Danflex®

Dantrolene Sodium USP

Description: **Danflex®** is a directly acting peripheral skeletal muscle relaxant that is used to treat muscle spasms & spasticity caused by conditions such as spinal cord injury, stroke, cerebral palsy, multiple sclerosis, malignant hyperthermia etc.

Mode of Action: In skeletal muscle cells, **Danflex®** interfering the release of Ca^{++} from the sarcoplasmic reticulum by blocking ryanodine receptor-1 which dissociates the excitation-contraction coupling interaction between actin and myosin thus produces relaxation.

Composition:
Danflex® 25 mg Capsule: Each capsule contains Dantrolene Sodium USP 25 mg.
Danflex® 50 mg Capsule: Each capsule contains Dantrolene Sodium USP 50 mg.

Indications:
- Relief of chronic spasticity of skeletal muscle in conditions such as spinal cord injury, cerebral palsy, multiple sclerosis and stroke.
- Malignant Hyperthermia susceptible patients (who require anesthesia and/or surgery).
- Succinylcholine-induced muscle fasciculation and postoperative myalgia.
- Acute low back pain.
- Neuroleptic malignant syndrome.

Dosage & administration:
- **Chronic spasticity resulting from upper motor neuron disorders** (e.g., spinal cord injury, stroke, cerebral palsy, multiple sclerosis)—

Adults: Initially, 25 mg once daily. In elderly patients, initiate cautiously. If needed, increase dose every 7 days. After initial dose- a gradual dose titration of 25 mg three times daily for 7 days, 50 mg three times daily for 7 days, and 100 mg three times daily is recommended. Doses higher than 400 mg/day (100 mg four times daily) should not be used. Administer the lowest possible dose that decreases spasticity severity and helps the patient's functionality.
Children 5 years of age and older: Initially, 0.5 mg/kg once daily. If needed, increase dose every 7 days. After initial dose- a gradual dose titration of 0.5 mg/kg three times daily for 7 days, 1 mg/kg three times daily for 7 days, and 2 mg/kg three times daily is recommended. Maximum dosage is 100 mg four times daily.

- **Malignant Hyperthermia susceptible patients** (who require anesthesia and/or surgery): 4 to 8 mg/kg/day in 3 to 4 divided doses starting 1 to 2 days before surgery. Give last dose 3 to 4 hours prior to surgery. For post crisis follow-up, give 4 to 8 mg/kg/day in 4 divided doses for 1 to 3 days.
- **Succinylcholine-induced muscle fasciculation and postoperative myalgia:** Adults > 45 kg: 150 mg, given 2 hours preoperatively; Adults < 45 kg: 100 mg, given 2 hours preoperatively.
- **Acute low back pain:** 25 mg once daily four to seven days.
- **Neuroleptic malignant syndrome:** 100 to 300 mg/day given in divided doses.

Contraindications:
Active hepatic disease, such as hepatitis and cirrhosis.

Side effects:
The most frequently occurring side effects of Dantrolene Sodium have been drowsiness, dizziness, weakness, general malaise, fatigue, diarrhea etc.

Use in pregnancy & Lactation: USFDA pregnancy category C. Dantrolene should not be used in nursing mothers.
Use in children: The long-term safety of Dantrolene Sodium in pediatric patients under the age of 5 years has not been established.

Precautions:
Dantrolene Sodium 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. It should be used with caution in patients with a history of previous liver disease or dysfunction. In view of the potential for liver damage Dantrolene Sodium should not be used without appropriate evaluation and monitoring of hepatic function before and throughout treatment. If any evaluation report reveal abnormal values as well as if no observable benefit is derived from the administration of Dantrolene after a total of 45 days, therapy should be discontinued.

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. While a definite drug interaction with estrogen therapy has not yet been established, caution should be observed if the two drugs are to be given concomitantly.

Overdosage: This medicine should not take more than the prescribed dose. In case of overdose, please go to the emergency department of the closest hospital or nursing home.

Storage: Keep out of reach of children. Store in a dry place, below 25°C temperature and protected from light.

Packaging:
Danflex® 25 mg capsule: Each carton contains 10x3 capsules in blister pack.
Danflex® 50 mg capsule: Each carton contains 10x2 capsules in blister pack.