



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.
- If you are allergic (hypersensitive) to wheat, due to the presence of wheat starch.

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 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.

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.

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

Do not take Dantrium Capsules 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.

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 monohydrate, wheat starch, talcum and magnesium stearate (see section 2).
- The capsule shell of Dantrium 25mg and 100mg capsules contains gelatine and colouring agents titanium (E171), erythrosine (127) 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:

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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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