



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Atriance (*nelarabine*)

An overview of Atriance and why it is authorised in the EU

### What is Atriance and what is it used for?

Atriance is a cancer medicine used to treat patients with T-cell acute lymphoblastic leukaemia (T-ALL) or T-cell lymphoblastic lymphoma (T-LBL). These are types of cancer where T-lymphoblasts (a type of immature white blood cell) multiply too quickly. In T-ALL the abnormal cells are mainly in the blood and bone marrow, and in T-LBL they are mainly in the lymphatic system (lymph nodes or thymus gland). Atriance is used when the cancer has not responded to, or has stopped responding to, at least two types of chemotherapy.

Atriance contains the active substance nelarabine.

### How is Atriance used?

Atriance can only be obtained with a prescription and is given by drip into a vein under the supervision of a doctor who has experience in the use of this type of medicine.

The dose and frequency of infusion depend on the patient's age and body surface area (calculated using the patient's height and weight). In adults and adolescents aged 16 years and over, the recommended starting dose is 1,500 mg per square metre of body surface area, given over two hours on days one, three and five, repeated every 21 days. Patients aged under 16 years receive a dose of 650 mg per square metre given over one hour on five consecutive days, repeated every 21 days. This schedule can also be used in patients aged 16 to 21 years. Treatment should be stopped if the patient develops serious side effects affecting the brain or nervous system. Treatment may be delayed if other side effects occur.

Patients receiving Atriance should be monitored regularly for changes in blood cell counts and should receive adequate hydration if they are at risk of tumour lysis syndrome (a complication due to the breakdown of cancer cells).

For more information about using Atriance, see the package leaflet or contact your doctor or pharmacist.

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## **How does Atriance work?**

The active substance in Atriance, nelarabine, is a cytotoxic, a medicine that kills cells that are dividing, such as cancer cells. It belongs to the group of cancer medicines called 'antimetabolites'.

Nelarabine is converted within cells into an analogue of guanine, one of the fundamental chemicals that make up DNA. In the body, this analogue takes the place of guanine and interferes with the enzymes involved in making new DNA, DNA polymerases. This stops the production of DNA and thus slows down the growth and multiplication of cells. Because the guanine analogue accumulates in T-cells and lasts longer in these cells, Atriance slows down the growth and multiplication of the cells involved in T-ALL and T-LBL.

## **What benefits of Atriance have been shown in studies?**

Atriance was shown to be effective in two main studies involving patients with T-ALL and T-LBL whose cancer had stopped responding to one or more previous cancer treatments. In both studies, the patients were treated with Atriance, but its effects were not compared with those of any other medicine. The first study involved 70 children and young adults below 21 years of age. Of those whose cancer had not responded to two or more previous treatments (39) five (13%) had a complete response to treatment after a month, with no evidence of disease and normal blood counts. In the second study, involving a total of 40 adults and adolescents above the age of 16. Of those whose cancer had not responded (28) five (18%) had a complete response to treatment. In both studies, compared to patients who had a complete response more patients had a partial response to Atriance treatment, with blood counts returning towards normal levels.

## **What are the risks associated with Atriance?**

The most common side effects with Atriance in adults (which may affect more than 1 in 10 people) are infection, febrile neutropenia (low white blood cell counts with fever), neutropenia (low white blood cell counts), thrombocytopenia (low platelet counts), anaemia (low red blood cell counts), somnolence (sleepiness), peripheral neuropathy (damage to the nerves in the extremities), hypoaesthesia (a reduced sense of touch), paraesthesia (unusual sensations like pins and needles), dizziness, headache, dyspnoea (breathlessness), cough, diarrhoea, vomiting, constipation, nausea (feeling sick), myalgia (muscle pain), oedema (swelling), peripheral oedema (swelling in ankles and feet), pyrexia (fever), pain, tiredness and weakness. Most of these side effects were also very common in children.

Severe side effects affecting the brain and nervous system have also been reported in patients taking Atriance, including somnolence, convulsions, and peripheral neuropathy causing numbness, unusual sensations, weakness and even paralysis. Patients should be monitored closely for these side effects and treatment stopped if necessary.

For the full list of side effects and restrictions of Atriance, see the package leaflet.

## **Why is Atriance authorised in the EU?**

The European Medicines Agency decided that Atriance's benefits are greater than its risks and it can be authorised for use in the EU. The Agency noted that, due to the small number of patients with these diseases, the information to support the authorisation of Atriance is limited, but it agreed that the medicine could allow some patients to go on to receive bone-marrow transplantation, increasing their chances of survival.

Atriance has been authorised under 'exceptional circumstances'. This means that because the diseases are rare, it has not been possible to obtain complete information about Atriance. Every year, the

Agency will review any new information that may become available and this overview will be updated as necessary.

### **What information is still awaited for Atriance?**

Since Atriance has been authorised under exceptional circumstances, the company that markets Atriance will provide yearly updates from a study on the effectiveness and safety of Atriance in children and young adults.

### **What measures are being taken to ensure the safe and effective use of Atriance?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Atriance have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Atriance are continuously monitored. Side effects reported with Atriance are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Atriance**

Atriance received a marketing authorisation valid throughout the EU on 22 August 2007.

Further information on Atriance can be found on the Agency's website:

<https://www.ema.europa.eu/en/medicines/human/EPAR/atricance>

This overview was last updated in 11-2019.