

DANTRIUM(R) Capsules

Dantrolene sodium

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully.

This leaflet answers some common questions about DANTRIUM capsules. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of treating you with DANTRIUM against the expected benefits it will have for you.

If you have any concerns about being treated with this medicine, ask your doctor.

What DANTRIUM is used for

DANTRIUM capsules are used to relax muscles which are in spasm as a result of spinal cord injury, stroke, cerebral palsy or multiple sclerosis.

It is of particular help to those patients whose rehabilitation is being slowed down by muscle spasm.

Your doctor may have prescribed DANTRIUM capsules for another reason. Ask your doctor if you have any questions about why DANTRIUM has been prescribed for you.

Before you take DANTRIUM

When you must not take it

Do not take DANTRIUM capsules if:

- * you have liver disease such as hepatitis and cirrhosis
- * muscle spasm allows you to keep an upright position, balance during movement or better physical function
- * you are allergic to it or any of the ingredients listed at the end of this leaflet
- * the bottle or packaging shows signs of tampering
- * the expiry date on the pack has passed

If this medicine is taken after the expiry date has passed, it may not work.

Before you start to take it

Tell your doctor if:

1. you have liver problems
It is essential to have your liver checked by your doctor before taking DANTRIUM, to determine if you have any existing problems with your liver.
2. you have problems with your breathing
3. you have heart problems
4. you have kidney problems

5. you are pregnant or intend to become pregnant
Your doctor will discuss the possible risks and benefits of using DANTRIUM during pregnancy.
6. you are breastfeeding or intend to breastfeed
DANTRIUM should not be used while breastfeeding.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and DANTRIUM may interfere with each other. These include:

- * medicines containing oestrogen, which include oral contraceptives and medicines used to treat symptoms of menopause.
- * calcium channel blockers such as verapamil, used to treat high blood pressure.
- * other muscle relaxant medicines which work differently to DANTRIUM
- * CNS depressants (medicines to reduce anxiety or help you sleep)

How to take DANTRIUM

How much to take

Your doctor will decide how much DANTRIUM you should take each day and how long your treatment with DANTRIUM should continue.

Take the capsules exactly as instructed by your doctor or pharmacist.

When to take it

Your doctor will tell you how many times a day you should take DANTRIUM.

Always read the pharmacist's label to check the exact dose and how often to take it.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you have missed.

If you are not sure whether to skip the dose, ask your doctor or pharmacist for advice.

If you take too much (overdose)

Immediately telephone your doctor, or the Australian Poisons Information Centre (telephone 131 126), or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much DANTRIUM. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using DANTRIUM

Things you must do

Keep all your doctor's appointments so your progress and health can be monitored.

DANTRIUM can cause damage to your liver, so your liver function needs to be checked regularly by your doctor to detect any abnormalities.

If you become pregnant while being treated with DANTRIUM, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being treated with DANTRIUM.

Tell all doctors, dentists and pharmacists who are treating you that you are taking DANTRIUM.

Things you must not do

Do not drive or operate machinery while you are taking DANTRIUM.

DANTRIUM causes drowsiness, dizziness and weakness in some people and therefore may affect alertness.

Avoid drinking alcohol or taking medicines to reduce anxiety or help you sleep.

These may increase the drowsiness and dizziness effects of DANTRIUM and should be avoided.

Things to be careful of

Be careful of exposure to sunlight while being treated with DANTRIUM.

DANTRIUM may increase sensitivity of the skin to sun. Symptoms of sunburn (such as redness, itching, swelling or blistering) may occur more quickly than normal.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being treated with DANTRIUM.

All medicines can have side effects. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * drowsiness
- * dizziness
- * weakness
- * fatigue
- * diarrhoea
- * general feeling of being unwell
- * shortness of breath and chest pain
- * constipation
- * loss of appetite
- * difficulty swallowing
- * stomach cramps/pain
- * vomiting
- * speech problems
- * headache
- * nausea
- * light-headedness
- * visual problems, including double vision
- * alteration of taste
- * trouble sleeping
- * depression
- * mental confusion
- * frequent urination
- * increased urination at night
- * difficulties in obtaining an erection
- * abnormal hair growth
- * rashes
- * sweating
- * backache
- * muscle pain
- * feeling of suffocation, excessive tearing, chills and fever

Tell your doctor immediately if you notice any of the following:

- * swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing
- * swelling of the liver which can result in yellowing of the skin and eyes, lower back pain, dark urine, nausea, vomiting, loss of appetite, fever, itching and a general feeling of being unwell
- * gastrointestinal bleeding
- * fits or convulsions
- * fast heart rate
- * shortness of breath and swelling of the feet or legs
- * crystals or blood in the urine
- * loss of control of the bladder
- * difficulty passing or inability to pass urine

These may be serious side effects of DANTRIUM. You may need urgent medical attention.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using DANTRIUM

Storage

Keep your capsules in a cool dry place where the temperature stays below 30 degrees C.

Do not store DANTRIUM or any other medicine in a bathroom or near a sink.

Do not leave it in the car or on window sills on hot days.

Heat and dampness can destroy some medicines.

Keep your DANTRIUM capsules where children cannot reach them.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking DANTRIUM, or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules that are left over.

Product description

What it looks like

DANTRIUM capsules are available in 25 mg and 50 mg strengths.

DANTRIUM 25 mg capsules are orange and tan and marked in black with "DANTRIUM 25 mg", "0149", "0030" and a single line. The 25 mg capsules are available in bottles of 100 capsules.

DANTRIUM 50 mg capsules are orange and tan and marked in black with "DANTRIUM 50 mg", "0149", "0031" and a double line. The 50 mg capsules are available in bottles of 100 capsules.

Ingredients

The active ingredient in DANTRIUM capsules is dantrolene sodium. DANTRIUM capsules also contain maize starch, purified talc, magnesium stearate, lactose, gelatin, iron oxide red CI77491, iron oxide yellow CI77492, sunset yellow FCF CI15985, titanium dioxide, black printing ink (TekPrint SW-9008 or TekPrint SW-9010).

Identification

DANTRIUM capsules can be identified by the Australian Register Number on the bottle:

25 mg: AUST R 42975

50 mg: AUST R 42976

Supplier

DANTRIUM capsules are supplied in Australia by:

Pfizer Australia Pty Ltd
ABN 50 008 422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll free number: 1800 675 229

DANTRIUM capsules are supplied in New Zealand by:

Pfizer New Zealand Ltd
PO Box 3998
Auckland, New Zealand

Toll Free Number: 0800 736 363

This leaflet was revised on 13 March 2007.

(R) Registered trademark

(C) Copyright Pfizer Australia Pty Ltd