

Atranel®

Nelarabine

Solution for Infusion

Read this leaflet carefully before you start taking Atranel®. This leaflet provides answers to the most common questions. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for your current illness only. Do not take it in similar conditions and do not pass it on to others. The information in this leaflet was last updated on the date listed on the bottom of the page. More recent information on the medicine may be available. You should ensure that you speak to your doctor or pharmacist to obtain the most up-to-date scientific information on the medicine. The latest version of this leaflet is available on www.nanoalvand.com.

What is in this leaflet

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1. What Atranel® is and what it is used for

Atranel® contains the active substance nelarabine, which belongs to a group of medicines known as antineoplastic agents, used in chemotherapy to kill some types of cancer cells.

Atranel® is used to treat patients with:

- a type of leukemia, called T-cell acute lymphoblastic leukemia. Leukemia causes an abnormal increase in the number of white blood cells. The abnormal high number of white blood cells can appear in the blood and other parts of the body. The type of leukemia relates to the type of white blood cell mainly involved. In this case, its cells are called lymphoblasts.

- a type of lymphoma, called T-cell lymphoblastic lymphoma. This lymphoma is caused by a mass of lymphoblasts, a type of white blood cell.

If you have any questions about your illness, talk to your doctor.

2. What you need to know before you take Atranel®

Do not use Atranel®

- if you are allergic to nelarabine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Severe nervous system side effects have been reported with the use of nelarabine. Symptoms may be mental (e.g. tiredness) or physical (e.g. convulsions, feelings of numbness or tingling, weakness and paralysis). Your doctor will check for these symptoms regularly during treatment. (see section 4, "Possible side effects".)

Talk to your doctor, before taking Atranel®:

- if you have any kidney or liver problems. Your dose of Atranel® may need to be adjusted.

- if you have recently been, or plan to be vaccinated with a live vaccine (for example polio, varicella, typhoid).

- if you have any blood problems (for example anemia).

Blood tests during treatment

Your doctor should perform blood tests regularly during treatment to check for blood problems that have been associated with the use of Atranel®.

Elderly patients

If you are an elderly person, you could be more sensitive to nervous system side effects (see the list above under "Warnings and precautions"). Your doctor will check for these symptoms regularly during treatment.

Tell your doctor if any of these apply to you.

Other medicines and Atranel®

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any herbal products or medicines you have bought without a prescription.

Remember to tell your doctor if you start to take any other medicines while you are on Atranel®.

Pregnancy and breast-feeding

Pregnancy

Atranel® is not recommended for pregnant women. It may harm a baby if conceived before, during or soon after treatment.

Contraception

Consideration to appropriate birth control is recommended to be discussed with your doctor. Do not try and become pregnant/father a child until your doctor advises you it is safe to do so.

Male patients, who may wish to father a child, should ask their doctor for family planning advice or treatment. If pregnancy occurs during treatment with Atranel®, you must tell your doctor immediately.

Breast-feeding

It is not known whether Atranel® is passed on through breast milk. Breast-feeding must be discontinued while you are taking Atranel®. Ask your doctor for advice before taking any medicine.

Driving and using machines

Atranel® can make people feel drowsy or sleepy, both during and for some days after treatment. If you feel tired or weak, do not drive, and do not use any tools or machines.

Atranel® contains sodium

Atranel® contains 88.5 mg sodium in each vial. This is equivalent to 4.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Atranel®

Atranel® should be administered under the supervision of a doctor experienced in the use of cancer medicines that are toxic to your cells.

Atranel® should only be administered as intravenous infusion. No further dilution is required. The dose of Atranel® you are given will be based on:

- Your body surface area (which will be calculated by your doctor based on your height and weight).
- The results of blood tests carried out before treatment.

Adults and adolescents (aged 16 years and older):

- The usual dose is 1,500 mg/m² of body surface area per day.

A doctor or nurse will give you the dose of Atranel® as an infusion (a drip). It is usually dripped into your arm over a period of about 2 hours.

You will have an infusion (a drip) once a day on days 1, 3 and 5 of treatment. This pattern of treatment will normally be repeated every three weeks. This treatment may vary, depending on the results of your regular blood tests. Your doctor will decide how many treatment cycles are required.

Children and adolescents (aged 21 years and younger):

- The recommended dose is 650 mg/m² of body surface area per day.

A doctor or nurse will give you a suitable dose of Atranel® as an infusion (a drip). It is usually dripped into your arm over a period of about 1 hour.

You will have an infusion (a drip) once a day for 5 days. This pattern of treatment will normally be repeated every three weeks.

This treatment may vary, depending on the results of regular blood tests. Your doctor will decide how many treatment cycles are required.

Stopping treatment with Atranel®

Your doctor will decide when to stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor if you get any side effects, including those not listed in this leaflet.

