P A C K A G E L E A F L E T : I N F O R M A T I O N F O R T H E U S E R
Dantrium® IV 20 mg

Powder for Solution for Injection
Dantrolene sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Dantrium IV is and what it is used for
2. What you need to know before you are given Dantrium IV
3. How Dantrium IV is given
4. Possible side effects
5. How to store Dantrium IV
6. Contents of the pack and other information

1. What Dantrium IV is and what it is used for

Dantrium IV belongs to the pharmacotherapeutic group of direct-acting muscle relaxants. It is used for the treatment of malignant hyperthermia. The ATC code is M03CA01.

Dantrium IV is a medicine which will be administered to you by a doctor or nurse.

2. What you need to know before you are given Dantrium IV

Do not use Dantrium IV
If you are allergic (hypersensitive) to dantrolene sodium or any of the other ingredients of Dantrium IV (see section 6).

Warnings and precautions
Take special care with Dantrium IV. You will probably have been given Dantrium IV before you read this leaflet. The urgent need for treatment will have been more important than anything else at the time. Before you are given this injection, your doctor will try to find out if you have had a serious reaction to dantrolene sodium or any of the other ingredients of Dantrium IV in the past.

Other medicines and Dantrium IV
Tell your doctor if you are taking, or have recently taken, or might use any other medicine.
The following medicines affect the way Dantrium IV works:
- drugs for high blood pressure and angina called “calcium channel blockers”
- muscle relaxants, like vecuronium
- other intravenous infusion fluids

Pregnancy, breast-feeding and fertility
Tell your doctor if you are pregnant or breastfeeding. Dantrium IV should not be given unless considered essential.

Driving and using machines
For a period of up to 48 hours after you have been given Dantrium IV, your hand and leg muscles may be weak and you may also have a feeling of "light headedness". If you are affected in this way, do not drive or operate machinery during this time.

Dantrium IV contains sodium
This medicine contains less than 1mmol sodium (23mg) per vial that is to say essentially "sodium free".

3. How Dantrium IV is given

This injection is given to you by a doctor, into a vein. The dose of Dantrium IV is based on body weight; in most cases, a total dose of up to 10mg may be given for each kilogram of your body weight. However, a total dose of up to 40mg for each kilogram of your body weight may be required in rare cases.

If you are given more Dantrium IV than you should
Malignant hyperthermia is an emergency situation where rapid infusion of a high Dantrium IV dose is necessary. There are no known specific symptoms of dantrolene sodium overdose. Caution is required if there are any signs of hyperkalaemia.

If you stop using Dantrium IV
If it should appear necessary to discontinue Dantrium IV therapy, intensive care and supportive therapeutic measures which have been initiated should be continued on an individual basis.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects were observed:

1) The most serious side effects are:
   Not known (Frequency cannot be estimated from the available data):
   - anaphylaxis, allergic reactions,
   - high blood potassium levels (hyperkaliemia), which can cause tiredness, muscle weakness, feeling sick and heart rhythm disturbances,
   - convulsion,
   - heart failure,
   - fluid in the lung (possible difficulty breathing),
   - difficulty breathing (respiratory failure),
   - liver failure.

2) All other side effects are:
   Not known (Frequency cannot be estimated from the available data):
   - drowsiness, dizziness, general weakness, somnolence, speech disorder, headache,
   - slowed heartbeat (bradycardia), accelerated heartbeat (tachycardia),
   - thrombophlebitis,
   - fluid collection in the chest (pleural effusion),
   - breathing that is too slow and shallow (respiratory depression),
   - gastrointestinal complaints such as nausea, vomiting, diarrhoea, abdominal pain/cramps, gastrointestinal bleeding,

- yellow eyes and skin (jaundice), and/or changes in blood test of liver function (signs of liver problems),
- liver damage due to inflammation (hepatitis),
- skin redness/itchy rash,
- increased sweat secretion (hyperhidrosis),
- muscle weakness, muscle tiredness,
- accumulation of crystals in urine sediment (crystalluria),
- weak contraction when giving birth (uterine hypotonia),
- tiredness,
- reactions at the administration site.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dantrium IV

Keep out of the sight and reach of children. Do not store Dantrium IV above 25°C.
The solution for injection should be stored between 15 and 25°C, not be refrigerated or frozen, protected from direct light and used within 6 hours of being made up.

Do not use Dantrium IV after the expiry "EXP" date which is stated on the label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Dantrium IV contains:
- The active substance is dantrolene sodium 20 mg.
- The other ingredients are mannitol and sodium hydroxide.

What Dantrium IV looks like and contents of the pack

The product is a pale orange-yellow powder for solution for injection, supplied to hospitals in packs of 12 and 36 glass vials. Not all pack sizes may be marketed. Each vial is provided with a single use filtration device.

Marketing Authorisation Holder:
Norgine Pharmaceuticals Limited
ARC Uxbridge, Building 01,
Sanderson Road,
Uxbridge,
UB8 1DH, UK

Manufacturer
Norgine BV
Antonio Vivaldistraat 150
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If you need the information on this leaflet in an alternative format such as large print, please ring from the UK 0800 198 5000.

This leaflet was last revised in March 2025.

<The following information is intended for healthcare professionals only:>

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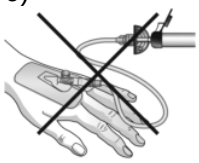
Information on reconstituting and filtering of Dantrium IV

1)	1) Add a sterile needle to a syringe and fill with 60 mL of Water for Injection.
2)	2) Take one vial of DANTRIUM IV and reconstitute with the water in the syringe. Gently swirl until the powder is dissolved. Discard the needle.
3)	3) Remove the safety cap and insert the spike of the single-use filtration device into the vial
4)	4) Connect syringe and withdraw all of the 60ml reconstituted solution from the vial into the syringe and then discard the filtration device

5) 	5) Attach the syringe containing the filtered reconstituted solution, directly to the patients intravenous cannula or giving set. The product may be administered immediately or as an infusion manually/via a pump depending on the clinical need. Refer to section 3 for maximum dose.
6) 	6) Do not use the filtration device in the transfer of the filtered solution from the syringe to the giving set or the cannula