

DANTRIUM® POWDER FOR INJECTION

Dantrolene sodium hemiheptahydrate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully.

This leaflet answers some common questions about Dantrium. It does not contain all the available information and 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 this medicine, ask your doctor.

Consider keeping this leaflet even after your treatment with Dantrium is finished.

You may need to read it again.

What Dantrium powder for injection is used for

Dantrium powder for injection 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 hyperthermia 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.

Treatment with Dantrium

How Dantrium is given

Dantrium will be given to you by your doctor as soon as malignant hyperthermia is recognised. It will be given by injection into a vein. Treatment must continue until all symptoms of malignant hyperthermia are gone.

The starting dose of Dantrium is calculated by your doctor according to your body weight. The recommended starting dose is 1 milligram per kilogram of body weight (1 mg/kg).

More Dantrium will be given by your doctor until all symptoms of malignant hyperthermia are gone. The highest recommended dose is 10 mg/kg.

Treatment may be repeated if symptoms return after initial recovery.

Ask your doctor if you have any questions about your treatment.

If you are given too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency (Casualty) at the

nearest hospital, if you think that you or anyone else may have been given too much DANTRIUM powder for injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep the telephone numbers for these services handy. Have the DANTRIUM powder for injection pack or this leaflet available to give details if needed.

After being treated with Dantrium

Things you must do

You must tell your doctor if:

- you are pregnant
 - you are taking any medicines including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.
- In particular, tell your doctor if you are taking any heart medicines or tranquillisers (medicines to reduce anxiety or help you sleep).

Things you must not do

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 down stairs.

You may experience lightheadedness, 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.

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.

After treatment with Dantrium tell your doctor if you notice:

- swelling or tenderness around a vein
- itchy skin rash or reddening of the skin
- breathlessness
- drowsiness or dizziness
- weakness in the legs or loss of grip strength.
- confusion
- nausea
- loss of appetite
- diarrhoea
- jaundice
- swollen abdomen
- easy bleeding

Tell your doctor if you notice any other side effect after treatment with Dantrium, even if it is not on this list.

Storage and disposal

Storage

Dantrium will normally be stored in a hospital. It should be stored below 25 degrees C and should be protected from light (kept in the packaging before use).

Disposal

Used or damaged vials should be disposed of by incineration.

Product description

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.

Each vial can be used once only.

Identification

Dantrium powder for injection can be identified by an Australian Register Number (AUST R 14435) which is found on the carton.

Ingredients

Dantrium powder for injection contains 20 mg of dantrolene sodium hemiheptahydrate as the active ingredient. It also contains:

- mannitol
- sodium hydroxide.

Supplier

Dantrium powder for injection is supplied in Australia by:

Pfizer Australia Pty Ltd
Sydney NSW
Toll Free Number: 1800 675 229
www.pfizer.com.au

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