Most serious side effects

Tell your doctor straight away if you notice the following very common side effects:

- Signs of infection. Atranel® may reduce the number of white blood cells and lower your resistance to infection (including pneumonia). This can even be life-threatening. Signs of an infection include:

- Fever
- Serious deterioration of your general condition
- Local symptoms such as sore throat, sore mouth or urinary problems (for example, a burning sensation when urinating, which may be a urinary infection)

Tell your doctor immediately if you get any of these. A blood test will be taken to check possible reduction of white blood cells.

Other side effects may include:

Very common (may affect more than 1 in 10 people)

- Changes in the sense of feeling in hands or feet, muscle weakness appearing as difficulty getting up from a chair, or difficulty walking (peripheral neuropathy); reduced sensitivity to light touch, or pain; abnormal sensations such as burning and, prickling, a sensation of something crawling on the skin
- Feeling generally weak and tired (temporary anemia). In some cases, you may need a blood transfusion.

- Unusual bruising or bleeding, caused by a decrease in the number of clotting cells in the blood. This can lead to severe bleeding from relatively small injuries such as a small cut. Rarely, it can lead to even more severe bleeding (hemorrhage). Talk to your doctor for advice on how to minimize the risk of bleeding.

- Feeling drowsy and sleepy; headache; dizziness
- Shortness of breath, difficult or labored breathing; cough

- Feeling of an upset stomach (nausea); being sick/ throwing up (vomiting); diarrhea; constipation
- Muscle pain

- Swelling of parts of the body due to accumulation of abnormal amounts of fluid (edema)

- High body temperature (fever); tiredness; feeling weak/loss of strength

Common (may affect up to 1 in 10 people)

- Violent, uncontrollable muscular contractions often accompanied by unconsciousness that can be due to an epileptic attack (seizures)

- Clumsiness and lack of coordination affecting balance, walking, limb or eye movements, or speech

- Unintentional rhythmic shaking of one or more limbs (tremors)

- Muscle weakness (possibly associated with peripheral neuropathy), joint pain, back pain; pain in hands and feet including a sensation of pins and needles sensation and numbness

- Lowered blood pressure

- Weight loss and loss of appetite (anorexia); stomach pain; sore mouth, mouth ulcers or inflammation

- Problems with memory, feeling disoriented; blurred vision; altered or loss of sense of taste (dysgeusia)

- Buildup of fluid around the lungs leading to chest pain and difficulty in breathing (pleural effusion); wheezing

- Increased amounts of bilirubin in your blood, which may cause yellowing of the skin and may make you feel lethargic

- Increases in blood levels of liver enzymes

- Increases in blood creatinine levels (a sign of kidney problems, which might lead less frequent urination)

- The release of tumor cell contents (tumor lysis syndrome), which may put extra stress on your body. Initial symptoms including nausea and vomiting, shortness of breath, an irregular heartbeat, clouding of urine, lethargy and/or joint discomfort. If this does occur, it is most likely to occur at the first dose. Your doctor will take appropriate precautions to minimize the risk of this.

- Low blood levels of some substances such as:

- Low calcium levels, which may cause muscle cramps, abdominal cramps or spasms.

- Low magnesium levels, which may cause muscle weakness, confusion, "jerky" movements, high blood pressure, irregular heart rhythms and decreased reflexes with severely low blood magnesium levels.

- Low potassium levels may cause a feeling of weakness.

- Low glucose levels, which may cause nausea, sweating, weakness, faintness, confusion or hallucinations.

Rare (may affect up to 1 in 1000 people):

- Serious disease that destroys skeletal muscle characterized by the presence of myoglobin (a breakdown product of muscle cells) in the urine (rhabdomyolysis), increase in blood creatine phosphokinase.

5. How to store Atranel®

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date.

- Store below 30°C.

- Store in the original package in order to protect from light.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Cytotoxic agent. Must be transported, stored, and disposed of according to guidelines for handling of cytotoxic compounds.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Atranel® contains

The active substance is nelarabine. The other ingredients are sodium chloride, hydrochloric acid, sodium hydroxide, and water for injection.

What Atranel® looks like and contents of the pack

Atranel® is a clear, colorless and free from any visible particular matter solution.

Each 1 ml of Atranel® contains 5 mg of nelarabine.

Each 50 ml vial contains 250 mg of nelarabine.

Each vial is packed in a box with a leaflet.

For medical or healthcare professionals only

Atranel® should only be administered as intravenous infusion. No further dilution is required.

The appropriate dose of Atranel® must be transferred into polyvinylchloride (PVC) or ethyl vinyl acetate (EVA) infusion bags or glass containers and administered intravenously as a two-hour infusion in adult patients and as a one-hour infusion in pediatric patients.

Atranel® is stable for up to 8 hours at up to 30°C once the vial is opened.

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