

Package leaflet: Information for the patient

Axumin 1,600 MBq/mL solution for injection Axumin 3,200 MBq/mL solution for injection fluciclovine (^{18}F)

Read all of this leaflet carefully before you are given 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 nuclear medicine doctor who will supervise the procedure.
- If you get any side effects, talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Axumin is and what it is used for
2. What you need to know before you use Axumin
3. How to use Axumin
4. Possible side effects
5. How to store Axumin
6. Contents of the pack and other information

1. What Axumin is and what it is used for

This medicine is a radiopharmaceutical product for diagnostic use only.

Axumin contains the active substance fluciclovine (^{18}F) and is given so that doctors can perform a special type of scan called a positron emission tomography (PET) scan. If you have previously had treatment for prostate cancer and information from other tests (e.g. prostate specific antigen, PSA) indicates that the cancer may have returned, an Axumin PET scan can help your doctor find the locations where the cancer has come back.

You should discuss the results of the test with the doctor that requested the scan.

The use of Axumin does involve exposure to small amounts of radioactivity. Your doctor and the nuclear medicine doctor have considered that the benefit of this procedure with the radiopharmaceutical outweighs the risk of being exposed to radiation.

2. What you need to know before you use Axumin

Axumin must not be used

- if you are allergic to fluciclovine (^{18}F) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your nuclear medicine doctor before you are given Axumin if you:

- have **kidney problems**
- are on a **low sodium diet** (see section "Axumin contains sodium").

Before administration of Axumin you:

- should avoid exercise for at least a day before the Axumin scan.
- should not eat or drink for **at least 4 hours** before the scan (you can take your usual medicines with small amounts of water).

- may urinate at the latest 60 minutes before the Axumin injection and you should avoid urination until after the scan has been completed.

Children and adolescents

Talk to your nuclear medicine doctor if you are under 18 years old. Axumin is not intended for use in children and adolescents aged under 18 years.

Other medicines and Axumin

Tell your nuclear medicine doctor if you are taking, have recently taken or might take any other medicines since they may interfere with the interpretation of the images.

Pregnancy and breast-feeding

This medicine is not indicated for use in women.

Driving and using machines

It is considered unlikely that Axumin will affect your ability to drive or to use machines.

Axumin contains sodium

This medicine contains up to 39 mg sodium (main component of cooking/table salt) in each dose. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Axumin

There are strict laws on the use, handling and disposal of radiopharmaceutical products.

Axumin will only be used in specially controlled areas. This medicine will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this medicine and will keep you informed of their actions.

The nuclear medicine doctor supervising the procedure will decide on the quantity of Axumin to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity to be administered usually recommended for an adult is 370 MBq (megabecquerel, the unit used to express radioactivity).

Administration of Axumin and conduct of the procedure

Axumin is administered intravenously as an injection into your vein followed by a flush of sodium chloride solution to ensure that you receive the full dose.

One injection is usually sufficient to conduct the test that your doctor needs.

Duration of the procedure

Your nuclear medicine doctor will inform you about the usual duration of the procedure. The scan will usually start approximately 5 minutes after the Axumin injection is given.

After administration of Axumin you should:

- **avoid any close contact** with **young children** and **pregnant women** for the 12 hours following the injection
- **urinate** frequently in order to eliminate the product from your body.

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

If you have been given more Axumin than you should

An overdose is unlikely because you will only receive a single dose of Axumin precisely controlled by the nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment. In particular, the nuclear medicine doctor in charge of the procedure may provide ways to increase the passing of urine and stools in order to facilitate the removal of radioactivity from your body.

Should you have any further question on the use of Axumin, please ask your nuclear medicine doctor who supervises the procedure.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In clinical studies side effects were reported by less than 1 in 100 patients given the medicine.

The following side effects of Axumin are **common** (may affect up to 1 in 100 people).

- Altered taste in the mouth, altered sense of smell, pain or rash at the site of injection.

This radiopharmaceutical will deliver low amounts of ionising radiation associated with the least risk of cancer and hereditary abnormalities.

Reporting of side effects

If you get any side effects talk to your nuclear medicine doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly **via the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Axumin

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

The following information is intended for the specialist only.

Axumin must not be used after the expiry date which is stated on the shield label after EXP.

6. Contents of the pack and other information

What Axumin contains

- The active substance is fluciclovine (^{18}F).
Axumin 1,600 MBq/mL solution for injection
Each mL of solution contains 1,600 MBq fluciclovine (^{18}F) at date and time of calibration (ToC).
The activity per vial ranges from 1,600 MBq to 16,000 MBq at the date and ToC.
Axumin 3,200 MBq/mL solution for injection
Each mL of solution contains 3,200 MBq fluciclovine (^{18}F) at date and ToC. The activity per vial ranges from 3,200 MBq to 32,000 MBq at the date and ToC.
- The other ingredients are sodium citrate, concentrated hydrochloric acid, sodium hydroxide, water for injections (see section 2 "Axumin contains sodium")

What Axumin looks like and contents of the pack

Axumin is a clear, colourless solution stored in a 10 mL or 15 mL glass vial.

Axumin 1,600 MBq/mL solution for injection

Each multidose vial contains 1 to 10 mL of solution, corresponding to 1,600 to 16,000 MBq at the date and ToC.

Axumin 3,200 MBq/mL solution for injection

Each multidose vial contains 1 to 10 mL of solution, corresponding to 3,200 to 32,000 MBq at the date and ToC.

Pack size: 1 vial.

Marketing Authorisation Holder

Blue Earth Diagnostics Ireland Ltd, 6th Floor, 2 Grand Canal Square, Dublin 2, Ireland

Manufacturer

Seibersdorf Labor GmbH, 2444 Seibersdorf, Austria.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

The complete SmPC of Axumin is provided as a separate document in the package of the medicinal product, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.
Please refer to the SmPC [SmPC should be included in the box]