divided doses, for a one to three day period to prevent recurrence of the manifestations of malignant hyperthermia.

Contraindications

Active hepatic disease, such as hepatitis and cirrhosis, is a contraindication for use of Dantrolene.

Warnings and precautions

Fatal and non-fatal liver disorders of an idiosyncratic or hypersensitivity type may occur with Dantrolene therapy. At the start of Dantrolene therapy, it is desirable to do liver function studies (SGOT, SGPT, alkaline phosphatase, total bilirubin) for a baseline or to establish whether there is pre-existing liver disease. If baseline liver abnormalities exist and are confirmed, there is a clear possibility that the potential for Dantrolene hepatotoxicity could be enhanced, although such a possibility has not yet been established. Liver function studies (e.g., SGOT or SGPT) should be performed at appropriate intervals during Dantrolene therapy. If such studies reveal abnormal values, therapy should generally be discontinued. If symptoms compatible with hepatitis, accompanied by abnormalities in liver function tests or jaundice appear, Dantrolene should be discontinued. Dantrolene should be used with particular caution in females and in patients over 35 years of age in view of apparent greater likelihood of drug-induced, potentially fatal, hepatocellular disease in these groups.

Dantrolene should be used with caution in patients with impaired pulmonary function, particularly those with obstructive pulmonary disease and in patients with severely impaired cardiac function due to myocardial disease. Dantrolene is associated with pleural effusion with associated eosinophilia. Patients should be cautioned against driving a motor vehicle or participating in hazardous occupations while taking Dantrolene. Caution should be exercised in the concomitant administration of tranquilizing agents. Dantrolene might possibly evoke a photosensitivity reaction; patients should be cautioned about exposure to sunlight while taking it.

Side-effects

The most frequently occurring side effects of Dantrolene have been drowsiness, dizziness, weakness, general malaise, fatigue and diarrhea. Other less frequent side effects are constipation, anorexia, abdominal cramps, nausea and/or vomiting, hepatitis, headache, visual disturbance, alteration of taste, insomnia, tachycardia, anemia, leukopenia, lymphocytic lymphoma, mental depression and mental confusion.

Drug interactions

Drowsiness may occur with Dantrolene therapy and the concomitant administration of CNS depressants such as sedatives and tranquilizing agents may result in further drowsiness. Hepatotoxicity has occurred more often in women over 35 years of age receiving concomitant estrogen therapy. Administration of Dantrolene may potentiate vecuronium-induced neuromuscular block.

Use in specific populations

Pregnancy: Pregnancy Category C.

Nursing Mothers: Dantrolene should not be used in nursing mothers.

Pediatric Patients: The long-term safety of Dantrolene in pediatric patients under the age of 5 years has not been established.

Storage

Store below 30° C protected from light and moisture. Keep all the medicines out of reach of children.

How supplied

Relatro™ 25 mg capsule: Each box contains 20 capsules in alu-alu blister packing.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
Salgaria, Pabna, Bangladesh

TM- Trade Mark

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