

Dantrium[®] Capsules

Dantrolene sodium hemiheptahydrate

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Dantrium Capsules?

Dantrium contains an active ingredient dantrolene sodium hemiheptahydrate. It is 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 patients whose rehabilitation is being slowed down by muscle spasm. For more information, see Section [1. Why am I taking Dantrium Capsules?](#) in the full CMI.

2. What should I know before I take Dantrium Capsules?

Do not take Dantrium capsules if you have ever had an allergic reaction to any medicine containing dantrolene sodium hemiheptahydrate or any of the ingredients listed at the end of this leaflet; are lactose intolerant; have liver disease such as hepatitis and cirrhosis; or your muscle

spasms allow you to keep an upright position, to balance during movement or for better physical function. Talk to your doctor if you have liver, heart or kidney problems; breathing difficulty; are pregnant, or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Dantrium Capsules?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dantrium and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Dantrium Capsules?

Your doctor will decide how much Dantrium you should take each day and how long your treatment with Dantrium should continue. More instructions can be found in Section [4. How do I take Dantrium Capsules?](#) in the full CMI.

5. What should I know while taking Dantrium Capsules?

Things you should do	<ul style="list-style-type: none">• Keep all your doctor's appointments so that your progress and health can be monitored.
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	<ul style="list-style-type: none"> ● If you become pregnant while being treated with Dantrium, tell your doctor immediately. ● Tell all doctors, dentists and pharmacists who are treating you that you are taking Dantrium. ● More information on "Things you should do" can be found in Section 5 in the full CMI.
<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not take Dantrium to treat any other medical complaints unless your doctor tells you to. ● Do not give your medicine to anyone else, even if they have the same condition as you.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Do not drive or operate machinery while you are taking Dantrium. It can cause drowsiness, dizziness and weakness in some people and therefore may affect alertness.

Drinking alcohol	<ul style="list-style-type: none"> • Avoid drinking alcohol which may intensify drowsiness, dizziness and weakness.
Looking after your medicine	<ul style="list-style-type: none"> • Store in original carton at below 30°C until ready for use.

For more information, see Section [5. What should I know while taking Dantrium Capsules?](#) in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include drowsiness; dizziness; weakness; fatigue; diarrhoea; constipation; loss of appetite; difficulty swallowing; stomach cramps/pain; indigestion; dry mouth; excessive saliva; vomiting; nausea; alteration of taste; swelling of the face, lips, tongue or other parts of the body; shortness of breath; wheezing; trouble breathing; chest pain; fits; speech problems; headache; light-headedness; visual problems; trouble sleeping; depression; confusion; rashes; bleeding or bruising more easily; sweating; backache; muscle pain; excessive tearing; chill; fever; frequent urination; abnormal colouration of the urine; incontinence; difficulty passing urine; erection problem; abnormal hair growth.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Dantrium® Capsules

Dantrolene sodium hemiheptahydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dantrium. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Dantrium capsules.**

Where to find information in this leaflet:

- [1. Why am I taking Dantrium Capsules?](#)
- [2. What should I know before I take Dantrium Capsules?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Dantrium Capsules?](#)
- [5. What should I know while taking Dantrium Capsules?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Dantrium Capsules?

Dantrium capsules contain the active ingredient dantrolene sodium hemiheptahydrate. The medicine is 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 it for another reason.

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

2. What should I know before I take Dantrium Capsules?

Warnings

Do not take Dantrium if you are allergic to:

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

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 if you have or have had any of the following medical conditions:

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

Do not take Dantrium if:

- the packaging is torn or shows signs of tampering
- the expiry date printed on the pack has passed.

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

Tell your doctor if you have or have had any of the following medical conditions:

- 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 lungs and breathing
- you have heart problems
- you have kidney problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Talk to your doctor if you are breastfeeding or intend to breastfeed. Your doctor can discuss with you the risks and benefits involved.

Dantrium should not be used while breastfeeding.

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

This medicine is available only with a doctor's prescription.

3. What if I am 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.

4. How do I take Dantrium Capsules?

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

They may differ from the information contained in this leaflet.

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

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 Dantrium

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 Dantrium

Immediately telephone your doctor, or the Australian Poisons Information Centre (telephone 131 126), 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.

5. What should I know while taking Dantrium Capsules?

Things you should do

Keep all your doctor's appointments so that 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 should 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.

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.

Driving or using machines

Do not drive or operate machinery while you are taking Dantrium capsules.

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

Drinking alcohol

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.

Looking after your medicine

Keep Dantrium in its original packaging until it is time to use it. If you take Dantrium out of its packaging, it may not keep as well.

Keep your Dantrium in a cool, dry place where the temperature stays below 30°C.

Do not store Dantrium or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

If your doctor tells you to stop taking this medicine, or it has passed its expiry date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below. Ask your doctor or pharmacist if you have any questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none">• drowsiness, fatigue, weakness• dizziness, light-headedness• diarrhoea or constipation• generally feeling unwell• loss of appetite• difficulty swallowing, indigestion• dry mouth, excessive saliva, alteration of taste• nausea, vomiting• speech problems• headache• visual problems, including double vision	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Common side effects	What to do
<ul style="list-style-type: none"> ● trouble sleeping ● depression, confusion ● frequent urination, abnormal colouration of the urine ● difficulties in obtaining an erection ● abnormal hair growth ● rashes ● sweating ● backache, muscle pain ● excessive tears ● chill ● fever. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● swelling of the face, lips, tongue or other parts of the body ● shortness of breath, trouble breathing, wheezing ● chest pain ● fast heart rate 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 feeling unwell ● stomach pain/ cramps or bleeding from the rectum ● fits or convulsions ● bleeding or bruising more easily ● 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 are serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Some of these side effects (for example certain liver conditions, and blood abnormalities) can only be found when your doctor does tests from time to time to check your progress.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

What Dantrium Capsules contain

Active ingredient (main ingredient)	<ul style="list-style-type: none">• dantrolene sodium hemiheptahydrate
Other ingredients	<ul style="list-style-type: none">• gelatin• iron oxide red

(inactive ingredients)

- iron oxide yellow
- lactose monohydrate
- magnesium stearate
- maize starch
- purified talc
- sodium lauryl sulfate
- sunset yellow FCF
- TekPrint SW-9008 Black Ink
- TekPrint SW-9010 Black Ink
- titanium dioxide

Do not take this medicine if you are allergic to any of these ingredients.

What Dantrium Capsules looks like

Dantrium 25 mg capsule (AUST R 42975): hard gelatin capsule with a tan opaque body and orange opaque cap, imprinted with "Dantrium" "25 mg" on the cap and "0149" "0030" and single coding bars on the body in black ink. Fill: deep orange cylindrical plug.

Dantrium 50 mg (AUST R 42976): hard gelatin capsule with a tan opaque body and orange opaque cap, imprinted with the logo "Dantrium" "50mg" on the cap and "0149" "0031" and single coding bars on the body in black ink. Fill: deep orange cylindrical plug.

Who distributes Dantrium Capsules

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in November 2024.

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