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® IVs 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, pharmacist or nurse.
- This medicine has been prescribed for you only.
- If you get any side effects, talk to your doctor, pharmacist or nurse. 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

Dantrium IV is a muscle relaxant. When given by intravenous injection (into a vein), it is useful in controlling malignant hyperthermia. This is a rare reaction to anaesthesia in which the body temperature rises extremely quickly. This serious condition produces a variety of symptoms such as a fast heartbeat and breathing rate, stiff muscles, changes in the acidity of the body and rhythm of the heart as well as high blood pressure. The reaction requires emergency treatment including oxygen, cooling the body, controlling its acidity, stopping the anaesthetic and giving Dantrium IV.
This injection is given to you by a doctor immediately when malignant hyperthermia is recognised.

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

Take special care with Dantrium IV. You will probably have been given Dantrium IV before you see 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 Dantrium IV in the past.

Other medicines and Dantrium IV

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
The following medicines affect the way Dantrium IV works:
- drugs for high blood pressure and angina called “calcium channel blockers”
- muscular 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.

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; a total dose of up to 10 mg may be given for each kilogram of your body weight. Care should be taken that Dantrium IV is not mixed with other intravenous infusion fluids. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

You may suffer an allergic reaction, symptoms of which include rash, itching, difficulty in breathing or swelling of the face, lips, throat or tongue. Reactions at site of injection may occur.

Immediately inform your health care provider if you have discoloured stool, generalised itch, yellowing of skin and eyes, loss of appetite, feeling sick, or abnormal tests, as this may be signs of a serious liver disorder.

Unknown: frequency cannot be estimated from the available data.

- inflammation around or, sometimes formation of a blood clot in the vein where Dantrium IV was injected

- excess fluid in the lungs

- weakness of hand and leg muscles and light headedness in the first 48 hours following injection.

- dizziness, tiredness, alteration of speech, convulsions (fits)

- change in heart rate

- excess fluid in the lungs or around the lungs

- difficulty breathing

- abdominal pain, nausea, vomiting, bleeding in the gut

- excessive sweating

- crystals in the urine and discoloured urine

- pain, redness, rash or inflammation around the vein where Dantrium IV was injected

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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
Norgine House, Widerwater Place
Moorhall Road, Harefield
Uxbridge
UB9 6NS UK

Manufacturer
Norgine BV
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The Netherlands

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 September 2021

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

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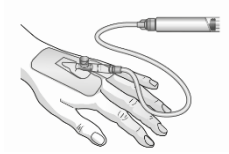
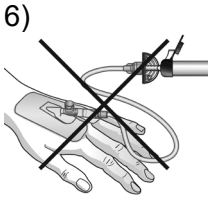
Information on reconstituting and filtering of Dantrium IV

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