

Aranesp[®]

darbepoetin alfa

Consumer Medicine Information (CMI)

WARNING FOR CANCER PATIENTS: Your doctor can use Aranesp to treat anaemia if you are receiving chemotherapy for cancer and your doctor decides that blood transfusion is not an option for you. In some clinical studies, the use of Aranesp to treat anaemia was associated with increased risk of death in patients receiving chemotherapy for cancer.

What is in this leaflet

This leaflet answers some common questions about Aranesp (darbepoetin alfa). It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Aranesp against the benefits he/she expects it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Read this leaflet carefully before you start Aranesp and keep it with the medicine.

You may need to read it again.

What Aranesp is used for

Aranesp is used to treat anaemia in cancer patients who are receiving chemotherapy. Anaemia is when your blood does not contain enough red blood cells.

Anaemia can occur as a result of chemotherapy medicines used to treat cancer. Some chemotherapy medicines can affect the bone marrow's ability to make red blood cells. When your red blood cell count

falls too low, you become anaemic. Some affects of anaemia can include tiredness, dizziness, increased heart beat, depression, anorexia, nausea, feeling cold and pale skin colour.

Aranesp is a recombinant erythropoietic protein produced by special mammalian cells. Your doctor has given you Aranesp to treat the anaemia caused by the chemotherapy medicines used to treat your cancer and where blood transfusion is not considered appropriate. Aranesp will help your bone marrow to produce more red blood cells, like your natural erythropoietin. The active ingredient of Aranesp is darbepoetin alfa that works in exactly the same way as the natural hormone erythropoietin.

It will take your body a short time to make red blood cells, so it will be about 4 weeks before you notice any effect.

Anaemia can occur as a result of cancer. Aranesp should not be used to treat anaemia that results from cancer.

Your doctor may have prescribed Aranesp for another reason. Ask your doctor if you have any questions about why Aranesp has been prescribed for you.

Before you use it

When you must not use Aranesp

Do not use Aranesp if you have:

- High blood pressure that is not controlled by other medicines.
- Allergies to other erythropoietin products, Aranesp, medicines made using mammalian cells, or to any of the other ingredients in Aranesp listed at the end of this leaflet.

Symptoms of a severe allergic reaction may include:

- Drop in blood pressure (faintness), fast pulse, difficulty breathing and sweating
- Swelling of the face, lips, mouth tongue or throat.
- Shortness of breath
- Skin rash, including rash over the whole body
- Hives

Talk to your doctor, nurse or pharmacist if you have any questions about this information.

Do not give Aranesp to a child.

There is not enough information at present to recommend using Aranesp in children.

Do not use Aranesp after the expiry date (Exp.) stamped on the pack.

If you use Aranesp after the expiry date has passed, it may not work as well.

Do not use Aranesp if the packaging is torn or shows signs of tampering.

Before you start to use it

You must tell your doctor if:

1. You have or have had any medical conditions, especially the following:

- Blood clotting diseases.
- Epilepsy or convulsions (fits or seizures).
- Any other illness or health problems. A number of conditions such as infections and vitamin deficiencies may affect how well you respond to Aranesp.
- An allergy to latex. The needle shield on the pre-filled pen and the needle cover on pre-filled syringe contain a derivative of latex.

2. You are pregnant or intend to become pregnant.

3. You are breastfeeding or planning to breastfeed.

It is not known whether Aranesp passes into breast milk.

If you have not told your doctor about any of the above, tell him/her before you use Aranesp.

Taking other medicines

Tell your doctor, nurse or pharmacist if you are taking any other medicines, including any medicines you buy without a prescription from your pharmacy, supermarket or health food shop.

How to use it

Following blood tests, your doctor has decided you need Aranesp. Your doctor will work out the correct amount of Aranesp for you and tell you how much you must take.

While you are taking Aranesp, your doctor will take blood samples to measure how your anaemia is responding and may change the strength if necessary.

Your doctor will check your blood pressure regularly.

In some cases your doctor may recommend that you take iron supplements.

Aranesp can be injected either:

- **under the skin (subcutaneous injection) using either the pre-filled pen, the pre-filled syringe or the pre-filled syringe with automatic needle guard; or**
- **into a vein (intravenous injection) using the pre-filled syringe or the pre-filled syringe with automatic needle guard.**

You can give yourself a subcutaneous injection after you have received training from your doctor or nurse. Intravenous injections are given by a doctor or nurse.

Aranesp is given by injection, once a week or in some cases once every three weeks. Your doctor will decide which injection frequency, strength of Aranesp and injection method is best for you.

Carefully follow all directions given to you by your doctor, pharmacist or nurse.

They may differ from the information in this leaflet.

If you do not understand the instructions, ask your doctor, pharmacist or nurse for help.

While you are using it

How much Aranesp to inject

Your doctor has prescribed the strength of Aranesp that is best for you. You need to inject the full contents of the syringe.

When to inject Aranesp

You will need to give yourself an injection once a week or in some cases once every three weeks. Your doctor will decide which injection frequency is best for you.

If you forget to use it

If you have forgotten to inject Aranesp, contact your doctor or nurse to discuss when you should next inject.

If you inject too much (overdose)

If you inject more Aranesp than you need, you should contact your doctor, nurse or pharmacist.

Things you must do

Always follow your doctor's instructions carefully.

If you are about to start taking a new medicine, tell your doctor, nurse and pharmacist that you are using Aranesp.

If you become pregnant while you are using Aranesp, tell your doctor.

Things you must not do

DO NOT use Aranesp to treat any other complaint unless your doctor says so.

DO NOT give Aranesp to anyone else, even if their symptoms seem similar to yours.

Side Effects

Tell your doctor as soon as possible if you have any problems while using Aranesp, even if you do not think the problems are connected with Aranesp or are not listed in this leaflet.

