Dantrium® Powder For Injection

Active ingredient(s): Dantrolene sodium

hemiheptahydrate

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about treatment with this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with Dantrium powder for injection?

Dantrium powder for Injection contains the active ingredient dantrolene sodium hemiheptahydrate. It is a muscle relaxant used to treat a condition known as malignant hyperthermia.

For more information, see Section <u>1. Why am I being</u> <u>treated with Dantrium powder for injection?</u> in the full CMI.

2. What should I know before treatment with Dantrium powder for injection?

Talk to your doctor if you have ever had an allergic reaction to dantrolene or mannitol which are ingredients contained in this medicine.

Talk to your doctor if you have any medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know before treatment with Dantrium powder for injection?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dantrium powder for injection 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 is Dantrium powder for injection given?

Dantrium powder for Injection is made into a solution, which is given by injection into a vein by your doctor.

More instructions can be found in Section <u>4. How is</u> <u>Dantrium powder for injection given?</u> in the full CMI.

5. What should I know during treatment with Dantrium powder for injection?

Things you should do	 Tell your doctor if
	you are taking any
	other medicines

	 including medicines for heart conditions, or tranquilisers. Take care when getting out of bed or walking downstairs. Be careful when eating or drinking on the day you have been treated with Dantrium.
Driving or using machines	 For 2 days after treatment, do not operate machinery or do anything else that could be dangerous when not fully alert.
Drinking alcohol	No information.
Looking after your medicine	 Dantrium powder for Injection is stored in the pharmacy or on the hospital ward under the correct conditions.

For more information, see Section <u>5. What should I know during treatment with Dantrium powder for injection?</u> in the full CMI.

6. Are there any side effects?

Side effects of this medicine may include swelling or tenderness around a vein; itchy skin rash or reddening of the skin; breathlessness; chest tightness or pain; gasping for air; wheezing; drowsiness; dizziness; weakness in the legs or loss of grip strength; difficulty in swallowing.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Dantrium® Powder For Injection

Active ingredient(s): Dantrolene sodium

hemiheptahydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about treatment with Dantrium powder for injection. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about treatment with Dantrium powder for injection.

Where to find information in this leaflet:

- 1. Why am I being treated Dantrium powder for injection?
- 2. What should I know before treatment with Dantrium powder for injection?
- 3. What if I am taking other medicines?
- 4. How is Dantrium powder for injection given?
- 5. What should I know during or after treatment with Dantrium powder for injection?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated Dantrium powder for injection?

Dantrium powder for injection contains the active ingredient dantrolene sodium hemiheptahydrate.

It is a muscle relaxant used to treat a condition known as malignant hyperthermia. This condition occurs rarely during or after surgery or anaesthesia. The tendency to develop malignant hyperthermia may be inherited.

Some of the symptoms of malignant hyperthermia are very high fever, fast and irregular heart-beat, difficulty breathing and rigid muscles.

Malignant hyperthemia may be fatal if not treated.

Your doctor may have prescribed Dantrium powder for injection for a purpose other than that listed above.

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

2. What should I know before treatment with Dantrium powder for injection?

Warnings

Tell your doctor if you have ever had an allergic reaction to dantrolene sodium hemiheptahydrate or mannitol.

Some of the symptoms of an allergic reaction may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

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

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Tell your doctor if you are taking any heart medicines or tranquillisers (medicines to reduce anxiety or help you sleep).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dantrium powder for injection.

4. How is Dantrium powder for injection given?

How much Dantrium powder for injection is given

The dose of Dantrium is calculated by your doctor according to your body weight.

How is Dantrium powder for injection given

Dantrium is given to you by your doctor as soon as malignant hyperthermia is recognised. It will be given by injection into a vein.

How long will I receive Dantrium powder for injection

Treatment must continue until all symptoms of malignant hyperthermia are gone.

Treatment may be repeated if symptoms return after initial recovery.

If you receive too much Dantrium powder for injection

As Dantrium powder for injection is given under the close supervision of your doctor, it is very unlikely that you will receive too much.

If you experience any side effects tell your doctor or nurse immediately.

Tell your doctor or nurse immediately if you are concerned that you may have been given too much Dantrium powder for injection.

5. What should I know during or after treatment with Dantrium powder for injection?

Things you should do

Driving or using machines

For 2 days after treatment, do not operate machinery or do anything else that could be dangerous when not fully alert.

Weakness, dizziness and drowsiness can continue for up to 48 hours after treatment.

Things to be careful of

Take care when getting out of bed or walking downstairs.

You may experience light-headedness, leg weakness or loss in grip strength after treatment with Dantrium.

Be careful when eating or drinking on the day you have been treated with Dantrium.

Some people have difficulty swallowing after treatment with Dantrium. Choking has been reported.

Drinking alcohol

Caution should be taken when drinking alcohol.

Looking after your medicine

Dantrium powder for injection is stored in the pharmacy or on the hospital ward under the correct conditions.

Disposal of the medicine

The hospital staff will dispose of any leftover Dantrium powder for injection.

6. Are there any side effects?

Tell your doctor as soon as possible if you have any concerns about being treated with Dantrium powder for injection.

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

Side effects	What to do
 swelling or tenderness around a vein itchy skin rash or reddening of the skin 	After treatment with Dantrium tell your doctor or nurse if you notice these side effects:

Side effects	What to do
 breathlessness, gasping for air, wheezing 	
• chest tightness or pain	
drowsinessdizziness	
 dizziness weakness in the legs or loss of grip strength difficulty in swallowing abnormal liver conditions. This may only be found when your doctor does tests from time to time to check your progress. 	

Tell your doctor, nurse 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.

7. Product details

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

What Dantrium powder for injection contains

Active ingredient (main ingredient)	dantrolene sodium hemiheptahydrate
Other ingredients	mannitol
(inactive ingredients)	sodium hydroxide

What Dantrium powder for injection looks like

Dantrium powder for injection is a powder which must be diluted with sterile water for injections before use.

Dantrium powder for injection: Aust R 14435.

Who distributes Dantrium powder for injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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