Package Leaflet: Information for the User

DANTRIUM® 25 mg Capsules

(dantrolene sodium)

Your medicine is known by the above name, but will be referred to as Dantrium® Capsules throughout this leaflet.

This medicine is also available in another strength.

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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® Capsules is a medicine that reduces increased muscle tension.

Dantrium® Capsules 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® Capsules

– if you are allergic to dantrolene sodium 3.5 H2O, 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® Capsules.

Take special care with Dantrium® Capsules

– 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® Capsules 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® Capsules your doctor will carry out regular blood tests to check your liver function. If the values are outside the normal range, treatment with Dantrium® Capsules 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® Capsules may cause the skin to become sensitive to light (photosensitisation), so you should protect yourself from strong sunlight during treatment.

Administration of Dantrium® Capsules 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® Capsules 25 mg capsule contains no more than 3.8 micrograms of gluten.

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

Children

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

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

Other medicines and Dantrium® Capsules

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® Capsules 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® Capsules 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® Capsules with food and drink

Do not drink alcohol while taking Dantrium® Capsules.

Pregnancy and breast-feeding

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

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

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® Capsules 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.

Dantrium® Capsules contain lactose and wheat starch.

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

3. HOW TO TAKE DANTRIUM® CAPSULES

Always take Dantrium® Capsules 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 Dantrium® Capsules 25 mg capsule once a day

Week 2: 1 Dantrium® Capsules 25 mg capsule two times a day

Week 3: 2 Dantrium® Capsules 25 mg capsules two times a day

Week 4: 2 Dantrium® Capsules 25 mg capsules three times a day

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® Capsules 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 a day

Week 6: 75 mg four times a day

Week 7: 100 mg four times a day

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® Capsules 25 mg capsule once a day

Week 2: 1 Dantrium® Capsules 25 mg capsule two times a day

Week 3: 1 Dantrium® Capsules 25 mg capsule three times a day

Week 4: 2 Dantrium® Capsules 25 mg capsules two times a day

Week 5: 2 Dantrium® Capsules 25 mg capsules three times a day

Week 6: 3 Dantrium® Capsules 25 mg capsules three times a day

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® Capsules is too strong or too weak.

If you take more Dantrium® Capsules 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® Capsules

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® Capsules

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® Capsules, 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® Capsules, 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DANTRIUM® CAPSULES

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Store in the original package in order to protect from light and moisture.
- If the capsules become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dantrium® Capsules contain

Each capsule contains 25 mg dantrolene sodium.

Also contains: lactose monohydrate, wheat starch, talc and magnesium stearate.

The capsule shell contains gelatin, erythrosine (E127), iron oxide and titanium dioxide (E171).

What Dantrium® Capsules look like and contents of the pack:

Dantrium® Capsules are a hard gelatine capsule with an opaque beige/peach body and an opaque orange cap containing a deep orange powder. The capsules have no markings.

Dantrium® Capsules comes in blister packs of 50 and 100 capsules.

Manufactured by Delpharm L'Aigle, Zone Industrielle N° 1, Route de Crulai, 61300 L'Aigle, France.

Procured from within the EU and repackaged by the Product Licence Holder Beachcourse Ltd., Unit 2-3, Townsend Industrial Estate, Waxlow Road, London, NW10 7NU.

Revision date: 17.03.2025

PL 16378/0772 **POM**

DANTRIUM® is a registered trademark of the Norgine group of companies.

Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Beachcourse,
Tel: 020 8896 9054 for help.
Ref. number 0772/V1