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Dantrium Capsules (dantrolene sodium) - Drug Summary

JHP Pharmaceuticals LLC

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Dantrium (dantrolene sodium)

BOXED WARNING

Has potential for hepatotoxicity. Symptomatic/overt hepatitis and liver dysfunction reported. Risk of hepatic injury greater in females, patients >35 yrs of age, and patients taking other medications. Monitor hepatic function. D/C if no benefit after 45 days. Lowest possible effective dose should be prescribed.

THERAPEUTIC CLASS

Direct-acting skeletal muscle relaxant

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Chronic Spasticity

To control manifestations of clinical spasticity resulting from upper motor neuron disorders

Usual: 25mg qd for 7 days, then 25mg tid for 7 days, then 50mg tid for 7 days, then 100mg tid
Max: 100mg qid

If no further benefit is observed at the next higher dose, decrease to previous lower dose

Malignant Hyperthermia

Used preoperatively to prevent or attenuate the development of signs of malignant hyperthermia in known, or strongly suspected, malignant hyperthermia susceptible patients who require anesthesia and/or surgery

Preoperatively:

4-8mg/kg/day in 3 or 4 divided doses for 1 or 2 days prior to surgery, w/ the last dose given approx 3-4 hrs before scheduled surgery w/ a minimum of water

Post Crisis Follow-Up:

4-8mg/kg/day in 4 divided doses for 1-3 days

PEDIATRIC DOSAGE & INDICATIONS

Chronic Spasticity

To control manifestations of clinical spasticity resulting from upper motor neuron disorders

≥5 Years:

Usual: 0.5mg/kg qd for 7 days, then 0.5mg/kg tid for 7 days, then 1mg/kg tid for 7 days, then 2mg/kg tid
Max: 100mg qid

If no further benefit is observed at the next higher dose, decrease to previous lower dose

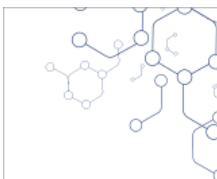
ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: 25mg, 50mg, 100mg

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CONTRAINDICATIONS

Active hepatic disease (eg, hepatitis and cirrhosis); where spasticity is utilized to sustain upright posture and balance in locomotion, or whenever spasticity is utilized to obtain or maintain increased function.

WARNINGS/PRECAUTIONS

Brief withdrawal for 2-4 days may exacerbate manifestations of spasticity. Obtain LFTs at baseline, then periodically thereafter. D/C if LFT abnormalities or jaundice appears. Caution with impaired pulmonary function (eg, obstructive pulmonary disease), severely impaired cardiac function due to myocardial disease, and history of liver disease/dysfunction.

ADVERSE REACTIONS

Hepatotoxicity, hepatitis, liver dysfunction, drowsiness, dizziness, weakness, general malaise, fatigue, diarrhea.

DRUG INTERACTIONS

See Boxed Warning. Not recommended with calcium channel blockers during the management of malignant hyperthermia; cardiovascular collapse with concomitant verapamil reported (rare). Caution with estrogens; hepatotoxicity reported especially in women >35 yrs of age. May potentiate vecuronium-induced neuromuscular block. Increased drowsiness with CNS depressants (eg, sedatives, tranquilizers).

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Direct-acting skeletal muscle relaxant; interferes with release of Ca^{2+} ions from the sarcoplasmic reticulum.

PHARMACOKINETICS

Absorption: Incomplete, slow. **Distribution:** Crosses placenta. **Metabolism:** Hepatic microsomal enzymes; 5-hydroxy and acetamido analog (major metabolites). **Elimination:** Urine; $T_{1/2}$ =8.7 hrs.

ASSESSMENT

Assess for active hepatic disease, if spasticity is used for upright posture and balance or increased function, history of liver disease/dysfunction, pulmonary dysfunction, impaired cardiac function due to myocardial disease, pregnancy/nursing status, and possible drug interactions. Perform baseline LFTs. Assess use in patients >35 yrs of age.

MONITORING

Monitor for liver disorders, jaundice, hepatotoxicity, and hepatitis. Monitor LFTs regularly.

PATIENT COUNSELING

Inform about risks and benefits of therapy. Caution against performing hazardous tasks (eg, operating machinery/driving). Caution about sunlight exposure; photosensitivity reactions may occur. Instruct to inform about other medications being taken. Notify if pregnant/nursing.

STORAGE

20-25°C (68-77°F).

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