



## 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, 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
2. What you need to know before you take Dantrium Capsules
3. How to take Dantrium Capsules
4. Possible side effects
5. How to store Dantrium Capsules
6. Contents of the pack and other 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. What you need to know 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).
- you have been told by your doctor that you are unable to take some sugars such as lactose.
- you have a known liver problem.
- you have acute skeletal muscle spasms (your muscles go rigid suddenly).
- you need spasticity to stand up, walk or cope with daily activities.

**DO NOT** give Dantrium Capsules to children.

#### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Dantrium Capsules.

**Take special care** with Dantrium Capsules if you:

- have heart or lung problems.
- 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.

### **Other medicines and Dantrium Capsules**

Please tell your doctor, pharmacist or nurse 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**).

### **Dantrium Capsules with food, drink and alcohol**

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

### **Pregnancy, breast-feeding and fertility**

Do not take the capsules if pregnant or breast-feeding unless advised otherwise by your doctor.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this 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.

### **Dantrium Capsules contain Lactose.**

If you have been told by your doctor that you have an intolerance to some sugars, speak to your doctor before taking this medicine.

**Dantrium 25 mg Capsules only, contain Sunset yellow colouring (E110) and may cause allergic reactions.**

## **3. How to take Dantrium Capsules**

Always take Dantrium Capsules exactly as your doctor or pharmacist or nurse has told you. You should check with your doctor or pharmacist or nurse 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.

### **Use in children**

**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 or nurse.

### **4. Possible side effects**

Like all medicines, this medicine 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.**

Immediately inform your health care provider if you have discoloured stool, generalised itch, yellowing of skin and eyes, loss of appetite, feeling sick, abnormal blood tests, as this may be signs of a serious liver disorder.

The following side effects have also been reported:

Common: may affect up to 1 in 10 people

- drowsiness
- dizziness
- weakness
- feeling tired
- general feeling of uneasiness
- seizures
- speech or visual disturbance
- headache
- 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, the use of Dantrium Capsules is usually stopped permanently.
- loss of appetite (anorexia)
- confusion, nervousness
- depression
- difficulty sleeping (insomnia)
- inflammation of the membrane around the heart, sometimes accompanied by fluid in the lungs.
- difficulty in breathing, bluish colouration in the skin, finger tips, or lips
- rapid shallow breathing
- chest pain
- feeling sick (nausea, vomiting)
- abdominal pain
- dry mouth
- abdominal fullness, heartburn
- fever, chills.



Uncommon: may affect up to 1 in 100 people

- worsening of heart problems
- difficulty in swallowing
- constipation (which may on rare occasions lead to a blockage in bowel movement).
- excessive 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.

Unknown: frequency cannot be estimated from the available data

- yellowing of the skin (jaundice)
- hepatitis (symptoms include: abdominal pain, joint pain, weakness and fatigue)
- blood in the stool or black stool
- slow heartbeat
- fast heartbeat

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

#### **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 Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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.

Store Dantrium Capsules below 30°C.

Do not take Dantrium Capsules after the expiry date which is stated on the label after “Exp”. The expiry date refers to the last day of that month.

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. Contents of the pack and other information**

##### **What Dantrium Capsules contain**

- The **active** substance is dantrolene sodium, 25 mg or 100 mg per capsule.
- The **other** ingredients are: lactose, maize starch, talc and magnesium stearate.
- The capsule shell of Dantrium 25mg capsules contains gelatin and colouring agents E171 and E110 (see end of section 2).
- The capsule shell of Dantrium 100mg capsules contains gelatin and colouring agents, E171, E172 and E132.

##### **What Dantrium Capsules look like and contents of the pack:**

- Dantrium 25 mg Capsules: The capsules are white/orange. The capsules are supplied in plastic containers of 100 capsules.
- Dantrium 100 mg Capsules: The capsules are white/green. The capsules are supplied in plastic containers of 100 capsules.



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If you need further information or this leaflet in an alternative format please ring 0800 198 5000.

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