Like other medicines, Aranesp may cause side effects. Some side effects may be serious and need medical attention. Other side effects are minor and are likely to be temporary. Some of the side effects listed below

may be due to your cancer or the chemotherapy used to treat the cancer rather than Aranesp.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

If any of the following happens, stop injecting Aranesp, contact your doctor immediately, or go to the Accident and Emergency at your nearest hospital, as you may need urgent medical attention:

- Serious allergic or hypersensitivity reactions:
 - Drop in blood pressure (faintness), fast pulse, difficulty breathing and sweating
 - Swelling of the face, lips, mouth tongue or throat which may cause difficulty in swallowing or breathing.
 - Shortness of breath
 - Skin rash, including rash over the whole body
 - Hives
- Severe skin reactions. A rash, which may be severe, may cover your whole body and can also include blisters or areas of skin coming off.
- Signs of a sudden rise in blood pressure such as sudden, stabbing, migraine-like headaches, confusion or seizures.
- Signs of a stroke such as tingling of the extremities, slight weakness on one side of the body, speech difficulties, double vision, dizziness, headache and imbalance.
- Signs of a heart attack such as chest pain.
- Sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness heat or swelling in the arms and legs.

The following symptoms may be serious and could possibly become life-threatening if not treated promptly.

Tell your doctor, nurse or pharmacist if you experience any of the following:

- Light-headedness, headache, pins and needles, diminished sense of touch.
- Nausea (feeling sick), vomiting, diarrhoea, constipation, loss of appetite.
- Pain in your joints, limbs, muscles or bones.
- Difficulty in breathing, cough, chest or throat infection.
- Hair loss, rash.
- Redness, swelling, pain or itching at the site of injection.

Very rarely convulsions (fits or seizures) have been reported in patients with receiving Aranesp.

A condition called pure red cell aplasia (PRCA) has been rarely reported after months to years of treatment with recombinant forms of erythropoietin.

This condition is found mostly in patients with chronic kidney disease and means the absence of very young red blood cells in the bone marrow. If this condition develops, patients lose the good response they have been having to the treatment for anaemia. The cause of this is presently not known.

Tell your doctor if you experience more tiredness than usual.

Although PRCA is rare, you should know that you would have to stop injecting Aranesp and would need to have regular blood transfusions to treat your anaemia.

Tell your doctor, nurse or pharmacist if you notice anything that worries you or that is making you feel unwell, even if it is not on this list. Other side effects not listed above may occur in some people.

After using it

Storage

Keep your Aranesp in the refrigerator (between 2 and 8°C), but not in the freezer.

You can use Aranesp if it has been left out of the refrigerator, for no longer than 2 days at room temperature (up to 30°C).

Do not use Aranesp if you think that it has been frozen for longer than 2 days.

You can use Aranesp if accidentally left frozen for less than 2 days.

Always keep Aranesp in the original box to protect it from light.

As with all medicines, you should keep Aranesp out of the reach and sight of children.

Disposal of used syringes

Do not attempt to put the needle cover back onto the used syringe.

Put used pre-filled pens and pre-filled syringes into the puncture-resistant sharps container and keep it out of the reach and sight of children.

Dispose of the full puncture-resistant sharps container as instructed by your doctor, nurse or pharmacist.

Never put the used pre-filled pens or used pre-filled syringes into your normal household rubbish bin.

Product Description

What it looks like

Aranesp is a clear, colourless liquid available as:

- pre-filled pens containing from 20 to 150 microgram of darbepoetin alfa in each pre-filled pen. Aranesp SureClick is available in packs containing 1 pre-filled pen.
- pre-filled syringes with automatic needle guard, containing from 20

to 150 microgram of darbepoetin alfa in each pre-filled syringe. Aranesp is available in packs containing 4 pre-filled syringes.

- pre-filled syringe containing 10 microgram of darbepoetin alfa. Aranesp is available in packs containing 4 pre-filled syringes.

Ingredients

Active ingredient

The active ingredient in Aranesp is darbepoetin alfa.

Other ingredients

- Polysorbate 80
- Monobasic Sodium phosphate monohydrate
- Dibasic Sodium phosphate
- Sodium chloride
- Water for Injection

The needle shield on the pre-filled pen and the needle cover on the pre-filled syringe contain a derivative of latex.

Aranesp does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Aranesp is supplied in Australia by:

Amgen Australia Pty Ltd

Level 7, 123 Epping Road

North Ryde NSW 2113

ABN 31 051 057 428

Tel: (02) 9870 1333

Fax: (02) 9870 1344

Medical Information: 1800 803 638

Australian Registration Numbers

Pre-filled pen:

Aranesp 20 microgram/0.5 mL

AUST R 122853

Aranesp 40 microgram/0.4 mL

AUST R 122851

Aranesp 60 microgram/0.3 mL

AUST R 122849

Aranesp 80 microgram/0.4 mL

AUST R 122855

Aranesp 100 microgram/0.5 mL

AUST R 122852

Aranesp 150 microgram/0.3 mL

AUST R 122854

Pre-filled syringe with automatic needle guard:

Aranesp 20 microgram/0.5 mL

AUST R 166090

Aranesp 30 microgram/0.3 mL

AUST R 166092

Aranesp 40 microgram/0.4 mL

AUST R 166094

Aranesp 50 microgram/0.5 mL

AUST R 166095

Aranesp 60 microgram/0.3 mL

AUST R 166688

Aranesp 80 microgram/0.4 mL

AUST R 166097

Aranesp 100 microgram/0.5 mL

AUST R 166087

Aranesp 150 microgram/0.3 mL

AUST R 166089

Pre-filled syringe:

Aranesp 10 microgram/0.4 mL

AUST R 77950

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