

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using Aranesp?

Aranesp contains the active ingredient darbepoetin alfa. Aranesp is used to treat anaemia that is associated with chronic renal failure (kidney failure) and anaemia in cancer patients who are receiving chemotherapy.

For more information, see Section [1. Why am I using Aranesp?](#) in the full CMI.

### 2. What should I know before I use Aranesp?

Do not use if you have ever had an allergic reaction to Aranesp or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Aranesp?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Aranesp and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Aranesp?

- Following blood tests, your doctor will prescribe the strength of Aranesp that is best for you.
- Aranesp can be self-administered by injection under the skin after training from your doctor or nurse. It can also be injected into a vein by a doctor or nurse.

More instructions can be found in Section [4. How do I use Aranesp?](#) in the full CMI.

### 5. What should I know while using Aranesp?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.</li><li>• Keep all of your doctor's appointments so that your progress can be monitored.</li><li>• Remind your doctor, dentist, nurse or pharmacist on your visit that you are using Aranesp.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not inject Aranesp into a vein yourself.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Aranesp in the refrigerator (between 2 to 8°C). Do not freeze.</li><li>• Keep in the original box to protect it from light until it's time to inject it. Do not shake.</li></ul>

For more information, see Section [5. What should I know while using Aranesp?](#) in the full CMI.

### 6. Are there any side effects?

Serious side effects include serious allergic or hypersensitivity reaction, severe skin reactions, sudden rise in blood pressure, seizures or fits, stroke, heart attack, blood clots, pure red cell aplasia (PRCA), problems with dialysis shunt and high blood pressure.

Very common side effects include redness, swelling, pain or itching at the injection site, tiredness, chest or throat infection, difficulty breathing, cough, itching, fast heart rate, shortness of breath, and chest tightness, fever, flu-like feeling, headache, dizziness, nausea, vomiting, diarrhoea, constipation, loss of appetite, stomach pain, pins and needles, diminished sense of touch, pain in joints, limbs, muscles or bones and fluid retention.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full 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.

# Aranesp<sup>®</sup>

Active ingredient(s): darbepoetin alfa

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Aranesp. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Aranesp.**

Where to find information in this leaflet:

- [1. Why am I using Aranesp?](#)
- [2. What should I know before I use Aranesp?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Aranesp?](#)
- [5. What should I know while using Aranesp?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Aranesp?

**Aranesp contains the active ingredient darbepoetin alfa.** Aranesp is recombinant erythropoietic protein produced by special mammalian cells.

Aranesp is used to treat anaemia. Anaemia is a condition where the blood does not contain a sufficient amount of red blood cells. The symptoms of anaemia may include fatigue, dizziness, increased heart rate, depression, nausea, loss of appetite, feeling cold, shortness of breath and pale skin colour.

Aranesp works in exactly the same way as the natural hormone erythropoietin. Erythropoietin is produced in the kidneys and encourages bone marrow to produce more red blood cells. It will take your body some time to make more red blood cells, so it can take about four weeks before you notice any effect.

**Aranesp is used to treat:**

- anaemia that is associated with chronic renal failure (kidney failure).**

In kidney failure, the kidney does not produce enough of the natural hormone erythropoietin which can often cause anaemia. If you are on dialysis, your normal dialysis routine will not affect the ability of Aranesp to treat your anaemia.
- anaemia in cancer patients who are receiving chemotherapy.**

Some chemotherapy medicines can affect the bone marrow's ability to produce enough red blood cells.

## 2. What should I know before I use Aranesp?

### Warnings

**Do not use Aranesp if:**

- you have high blood pressure that is not controlled by other medicines.
- you are allergic to other erythropoietin products, Aranesp, medicines made using mammalian cells, or to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

**Do not misuse Aranesp.**

Misuse by healthy people can cause life-threatening problems with the heart or blood vessels.

