

PACKAGE LEAFLET: INFORMATION FOR THE USER

DANTRIUM® 25mg CAPSULES (dantrolene sodium)

Your medicine is called Dantrium® 25mg Capsules but will be referred to as Dantrium Capsules throughout the remainder of the leaflet.

Information for other strength of Dantrium Capsules (Dantrium 100mg Capsules) also may be present in this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Dantrium Capsules are and what they are used for
2. Before you take Dantrium Capsules
3. How to take Dantrium Capsules
4. Possible side effects
5. How to store Dantrium Capsules
6. Further information

1. WHAT DANTRIUM CAPSULES ARE AND WHAT THEY ARE USED FOR

Dantrium Capsules contain the active substance dantrolene sodium – this is a muscle relaxant which is used to treat severe, long term muscle stiffness (spasticity) in adults.

2. BEFORE YOU TAKE DANTRIUM CAPSULES

DO NOT take Dantrium Capsules if you:

- are allergic to any ingredients in the product (see section 6 and end of Section 2)
- have a known liver function impairment
- have acute skeletal muscle spasms (your muscles go rigid suddenly)
- need spasticity to stand up, walk or cope with daily activities.

DO NOT give Dantrium Capsules to children.

Take special care with Dantrium Capsules if you:

- have heart or lung function impairment
- have liver disorders or notice signs or symptoms of liver toxicity (e.g. discoloured faeces, intense itching, jaundice, anorexia, nausea, vomiting during therapy) – contact your doctor immediately
- are elderly.

Liver function tests should be performed frequently before start and during Dantrium Capsules therapy as the risk of liver toxicity appears to be greater in

- females
- patients over 30 years old
- patients taking other medication
- females using oral oestrogen contraception.

Taking other medicines:

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Talk to your doctor before taking Dantrium Capsules if you are already taking:

- **Oestrogen** (found in most oral contraceptive pills and hormone replacement therapy) or other drugs which might affect the liver.
- **Tranquillisers** (e.g. diazepam, lorazepam or temazepam).
- Medicines used to treat abnormal heartbeat, angina or high blood pressure (e.g. products containing **verapamil**)
- Products normally used to help doctors anaesthetise patients (e.g. products containing **vecuronium**).

Taking Dantrium Capsules with food and drink

Avoid taking alcohol with this medicine as it may make you feel dizzy or drowsy.

Pregnancy and breast-feeding

Do not take the capsules if pregnant or breastfeeding unless advised otherwise by your doctor.

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

Driving and using machines

Dantrium Capsules may cause drowsiness or dizziness. These symptoms may be intensified if you have consumed alcohol.

Do not take the capsules without talking to your doctor if you drive or are involved in hazardous activities.

Important information about some of the ingredients of Dantrium Capsules

Lactose – if you know you have intolerance to some sugars, speak to your doctor before taking this medicine.

Sunset yellow colouring (E110) – may cause allergic reactions (Dantrium Capsules 25 mg only).

3. HOW TO TAKE DANTRIUM CAPSULES

Always take Dantrium Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will want to make sure that the capsules do not affect your liver. This will mean having **blood tests** before you start and while you are taking them.

Adults and Elderly:

Dantrium Capsules are to be taken by mouth. Swallow the capsule with a glass of water. The dose will vary from person to person:

- **The starting dose is usually one 25 mg capsule a day.**
- If there is no improvement, your doctor may increase your dose every week until the right dose for you is reached.
- The normal maximum dose is one 100 mg capsule four times a day. It is important to take the **lowest dose which works for you.**
- If there is no improvement after about 6-8 weeks, your medication will be stopped by your doctor.

Children should NOT be given Dantrium Capsules.

If you take more Dantrium Capsules than you should

Do not exceed the recommended dose. If you take too much medicine, tell your doctor immediately or go to your nearest Accident & Emergency Department (take the pack with you if possible).

If you forget to take Dantrium Capsules

If you miss a dose, do not take a double dose to make up for a forgotten capsule; continue taking your medicine as normal at the correct time.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dantrium Capsules can cause side effects, although not everybody gets them.

You may suffer an allergic reaction, symptoms of which include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. If this happens to you, stop taking the capsules immediately and seek urgent medical attention.

The following side effects have also been reported:

Most common side effects

- dizziness, drowsiness
- weakness, tiredness
- feeling generally unwell
- diarrhoea - if severe diarrhoea occurs, your doctor may stop the capsules for a short while. If you start taking them again and the diarrhoea returns, Dantrium Capsules is usually stopped permanently.

Less common side effects

- loss of appetite (anorexia)
- seizures
- speech or visual disturbance
- headache
- inflammation of the membrane around the heart, sometimes accompanied by fluid in the lungs
- feeling sick (nausea, vomiting)
- abdominal pain
- liver toxicity (characterised by inflammation of the liver), problems with liver function
- skin rash, acne
- fever, chills.

Rare side effects

- confusion, nervousness
- depression
- difficulty sleeping (insomnia)
- fast heartbeat
- worsening of heart problems
- unstable blood pressure
- difficulty in breathing
- difficulty in swallowing
- constipation (which may on rare occasions lead to a blockage in bowel movement)
- sweating
- increased urinary frequency
- tiny crystals or traces of blood in the urine, difficulty in controlling the bladder (incontinence), being unable to pass urine easily.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE DANTRIUM CAPSULES

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 30°C.
- Store in the original package to protect from light and moisture.
- If your doctor stops your treatment, take any leftover capsules back to the pharmacy for safe disposal.
- Do not take your capsules after the expiry date on the container. Take any capsules which are out of date back to the pharmacy.
- If the medicine becomes discoloured or shows 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 dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Dantrium Capsules contains

- Each capsule contains 25mg dantrolene sodium. Dantrium Capsules also contain the following: lactose monohydrate, wheat starch, talc, magnesium stearate, gelatin, erythrosine (E127), ferric oxide (E172), titanium dioxide (E171).

What Dantrium Capsules look like and contents of the pack

- Dantrium Capsules have orange cap with beige body with no markings on the cap and body
- Dantrium Capsules are available as blister packs of 50 and 100 capsules.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by Famar L'Aigle, Zone Industrielle No 1, Route de Crulai, 61300 L'Aigle, France.

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