Trolen-25

Capsule

Composition : Dantrolene Sodium USP 25 mg.

Indications : In Chronic Spasticity : Dantrolene Sodium is indicated in controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders such as spinal cord injury, stroke, cerebral palsy or multiple sclerosis. It is of particular benefit to the patient whose functional rehabilitation has been retarded by the sequelae of spasticity.

Malignant Hyperthermia : It 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. It should be administered following a malignant hyperthermic crisis to prevent recurrence of the signs of malignant hyperthermia.

Dosage and administration : For use in Chronic Spasticity : Adults Patients : The following gradual titration schedule is suggested. Some patients will not respond until higher daily dosage is achieved. 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. 25 mg once daily for seven days, then 25 mg 3 times for seven days, 50 mg 3 times for seven days, 100 mg 3 times. **For Malignant Hyperthermia : Preoperatively :** Administer 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 :** 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. Or, as directed by the registered physicians.

Warning & Precaution : In view of the potential for liver damage in long-term **Trolen-25** use, therapy should be stopped if benefits are not evident within 45 days. Liver function studies (e.g., SGOT or SGPT) should be performed at appropriate intervals during **Trolen-25** therapy. Patients should be cautioned against driving a motor vehicle or participating in hazardous occupations while taking **Trolen-25**. Dantrolene Sodium should be used with caution in patients with impaired pulmonary function and in patients with severely impaired cardiac function due to myocardial disease.

Side effects : The most frequently occurring side effects are drowsiness, dizziness, weakness, general malaise and diarrhea.

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

Use in Pregnancy and lactation : Pregnancy Category C. Dantrolene should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Dantrolene should not be used in nursing mothers.

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.

Packing : Trolen-25 : 2 x 10's capsules in blister pack.