**Check with your doctor if you:**

- have any blood clotting diseases,
- have epilepsy or convulsions (fits or seizures),
- have 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,
- have any other illness or health problems, a number of conditions such as infections, vitamin deficiencies or cancers may affect how well you respond to Aranesp,
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

**Patients with cancer**

**In some clinical studies, the use of Aranesp to treat anaemia was associated with increased risk of death in patients receiving chemotherapy for cancer.**

**Discuss this with your doctor.**

**Pregnancy**

Check with your doctor if you are pregnant or intend to become pregnant.

**Breastfeeding**

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if Aranesp passes into breast milk.

## Use in children

Do not give Aranesp to a child.

### 3. What if I am taking other medicines?

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Aranesp.**

### 4. How do I use Aranesp?

#### How much to use

- Following blood tests, your doctor has prescribed the strength of Aranesp that is best for you. You need to inject the full contents of the syringe.
- While you are taking Aranesp, your doctor will take blood samples to measure how well your anaemia is responding and may change the strength if necessary.
- Follow the instructions provided and use Aranesp until your doctor tells you to stop.

#### When to use Aranesp

- Your doctor will decide which injection frequency is best for you. Aranesp should be used once a week, once every two weeks, once every three weeks, or once a month.

#### How to inject Aranesp

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.

#### Never inject Aranesp into a vein yourself.

If you have any questions regarding injecting instructions, please ask your doctor, nurse or pharmacist for assistance.

#### If you forget to use Aranesp

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

**Do not take a double dose to make up for the dose you missed.**

#### If you use too much Aranesp

If you think that you have injected too much Aranesp, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using Aranesp?

#### Things you should do

- Tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- If you are about to start a new medicine, remind your doctor, nurse and pharmacist that you are taking Aranesp.
- If you are going to have surgery, tell the surgeon that you are taking this medicine.
- Keep all of your doctor's appointments so that your progress can be monitored. 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.

**Always follow your doctor's instructions carefully.**

#### Call your doctor straight away if you have:

- Serious allergic or hypersensitivity reactions such as drop in blood pressure (faintness), fast pulse, difficulty breathing, 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 such as 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, seizures or fits.
- Signs of stroke such as tingling of the extremities, slight weakness on one side of the body, speech difficulties, double vision, dizziness, headache, 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.
- If you have symptoms which include unusual tiredness and a lack of energy this could mean you have pure red cell aplasia (PRCA), which has been reported in patients with chronic kidney failure. PRCA means the absence of very young red blood cells in the bone marrow.

Remind any doctor, dentist or pharmacist you visit that you are using Aranesp.

## Things you should not do

- Do not inject Aranesp into a vein yourself.
- Do not stop using this medicine suddenly.
- Do not use Aranesp to treat any other condition unless your doctor says so.
- Do not give Aranesp to anyone else, even if their symptoms seem similar to yours.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Aranesp affects you.**

The effects on your ability to drive or use machines whilst taking Aranesp are not known.

## Looking after your medicine

- Keep Aranesp in the refrigerator (between 2 and 8°C). 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 freeze. 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.
- Do not shake.

Follow the instructions on the carton on how to take care of your medicine properly.

The pre-filled syringe with automatic needle guard can be taken out of the refrigerator 30 minutes before injection, provided it is kept in the carton. This may make the injection more comfortable.

The pre-filled pen can be taken out of the refrigerator at least 30 minutes before injection, provided it is kept in the carton.

Do not use this medicine after the expiry date.

