

DANTRIUM® Capsules

Dantrolene sodium

Consumer Medicine Information

What is in this leaflet

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 taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

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.

Ask your doctor if you have any questions about why DANTRIUM has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take DANTRIUM

When you must not take it

Do not take DANTRIUM capsules if you have an allergy to:

- any medicine containing dantrolene sodium
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take DANTRIUM Capsules if you have or have had any of the following medical conditions:

- liver disease such as hepatitis and cirrhosis
- muscle spasm to allow you to keep an upright position, to balance during movement or for better physical function.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- 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.

- you have problems with your breathing
- you have heart problems
- you have kidney problems
- you are pregnant or intend to become pregnant
Your doctor will discuss the possible risks and benefits of using DANTRIUM during pregnancy.
- you are breastfeeding or intend to breastfeed
DANTRIUM should not be used while breastfeeding.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by DANTRIUM or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- 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).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take DANTRIUM

Follow all directions given to you by your doctor or pharmacist carefully.

These may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

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 taking 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 take DANTRIUM to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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 or pharmacist as soon as possible if you do not feel well while you are taking DANTRIUM.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking DANTRIUM, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of side effects.

You may not experience any of them.

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

Tell your doctor if...

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
- indigestion
- dry mouth
- 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
- abnormal colouration of the urine
- difficulties in obtaining an erection
- abnormal hair growth
- rashes
- bleeding or bruising more easily
- sweating
- backache
- muscle pain
- feeling of suffocation, excessive tearing, chills and fever.

Tell your doctor as soon as possible if...

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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

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

After using DANTRIUM

Storage

Keep your capsules in a cool dry place where the temperature stays below 30°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).

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 Limited
PO Box 3998
Auckland, New Zealand

Toll Free Number: 0800 736 363

Australian registration numbers

25 mg capsule: AUST R 42975

50 mg capsule: AUST R 42976

Date of preparation

This leaflet was prepared in August 2016.

® = Registered trademark

© Pfizer Australia Pty Ltd