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

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

Dantrium Intravenous 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 Intravenous 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 Intravenous

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

Warning and precautions
Take special care with Dantrium Intravenous. You will probably have been given Dantrium Intravenous 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 Intravenous in the past.

Other medicines and Dantrium Intravenous
Tell your doctor if you are taking, have recently taken or might use any other medicines.

The following medicines affect the way Dantrium Intravenous 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 Intravenous 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 Intravenous, 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 Intravenous contains sodium

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

3. How Dantrium Intravenous is given

This injection is given to you by a doctor into a vein. The dose of Dantrium Intravenous is based on body weight; in most cases a total dose of up to 10 mg may be given for each kilogram of your body weight is sufficient 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 Intravenous than you should

Malignant hyperthermia is an emergency situation where rapid infusion of a high Dantrium Intravenous dose is necessary. There are no known specific symptoms of dantrolene overdose. Caution is required if there are any signs of hyperkalaemia.

If you stop using Dantrium Intravenous

If it should appear necessary to discontinue Dantrium Intravenous 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:

Not known (Frequency cannot be estimated from the available data):
muscle weakness, tiredness, dizziness, headache, gastrointestinal complaints such as nausea, vomiting, diarrhoea, anaphylaxis, allergic reactions, mostly of the skin, as well as thrombophlebitis or reactions at the application site, somnolence, convulsion, speech disorder, bradycardia (slowed heartbeat), tachycardia (accelerated heartbeat), pleural effusion (fluid collection in the chest), respiratory failure, abdominal pain, gastrointestinal bleeding, jaundice, hepatitis, hyperhidrosis (increased sweat secretion), crystalluria (accumulation of crystals in urine sediment), heart failure.

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 HPRA Pharmacovigilance Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dantrium Intravenous

Before opening and after reconstitution, the product should not be stored above 25°C.

After reconstitution it should not be refrigerated or frozen and should be protected from direct light. The reconstituted solution should be prepared in controlled and validated aseptic conditions and be used within six hours.

Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of the month.

Do not use this medicine if you notice that the pack is damaged.

Keep this medicine out of the sight and reach of children.

Do not throw away any medicines 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 Intravenous contains 20 mg dantrolene sodium, as **active** substance.
- 3000 mg mannitol and a small amount of sodium hydroxide, as **other** ingredients.

What Dantrium Intravenous looks like and contents of the pack:
Dantrium Intravenous is a pale orange-yellow powder for solution for injection, supplied to hospitals in packs of 12 or 36 glass vials.

Each vial is provided with a single-use filtration device.

Marketing Authorisation Holder and Manufacturer:

Norgine B.V.

Antonio Vivaldistraat 150,

1083 HP Amsterdam

Netherlands

If you need further information on this leaflet in an alternative format, please ring Medical Information on +44 (0)1895 826 606.

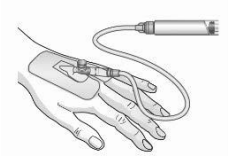
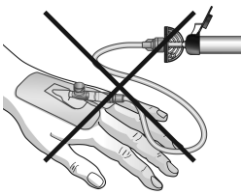
This leaflet was last revised in 02/2022.

The following information is intended for healthcare professionals only:

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