Package Leaflet: Information for the user

Dantrium® 25 mg Capsules
Dantrium® 100 mg Capsules
(dantrolene sodium)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.
This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. (See section 4).

What is in this leaflet

1.What Dantrium Capsules are and what they are used for

Dantrium is a medicine that reduces increased muscle tension.

Dantrium is used for spastic movement disorders with abnormally increased muscle tension due to various causes in adults and children over the age of 5 years old weighing 25 kg or more.

2. What you need to know before you take DANTRIUM Capsules

Do not take Dantrium

- if you are allergic to dantrolene sodium 3.5 H_2O, or any of the other ingredients of this medicine (listed in section 6),
- if you have liver disease,
- in cases where abnormally increased muscle tension is required to improve function, posture or movement balance,
- if you have impaired lung function,
- if you have severe heart muscle damage,

- if you are pregnant or breast-feeding,
- If you are allergic (hypersensitive) to wheat, due to the presence of wheat starch.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dantrium.

Take special care with Dantrium:

- if you suffer from amyotrophic lateral sclerosis (ALS, a disorder of the nervous system), if you have symptoms of bulbar paralysis (symptoms caused by damage to certain cranial nerves), as Dantrium can exacerbate symptoms of paralysis,
- if you have heart disease, particularly heart damage and/or heart arrhythmia. Your doctor will carefully monitor you for heart disease.

Before and during treatment with Dantrium your doctor will carry out regular blood tests to check your liver function. If the values are outside the normal range, treatment with Dantrium must be discontinued.

If you notice any signs that might indicate liver damage, such as unusual fatigue, light stools, itching all over the body, yellowing of the skin or eyes, loss of appetite, nausea and vomiting, you should seek medical attention immediately.

The risk of liver damage appears to be particularly high at daily doses of more than 300 mg, with prolonged treatment, in female patients over 30 years of age, with a history of liver damage and concomitant use of other medicines that can cause liver damage. Liver damage can be life-threatening, especially in the elderly.

If you suffer from multiple sclerosis, the risk of serious liver damage appears to be even higher.

Dantrium may cause the skin to become sensitive to light (photosensitisation), so you should protect yourself from strong sunlight during treatment.

Administration of Dantrium must be discontinued if patients have developed cardiac and pleural reactions with fluid accumulation (pleural or pericardial effusion or pleuropericarditis).

Doses of more than 200 mg dantrolene per day are more likely to cause side effects.

This medicine contains only very low levels of gluten (from wheat starch). It is regarded as ‘gluten-free’ and is very unlikely to cause problems if you have coeliac disease.

One Dantrium 25mg capsule contains no more than 3.8 micrograms of gluten.

One Dantrium 100mg capsule contains no more than 3.3 micrograms of gluten.

Children

Dantrium can be used in children over 5 years of age under supervision from your doctor.

Dantrium should not be given to children under 5 years of age as there is insufficient experience with the use of Dantrium in this patient group to determine tolerability.

Other medicines and Dantrium

Tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, even if they are not prescription medications.

If taken at the same time as

- oestrogens (certain hormones) or other potentially liver-damaging substances there is an increased risk of liver damage,
- vecuronium (muscle relaxant drug) its effect can be amplified,
- metoclopramide (a medicine used to treat certain gastrointestinal disorders), the absorption of the active ingredient of Dantrium in the body may be increased, leading to an increase in the effect and side effects of dantrolene.

Simultaneous use of medicines that depress the central nervous system (sedatives, such as benzodiazepines, antihistamines) and alcohol is to be avoided as the side effects of Dantrium may be increased (in particular the central nervous system depressant effect and muscle weakness).

In patients predisposed to malignant hyperthermia (certain complications of anaesthesia) who received intravenous dantrolene, it has been observed that simultaneous administration of calcium antagonists and/or beta-blockers (antihypertensive/heart disease drugs) resulted in elevated potassium levels and cardiac insufficiency.

Dantrium with food and drink

Do not drink alcohol while taking Dantrium.

Pregnancy and breast-feeding

Dantrium should not be used during pregnancy, as the safety of Dantrium for use during pregnancy has not been established.

The active substance of Dantrium passes into breast milk. Dantrium should not be used while breast-feeding, since adverse effects on the breastfed child cannot be excluded, particularly under long-term treatment with Dantrium. Breast-feeding must be discontinued if treatment is required while breast-feeding.

Ask your doctor or pharmacist for advice before taking/using any medicine.

Driving and using machines

You must not drive or operate machinery without consulting your doctor.

When Dantrium or other medicines that also affect the central nervous system are taken at the same time, central nervous system effects, such as drowsiness or confusion, can change the ability to react to such an extent that it reduces the ability to drive or operate tools and machines. This particularly applies at the start of treatment, when dosage is increased and when taken together with alcohol.

Important information about some of the ingredients of Dantrium

This medicine contains lactose and wheat starch. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dantrium Capsules

Always take Dantrium exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will slowly adjust the number of capsules you take until the optimal dose required for your treatment is reached. The lowest dose compatible with optimal response is recommended.

Adults

Unless prescribed otherwise by your doctor, the usual dose for adults at the beginning of treatment is 1 capsule daily. This dose should be increased weekly until the optimal dose is reached.

The dose should not be increased faster than as per the following schedule:

Week 1: 1 capsule of Dantrium 25 mg daily

Week 2: 1 capsule of Dantrium 25 mg 2 x daily

Week 3: 2 capsules of Dantrium 25mg 2 x daily

Week 4: 2 capsules of Dantrium 25 mg 3 x daily

Once the optimal dose is reached, the patient should take their total daily dose subdivided between 2 to 4 individual doses.

