

RADPHARM LEUCOCYTE LABELLING KIT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RADPHARM LEUCOCYTE LABELLING KIT?

RADPHARM LEUCOCYTE LABELLING KIT contains the active ingredient Sodium Fluoride. RADPHARM LEUCOCYTE LABELLING KIT is used to image acute inflammation or infection.

For more information, see Section [1. Why am I using RADPHARM LEUCOCYTE LABELLING KIT?](#) in the full CMI.

2. What should I know before I use RADPHARM LEUCOCYTE LABELLING KIT?

Do not use if you have ever had an allergic reaction to RADPHARM LEUCOCYTE LABELLING KIT or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RADPHARM LEUCOCYTE LABELLING KIT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RADPHARM LEUCOCYTE LABELLING KIT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RADPHARM LEUCOCYTE LABELLING KIT?

- Your doctor or health care provider will decide how much RADPHARM LEUCOCYTE LABELLING KIT you will be given. This depends on your condition and other factors, such as weight.

More instructions can be found in Section [4. How do I use RADPHARM LEUCOCYTE LABELLING KIT?](#) in the full CMI.

5. What should I know while using RADPHARM LEUCOCYTE LABELLING KIT?

Things you should do	<ul style="list-style-type: none">Inform your doctor or health care provider immediately if you do not feel well during the injection or after being given RADPHARM LEUCOCYTE LABELLING KIT.
Things you should not do	<ul style="list-style-type: none">Do not take any other medicines until advised by your doctor
Driving or using machines	<ul style="list-style-type: none">Do not drive or operate machinery until you know how RADPHARM LEUCOCYTE LABELLING KIT affects you.

For more information, see Section [5. What should I know while using RADPHARM LEUCOCYTE LABELLING KIT?](#) in the full CMI.

6. Are there any side effects?

Reported side effects of RADPHARM LEUCOCYTE LABELLING KIT include Hypersensitivity reactions with technetium (99mTc) preparations.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RADPHARM LEUCOCYTE LABELLING KIT

Active ingredient(s): *sodium fluoride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RADPHARM LEUCOCYTE LABELLING KIT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RADPHARM LEUCOCYTE LABELLING KIT.**

Where to find information in this leaflet:

- [1. Why am I using RADPHARM LEUCOCYTE LABELLING KIT?](#)
- [2. What should I know before I use RADPHARM LEUCOCYTE LABELLING KIT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RADPHARM LEUCOCYTE LABELLING KIT?](#)
- [5. What should I know while using RADPHARM LEUCOCYTE LABELLING KIT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RADPHARM LEUCOCYTE LABELLING KIT?

RADPHARM LEUCOCYTE LABELLING KIT contains the active ingredient **Sodium Fluoride**. RADPHARM LEUCOCYTE LABELLING KIT is a prescription medicine which is only available to the Healthcare Practitioners for diagnostic use only. It belongs to a group of medicines called radiopharmaceutical agents, which are radioactive. It is administered to you via intravenous injection after mixing with a radioactive solution.

RADPHARM LEUCOCYTE LABELLING KIT is mixed with an imaging agent Technetium (99mTc) before injection to image areas of inflammation or infection that may be present.

The imaging agent used is a radiotracer called Technetium-99m. Technetium-99m emits small amounts of radiation similar to X-rays. A special camera, called a gamma camera, can detect this radiation and produces an image known as a scan. A nuclear medicine specialist interprets these scans and provides you with information related to your referral that otherwise may not be known or seen on plain X-rays.

Your doctor may have prescribed RADPHARM LEUCOCYTE LABELLING KIT for another purpose. Ask your doctor if you have any questions about why RADPHARM LEUCOCYTE LABELLING KIT has been prescribed for you. If you have any concerns, you should discuss these with your doctor.

2. What should I know before I use RADPHARM LEUCOCYTE LABELLING KIT?

Warnings

Do not use RADPHARM LEUCOCYTE LABELLING KIT if:

- you are allergic to sodium fluoride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition including medicines that you buy without a prescription from the pharmacy, supermarket or health food shop.
- Have any allergies to ingredients listed at the end of this leaflet or any other substances such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. It is not known whether the injection is harmful to an unborn baby when administered to a pregnant woman. If you are pregnant, the nuclear medicine specialist will need to talk to your referring doctor before deciding whether you should have the injection.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Suspend breast-feeding for not less than 12 hours after your nuclear medicine scan. Express milk prior to your scan and store it. Discard breast milk expressed after your scan for at least 12 hours. It is known that Technetium-99m passes into breast milk. Ask your nuclear medicine technologist to confirm how long you should suspend breast-feeding.

Restrict your contact with your baby to no more than 5 hours in the next 24 hours.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RADPHARM LEUCOCYTE LABELLING KIT.

4. How do I use RADPHARM LEUCOCYTE LABELLING KIT?

How much to take / use

- Your doctor will decide how much you will be given RADPHARM LEUCOCYTE LABELLING KIT. This depends on your condition and other factors, such as weight.

When to take / use RADPHARM LEUCOCYTE LABELLING KIT

- RADPHARM LEUCOCYTE LABELLING KIT will only be given to you by qualified staff with specific training in the safe use and handling of radiopharmaceuticals.
- Approx 20mLs of blood is taken from your arm. You may feel a pin prick from the needle when it is inserted. This blood is then combined with the LLK Radpharm and mixed for one hour. The blood is then reinjected into a vein in your arm.
- Depending on your condition you may require multiple scans to help establish clear images to make an accurate diagnosis. The scan is painless and may take up to an hour.

If you use too much RADPHARM LEUCOCYTE LABELLING KIT

If you think that you have been given too much RADPHARM LEUCOCYTE LABELLING KIT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using RADPHARM LEUCOCYTE LABELLING KIT?

Things you should do

Call your doctor straight away if you do not feel well during the injection or after being given RADPHARM LEUCOCYTE LABELLING KIT.

Drink plenty of fluids, and pass urine frequently, following the scan to help flush the agent from your body.

Things you should not do

- Do not take any other medicines until advised by your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how RADPHARM LEUCOCYTE LABELLING KIT affects you.

Do not drive or operate machinery until you know how RADPHARM LEUCOCYTE LABELLING KIT affects you.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Hypersensitive reactions	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">No serious side effects reported currently.	N/A

Do not be alarmed by this list of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription and only made available to your doctor or healthcare practitioner.

What RADPHARM LEUCOCYTE LABELLING KIT contains

Active ingredient (main ingredient)	Sodium Fluoride
Other ingredients (inactive ingredients)	Stannous Fluoride, Water for Injections
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

This product contains no preservatives.

What RADPHARM LEUCOCYTE LABELLING KIT looks like

RADPHARM LEUCOCYTE LABELLING KIT is available to your healthcare practitioner or doctor as a composite kit which contains two vials described below:

- a) Vial A- clear concentrated liquid for Intravenous Injection in 10 mL vials.
- b) Vial B- dry while lyophilized powder in multi-dose 8 mL vacuum sealed vials for intravenous injection.

The Australian Register Number for RADPHARM LEUCOCYTE LABELLING KIT is 14333.

Who distributes RADPHARM LEUCOCYTE LABELLING KIT

Global Medical Solutions Australia Pty Limited T/A
Radpharm Scientific

53-57 Oatley Court, BELCONNEN, ACT 2617 Australia

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