

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

NETSPOT®

40 microgram kit for preparation of gallium (⁶⁸Ga) oxodotreotide injection

Read this carefully before you start taking **Netspot**®. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Netspot**.

Serious Warnings and Precautions

- Because gallium (⁶⁸Ga) oxodotreotide injection is a radiopharmaceutical (radioactive substance), it can only be given by doctors and other health professionals who are specially trained and experienced in the safe use and handling of these substances.

What is Netspot used for?

Netspot is a kit used:

- To prepare the radiopharmaceutical (radioactive) product **gallium (⁶⁸Ga) oxodotreotide injection**, which is used to find and diagnose certain cancer tumours called somatostatin receptor positive neuroendocrine tumours (NETs).

How does Netspot work?

The active ingredient in Netspot is called oxodotreotide. This ingredient binds to tumours that have certain proteins (somatostatin receptors) on their surface. Before it can be used, Netspot must be mixed with another solution and radioactive gallium-68 chloride to make gallium (⁶⁸Ga) oxodotreotide. This process is called radiolabeling.

Gallium (⁶⁸Ga) oxodotreotide injection prepared using the Netspot kit contains a small amount of radioactivity. After it is injected into a vein, gallium (⁶⁸Ga) oxodotreotide can help doctors see parts of the body containing somatostatin receptors on their surface, including some types of tumours. Your doctor will use a procedure called positron emission tomography (PET) to develop a picture of where gallium (⁶⁸Ga) oxodotreotide has gone in your body. This picture will help your doctor locate tumours and abnormal cells. This picture provides your doctors with valuable information about your disease.

The use of gallium (⁶⁸Ga) oxodotreotide involves exposure to small amounts of radioactivity. Before you are treated with gallium (⁶⁸Ga) oxodotreotide, your doctor will determine whether the benefits of gallium (⁶⁸Ga) oxodotreotide outweigh the potential risks due to radiation exposure.

What are the ingredients in Netspot?

Medicinal ingredients: oxodotreotide, which is combined with the radioactive substance gallium.

Non-medicinal ingredients: 1,10-phenanthroline; gentisic acid; mannitol; formic acid; sodium hydroxide; and water for injection.

Netspot comes in the following dosage forms:

Kit for the preparation of gallium (⁶⁸Ga) oxodotreotide for injection.

Do not use Netspot if:

- If you are allergic to gallium (^{68}Ga) oxodotreotide or any of the other ingredients of this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Netspot. Talk about any health conditions or problems you may have, including if you:

- Have experienced any signs of allergic reaction after previous administration of Netspot prepared gallium (^{68}Ga) oxodotreotide or other somatostatin analogs;
- Are under 18 years of age;
- Have signs of dehydration (feeling very thirsty) before or after the examination;
- Have any other medical condition as these could affect the interpretation of the image;
- Have been taking other medicines such as somatostatin-type drugs, and glucocorticoids, which may interact with Netspot;
- Are pregnant or believe you may be pregnant; and/or
- Are breast-feeding.

Other warnings you should know about:**Children and adolescents**

The safety and efficacy of this medicine in children and adolescents under 18 years of age has not yet been established.

Pregnancy and breast feeding

If you are breast-feeding the nuclear medicine doctor may either delay the medical procedure until you no longer breast-feed or ask you to stop breastfeeding and to collect then discard your milk until there is no radioactivity in your body (usually 12 hours after treatment with Netspot). Be sure to ask your nuclear medicine doctor when you can resume breast-feeding.

Netspot contains sodium

This medicine contains up to 32.4 mg of sodium per dose.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**The following may interact with Netspot:**

- Other somatostatin drugs – you may be asked to stop and/or change your treatment for a short period of time while receiving gallium (^{68}Ga) oxodotreotide.
- Corticosteroids – speak to your doctor if you are taking a corticosteroid.

How to take Netspot:

- There are strict laws on the use, handling and disposal of radiopharmaceutical products. Netspot prepared gallium (^{68}Ga) oxodotreotide will be given to you by a healthcare professional who is experienced in the use of radiopharmaceuticals.

Usual dose:

The doctor or specialist supervising the procedure will decide on the dose of Netspot prepared gallium (^{68}Ga) oxodotreotide you will receive. The dose will be the smallest amount needed to get the desired information. The dose is based on your weight. The recommended dose for an adult is usually 100 MBq to 200 MBq (MBq = megabecquerel, which is the unit used to express radioactivity).

Administration of Netspot prepared gallium (⁶⁸Ga) oxodotreotide and conduct of the procedure:

- Netspot prepared gallium (⁶⁸Ga) oxodotreotide is administered by intravenous injection (directly into the vein);
- A single injection is enough for your doctor to conduct the test and make a diagnosis; and
- You will be asked to urinate just before the test. After injection, you will be offered something to drink and you will be asked to urinate as often as possible.

After gallium (⁶⁸Ga) oxodotreotide administration, you should:

- Avoid any close contact with young children and pregnant women for 12 hours after the injection; and
- Urinate frequently in order to eliminate the medicine from the body.

The nuclear medicine doctor will tell you if you need to take any special precautions after receiving this medicine. Contact your nuclear medicine doctor if you have any questions.

Duration of the procedure:

Your nuclear medicine doctor will inform you about the usual amount of time the procedure requires.

Overdose:

An overdose is unlikely because you will only receive a single dose in a controlled clinical setting. However, in the case of an overdose, you will receive the appropriate treatment. Drinking water and emptying your bladder frequently will help remove the medicine from your body more quickly.

Should you have any further questions on the use of this medicine, please ask your doctor who supervises the procedure.

What are possible side effects from using Netspot?

These are not all the possible side effects you may have when taking Netspot. If you experience any side effects not listed here, tell your healthcare professional. In a literature report of a clinical study with gallium (⁶⁸Ga) oxodotreotide, there were no serious adverse events reported and no participants had a trial related event requiring additional medical care, however, there were rare reports of mild changes in heart rate, increased liver protein (aspartate amino transferase) and increased blood sugar.

Short-term non-serious nausea, vomiting, injection site reactions (pain, burning sensation), hives, rash, redness and itching have been reported following Netspot prepared gallium (⁶⁸Ga) oxodotreotide administration.

| Serious side effects and what to do about them | | |
|---|--------------------------------------|--------------|
| Symptom / effect | Talk to your healthcare professional | |
| | Only if severe | In all cases |
| Injection site reactions (itching, swelling, redness, warm feeling at the injection site) | | X |
| Nausea and vomiting | | X |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

You will not have to store this medicine. This medicine is stored under the responsibility of your healthcare specialist.

If you want more information about Netspot:

- Talk to your healthcare professional; and/or
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or the manufacturer's website (<https://www.novartis.ca>).

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