Doses of more than 200 mg should not be given in long-term Dantrium treatment, as doses of more than 200 mg of dantrolene per day are more likely to result in side effects.

If it is foreseeable that the patient will face stress or stressful situations, the dose can be increased temporarily and gradually up to 400 mg per day. The increased dose should be titrated as follows:

Week 5: 75 mg three times daily

Week 6: 75 mg four times daily

Week 7: 100 mg four times daily

Doses of more than 200 mg per day should not be given for more than 2 months.

Children

Unless prescribed otherwise by your doctor, the following dosage should be used for children aged 5 years and older (from 25 kg body weight):

Week 1: 1 Dantrium 25 capsule once daily
Week 2: 1 Dantrium 25 capsules twice daily
Week 3: 1 Dantrium 25 capsule three times daily
Week 4: 2 Dantrium 25 capsules twice daily
Week 5: 2 Dantrium 25 capsules three times daily
Week 6: 3 Dantrium 25 capsules three times daily

Children weighing 50 kg or more:

See dosage for adults.

The dose can be gradually increased up to 200 mg daily.

Please take the capsules whole with plenty of liquid (preferably with a glass of water).

If no improvement is achieved after a total of 6-8 weeks, treatment should be discontinued by the doctor.

Please talk to your doctor or pharmacist if you feel that the effect of Dantrium is too strong or too weak.

If you take more Dantrium than you should
Tell your doctor immediately. He or she will take the necessary measures. Signs of overdose may include disorders of consciousness (e.g. lethargy, coma), muscle weakness, fatigue, dizziness, weakness, impaired vision, rapid heartbeat, itching, loss of appetite, nausea, vomiting, diarrhoea, light stools, yellowing of the skin or eyes.

If you forget to take Dantrium
Do not take a double dose to make up for an omitted dose. Take the same number of capsules as prescribed, when your next dose is due. If you are unsure what to do, please talk to your doctor.

If you stop taking Dantrium
If you temporarily want to stop treatment or stop it early, e.g. because the side effects appear too severe, please talk to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequencies for the following list of adverse drug reactions are based on estimates after reports of adverse drug reactions to the approved drug.

Very common (may affect more than 1 in 10 people): Fatigue, weakness, malaise, dizziness, drowsiness and diarrhoea. In persistent diarrhoea, the medicinal product must be discontinued.

Common (may affect up to 1 in 10 people): In patients treated with Dantrium, the following occurred: Headache, speech disorders, seizures, loss of appetite, impaired vision, abdominal cramps, nausea, vomiting, skin rashes, acne-like skin reactions, muscle weakness, which may cause functional impairment and coordination disorders, chills, fever, depression, confusion, nervousness, insomnia, respiratory failure, Abnormal liver function test, liver damage: Even daily doses of up to 200 mg can cause liver-damaging side effects, usually as inflammation of the liver with jaundice.

Uncommon (may affect up to 1 in 100 people): In patients treated with Dantrium, the following occurred: Reduction of red blood cells due to impaired or lack of production (aplastic anaemia), reduction of white blood cells (leukopaenia), lymph node cancer (lymphocytic lymphoma), thrombocytopaenia, allergic reaction, acute allergic reaction (anaphylaxis) hallucinations, triggering of cerebral seizures, particularly in children with cerebral palsy; aggravation of paralysis in amyotrophic lateral sclerosis (ALS, a disorder of the nervous system) or presence of symptoms of bulbar paralysis (symptoms caused by damage to certain cranial nerves). Double vision, increased tear-flow, increased heart rate, insufficient cardiac output (heart failure); phlebitis, fluctuations in blood pressure, constipation, in rare cases including intestinal obstruction; difficulty swallowing, taste disorders, shortness of breath, bleeding in the gastrointestinal tract, abdominal pain, increased salivation.

Increased sweating, abnormal hair growth, itching, photosensitivity, muscle and back pain, excretion of crystals or red blood cells in the urine (crystalluria, haematuria), involuntary urinary incontinence, urinary retention or increased urinary frequency, Cardiac and pleural reactions with fluid accumulation (pleural or pericardial effusion or pleuropericarditis), accompanied by eosinophilia (proliferation of certain cells in the blood) has been reported, as well as respiratory disorders, presumably due to weakening of the respiratory muscles.

Very Rare

Feeling of suffocation, skin rash with red swollen bumps, eczema, Micturition disorder, Erectile dysfunction.

Not known (frequency cannot be estimated from the available data):
Decreased heart rate, disorientation. Reduced muscle tone, dry mouth, nocturnal urination (nocturia), discoloured urine, indigestion.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dantrium Capsules

Store capsules in the blister and outer packaging away from light and moisture.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and the blister after 'EXP'.
The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dantrium Capsules contains

- The **active** substance is dantrolene sodium, 25 mg or 100 mg per capsule.

- The **other** ingredients are: lactose monohydrate, wheat starch, talc and magnesium stearate (see section 2).

- The capsule shell of Dantrium 25mg and 100mg capsules contains gelatin and colouring agents titanium dioxide (E171), erythrosine (E127) and iron oxide.

What Dantrium Capsules look like and contents of the pack

Dantrium 25 mg Capsules: The capsules are light brown/orange. They are packed in blisters and available in packs of 100 hard capsules.

Dantrium 100 mg Capsules: The capsules are orange/orange. They are packed in blisters and available in packs of 100 hard capsules.

Marketing Authorisation Holder:

Norgine BV

Antonio Vivaldistraat 150,

1083 HP Amsterdam

The Netherlands

Manufacturer:

Delpharm L'Aigle

Zone Industrielle Nº1

Route De Crulai

61300 L'Aigle

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Other sources of information

If you need the information on this leaflet in an alternative format, such as large print, please ring 00 44 1895 826 606.