**Keep it where young children cannot reach it.**

## When to discard your medicine

**Do not use Aranesp if it has been left out of the refrigerator at room temperature for longer than 2 days.**

**Do not use Aranesp if it has been frozen for longer than 2 days.**

## 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.

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

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

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may be serious and need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Injection site:</b></p> <ul style="list-style-type: none"><li>• redness</li><li>• swelling</li><li>• pain</li><li>• itching</li></ul> <p><b>Lung and upper airways:</b></p> <ul style="list-style-type: none"><li>• chest or throat infection</li><li>• shortness of breath or difficulty breathing</li><li>• chest tightness or pain (non-cardiac)</li><li>• cough</li><li>• flu-like symptoms</li><li>• bleeding from the nose</li></ul> <p><b>Brain and nerves:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• dizziness, light-headedness</li><li>• pins and needles</li><li>• diminished sense of touch</li></ul> <p><b>Skin:</b></p> <ul style="list-style-type: none"><li>• itching</li><li>• hair loss</li></ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"><li>• nausea (feeling sick)</li><li>• stomach pain</li><li>• diarrhoea, constipation</li><li>• vomiting</li><li>• decreased appetite</li></ul> <p><b>Muscle and skeleton:</b></p> <ul style="list-style-type: none"><li>• pain in joints, limbs, back, muscles or bones</li></ul> <p><b>Urinary:</b></p> <ul style="list-style-type: none"><li>• urinary tract infection (pain in abdomen or pelvic region, stinging or burning urine, more frequent need to pass urine)</li></ul> <p><b>General:</b></p> <ul style="list-style-type: none"><li>• tiredness and weakness</li><li>• fever, chills</li><li>• fast heart rate</li><li>• trouble sleeping</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Signs of a condition called pure red cell aplasia (PRCA)</b></p> <ul style="list-style-type: none"> <li>more tiredness than usual</li> </ul> <p><b>Signs of problems with your dialysis shunt:</b></p> <ul style="list-style-type: none"> <li>bleeding, infection or clotting in your shunt (a channel that bypasses normal blood circulation) if you are receiving haemodialysis</li> </ul> <p><b>Signs of high blood pressure:</b></p> <ul style="list-style-type: none"> <li>headache</li> <li>bleeding from the nose</li> </ul>	<p><b>Call your doctor straight away if you notice any of these serious side effects.</b></p>
<p><b>Signs of a serious allergic or hypersensitivity reaction:</b></p> <ul style="list-style-type: none"> <li>drop in blood pressure (faintness)</li> <li>fast pulse</li> <li>difficulty breathing</li> <li>sweating</li> <li>swelling of the face, lips, mouth tongue or throat which may cause difficulty in swallowing or breathing</li> <li>shortness of breath</li> <li>skin rash, including rash over the whole body, hives</li> </ul> <p><b>Signs of severe skin reactions:</b></p> <ul style="list-style-type: none"> <li>a rash, which may be severe, may cover your whole body and can also include blisters or areas of skin coming off</li> </ul> <p><b>Signs of a sudden rise in blood pressure:</b></p> <ul style="list-style-type: none"> <li>sudden, stabbing, migraine-like headaches</li> <li>confusion</li> <li>seizures or fits</li> </ul> <p><b>Signs of stroke:</b></p> <ul style="list-style-type: none"> <li>tingling of the extremities</li> <li>slight weakness on one side of the body</li> <li>speech difficulties</li> <li>double vision</li> <li>dizziness</li> <li>headache</li> <li>imbalance</li> </ul> <p><b>Signs of a heart attack:</b></p> <ul style="list-style-type: none"> <li>chest pain</li> <li>dizziness</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>shortness of breath or difficulty breathing</li> </ul> <p><b>Other side effects:</b></p> <ul style="list-style-type: none"> <li>sudden severe headache</li> <li>loss of vision</li> <li>loss of coordination</li> <li>slurred speech, shortness of breath</li> <li>chest pain</li> <li>numbness, heat or swelling in the arms and legs</li> <li>convulsions, fits or seizures</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Aranesp contains

<b>Active ingredient (main ingredient)</b>	darbepoetin alfa
<b>Other ingredients (inactive ingredients)</b>	polysorbate 80 monobasic sodium phosphate monohydrate dibasic sodium phosphate sodium chloride water for Injection

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Aranesp 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.

#### 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)

### **Who distributes Aranesp**

Amgen Australia Pty Ltd

Level 11, 10 Carrington St

Sydney NSW 2000

Ph: 1800 803 638

[www.amgenmedinfo.com.au](http://www.amgenmedinfo.com.au)

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