

NEUROLITE® bicisate dihydrochloride 0.9mg/mL kit for the preparation of technetium [99Tc] bicisate injection vial composite pack

▼ 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 NEUROLITE®?

NEUROLITE® contains the active ingredient bicisate dihydrochloride. NEUROLITE® is used in the evaluation and localisation of regional perfusion abnormalities in adult patients with the central nervous system disorders of stroke and dementia.

For more information, see Section [1. Why am I using NEUROLITE®?](#) in the full CMI.

2. WHAT SHOULD I KNOW BEFORE I USE NEUROLITE®?

Do not use if you have ever had an allergic reaction to NEUROLITE® 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 NEUROLITE®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NEUROLITE® 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 NEUROLITE®?

- Your doctor or health care professional will decide how much NEUROLITE® you will be given. Dosage administered will be dependent on your weight.
- NEUROLITE® is given by intravenous injection.

More instructions can be found in Section [4. How do I use NEUROLITE®?](#) in the full CMI.

5. What should I know while using NEUROLITE®?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, or health care professional you visit if you suffer from any renal impairment that may interfere with the excretion of NEUROLITE®.• Let your doctor or health care professional know before administration if you are or plan to become pregnant and if you are breastfeeding or plan to breastfeed.• Drink about 2L of fluid and void urine frequently immediately after administration of NEUROLITE® to increase the rate of clearance from the body.• Tell your doctor if you experience any side effects during or after the NEUROLITE® administration.
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 NEUROLITE® affects you.

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

6. Are there any side effects?

Common side effects of NEUROLITE® are; Headache, Agitation/Anxiety, Nausea, Cough, Dizziness, Rash (which maybe red and itchy), mild aromatic odour immediately after the injection, feeling unwell, sleepiness or drowsiness.

Serious side effects include; Seizure/fit/convulsion, hallucinations, fast heart rate, temporary breathing stop, skin turning blue and chest pain

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.

Active ingredient(s): bicisate dihydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using NEUROLITE®. 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 NEUROLITE®.

Where to find information in this leaflet:

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

1. Why am I using NEUROLITE®?

NEUROLITE® contains the active ingredient bicisate dihydrochloride. NEUROLITE® 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 all radioactive. It is administered to you via intravenous injection after mixing with a radioactive solution.

NEUROLITE® is used in the evaluation and localisation of regional perfusion abnormalities in adult patients with the central nervous system disorders of stroke and dementia. In other words, Neurolite is used to show the blood flow inside your brain during the scan.

Your doctor may have prescribed Neurolite for another purpose. Ask your doctor if you have any questions about why Neurolite 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 NEUROLITE®?

Warnings

Do not use NEUROLITE® if:

- You are allergic to bicisate dihydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Below 18 years of age. If your doctor believes it is necessary to give Neurolte to a patient under 18, he or she will discuss the benefits and risks with you.

Check with your doctor if you:

- Have any other medical conditions such as Renal impairment or kidney disease. take any medicines for any other condition.

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. Like most medicines, Neurolite is not recommended for use during pregnancy. If there is a need to consider Neurolite during your pregnancy, your doctor will discuss the benefits and risks of giving it to you.

Tell your doctor if you are breastfeeding or intend to breastfeed. Like most medicines Neurolite is not recommended while you are breastfeeding. However if you are breastfeeding, formula feedings should be substituted for breastfeeding for 24 hours following administration of Neurolite. Breast milk produced within that time should be discarded.

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 NEUROLITE®.

4. How do I use NEUROLITE®?

How much to take / use

- Your doctor or health care professional will decide how much NEUROLITE® you will be given. Dosage given will be dependent on your condition and other factors, such as your weight.

When to take / use NEUROLITE®.

- Your doctor or health care professional will decide when to administer NEUROLITE® to you.

If you use too much NEUROLITE®.

If you think that you have been injected with too much NEUROLITE®, drink plenty of water or fluid for frequent urination. This will remove as much radioactivity as possible from your bladder.

If you experience any immediate side effects 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 NEUROLITE®?

Things you should do

Drink about 2 litres of fluids and void urine frequently immediately after the administration of NEUROLITE® to remove as much radioactivity as possible from your bladder.

Tell your doctor or health care provider straight away if you:

- Feel unwell during or after being given NEUROLITE®

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 NEUROLITE® affects you.

NEUROLITE® may cause dizziness and headache in some people. Make sure you know how you react to Neurolite before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

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
<ul style="list-style-type: none">• Headache• Agitation/Anxiety• Nausea• Cough• Dizziness• Rash, which maybe red and itchy• Mild aromatic odour immediately after the injection• Feeling unwell, sleepiness or drowsiness• Fainting	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Tachycardia/fast heart rate• Seizure, fit or convulsion• Chest pain• Temporary breathing stop, skin turning blue	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 only.

What NEUROLITE® contains

Active ingredient (main ingredient)	bicisate dihydrochloride
Other ingredients (inactive ingredients)	dibasic sodium phosphate heptahydrate monobasic sodium phosphate monohydrate disodium edetate mannitol stannous chloride dehydrate water for injection

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

What NEUROLITE® looks like

NEUROLITE® is supplied as a composite pack consisting of 2 vials, Vial A and Vial B. An injection is prepared from the kit and administered to you by a doctor or trained healthcare professional (Aust R 73014).

Who distributes NEUROLITE®

Global Medical Solutions Australia Pty Limited T/A Radpharm Scientific
53-57 Oatley Court, BELCONNEN, ACT 2617 Australia

This leaflet was prepared in 06/2022.