QUADRAMET

Samarium (153 Sm) Lexidronam Pentasodium Injection 6.0GBq/3ml Injection Vial

Consumer Medicine Information

What is this leaflet

This leaflet answers some common questions about Quadramet. It does not contain all the available information. It does not take the place of you talking to your nuclear medicine specialist.

All medicines have risks and benefits. Your physician has weighed the small risk of you being treated with Quadramet against the benefits it is expected that you will receive.

If you have any concerns about being given this injection, discuss them with your nuclear medicine specialist.

Keep this leaflet.

You may need to read it again.

What Quadramet is used for

Quadramet is used to help in relieving the pain caused by tumour deposits in the bone. The drug is taken up particularly strongly in injured bone, which is often where the tumour is located. The radioactive component of the drug gives off radiation, which reduces tumour activity and associated pain.

The purpose of Quadramet is to relieve pain caused by tumour in bone. It is not a cure for cancer and will not have any effect upon tumour not in the bone.

How long the relief will last is unpredictable, and may vary from weeks to months. Not all pain is due to tumour in bone, and this drug will not help relieve pain caused by tumour outside the bone.

Quadramet is usually given following other treatments. Ask your specialist to explain why this treatment has been proposed for you.

For more information, ask for a copy of the booklet Nuclear Medicine - Answering Your Questions, available from the hospital, clinic or supplier.

Before you are given it

Tell the doctor who is to treat you if:

1. You are pregnant or intend to become pregnant

It is not know whether Quadramet is harmful to an unborn baby when administered to a pregnant woman.

If you intend to become pregnant consult your doctor about the advised waiting period.

2. You are breast-feeding

Quadramet has a serious potential to harm breast-fed infants. You should stop breast-feeding before and during your treatment with Quadramet.

3. You have had any chemotherapy or radiotherapy in the last 6 weeks

Quadramet treatment may make worse unwanted side effects of previous chemotherapy or radiotherapy.

Preparation

You will be asked to drink at least 2 cups of fluid prior to the injection. You may eat or drink or take your usual medications.

How Quadramet is used

The person administering the dose will insert a small plastic tube into a vein in your arm to allow the Quadramet to be given. It may sting during insertion and for a short time after, but then the injection can be given through the tube. After a check that the tube is in position, the Quadramet will be injected followed by a little water to make sure all the Quadramet has been injected. The tube will then be removed.

Occasionally there may be some residual discomfort at the injection site and, rarely, some bleeding or bruising.

After being given the injection, you may need to wait in the clinic for about 2 hours to make sure that you have no problems with the treatment. Your physician may keep you in the hospital for one or two days after the treatment, if required.

After being given Quadramet

You should drink plenty of fluids in the first six hours after treatment, and empty your bladder frequently - at least every hour. For the first 24 hours after your treatment you should be careful when going to the toilet not to spill any urine and to flush the toilet well.

Whenever possible, use a toilet rather than a urinal. Clean up spilled urine complete and wash your hands thoroughly. No other activity will be affected by this treatment. You should be able to do things that you could do before the injection. physician and the possibility of overdosing is minimal.

located at Lucas Heights, in Sydney, NSW.

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Side effects

Tell the person treating you as soon as possible if you do not feel well after having had the injection of Quadramet.

About 10% of patients will experience a temporary increase in pain some time in the first week of treatment. The paint usually responds to an increase in pain killers and is temporary.

Treatment often produces a fall in the number of red cells and white cells produced in the bone marrow. This is usually temporary and does not pose a problem. You may need to have weekly blood tests, starting 2 weeks after treatment, until this effect has diminished.

In some patients, especially those who have received considerable chemotherapy or radiotherapy, the fall in the number of red cells and white cells may be severe with increase chances of bleeding, injection or anaemia developing. This may require transfusions with blood products to correct, and may be fatal in a very small number of cases. In the very unlikely event that the bone marrow should be severely affected, any further chemotherapy or radiotherapy may have to be delayed until it recovers.

Other less serious side effects experienced are diarrhoea, nausea and/or vomiting, fever and/or chills and dizziness. This is not a complete list. If you experience any of these or other side effects, consult with your doctor.

Overdosage

The usual dose will be calculated by a qualified nuclear medicine

Storage

Quadramet is stored by the hospital or clinic in a freezer at -10 to -20°C inside a shielded container. The injection is thawed out before administration.

The Nuclear Medicine technologist or specialist will be responsible for checking the expiry date of the product before administering it to you.

Product description

What it looks like

Quadramet is a colourless or light amber aqueous FROZEN solution that comes in a 10 ml vial.

Ingredients

Active

Samarium (¹⁵³Sm) Lexidronam Pentasodium

Inactive

- Ethylenediaminetetramethylene (phosphonic acid monohydrate)
- Calcium hydroxide
- · Sodium hydroxide
- · Hydrochloric acid
- Water

Aust R 62521

Supplier

Quadramet is supplied in Australia by:

ANSTO Health Locked Bag 2001 Kirrawee DC, NSW 2232 Telephone: 1800 251 572 Facsimile: 02 9543 6511

ANSTO Health is a commercial enterprise of the Australian Nuclear Science and Technology Organisation (ANSTO), which is