

Aranesp[®]

darbepoetin alfa

Consumer Medicine Information (CMI)

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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 that comes about because of chronic renal failure (kidney failure). Anaemia is when your blood does not contain enough red blood cells.

In kidney failure, the kidney does not produce enough of the natural hormone erythropoietin.

Erythropoietin encourages your bone marrow to produce more red blood cells. Kidney failure can often cause anaemia, which may require you to have blood transfusions.

Aranesp is a recombinant erythropoietic protein produced by special mammalian cells. Your doctor has given you Aranesp to treat your anaemia. It will reduce your need for blood transfusions. 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. If you are on dialysis, your normal dialysis routine will not affect the ability of Aranesp to treat your anaemia.

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 it

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, vitamin deficiencies or cancers 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 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 two weeks or once every month.

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.

How to inject using the Aranesp[®] SureClick[®] (pre-filled pen)

This section contains information on how to give yourself an injection using the Aranesp SureClick (pre-filled pen). It is important that you DO NOT try to give yourself the injection unless you have received special training from your doctor or nurse. If you are not sure about giving the injection or you have any questions, please ask your doctor or nurse for help.

Things to do before you inject:

To give yourself a subcutaneous injection you will need:

- a new Aranesp pre-filled pen

- a puncture-resistant sharps container
- an alcohol swab



Do the following before you give yourself a subcutaneous injection of Aranesp:

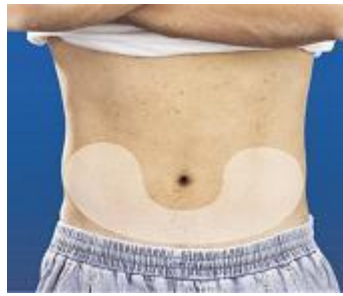
1. Find a comfortable, well-lit, clean surface and put all the equipment you need within reach.
2. Remove the pre-filled pen from the refrigerator.
3. DO NOT shake the pre-filled pen.
4. DO NOT remove the grey needle shield from the pre-filled pen until you are ready to inject.
5. Check that it is the correct strength that your doctor has prescribed.
6. Check the expiry date on the pre-filled pen label (Exp.). DO NOT use it if the date has passed the last day of the month shown.
7. Check the appearance of Aranesp through the inspection window. It must be a clear colourless liquid. If it is cloudy or there are particles in it, you must not use it.
8. For a more comfortable injection, leave at room temperature for approximately 30 minutes. DO NOT warm Aranesp in any other way (for example, DO NOT warm it in a microwave or in hot water). DO NOT leave the pre-filled pen exposed to direct sunlight.
9. Wash and dry your hands.

Where to inject

The best injection sites (see pictures below) are:

- your abdomen, except for the area around the navel (belly button) or
- the top and side of your thighs.

Change the place that you inject each time so you do not become sore in one area. If someone else is injecting you, they can also use the back of your arms.



How to inject into the abdomen using Aranesp SureClick (pre-filled pen)

Remove the grey needle shield.



Important skin pinch technique

- The skin pinch technique will create a firm site for the injection. If a firm site is not used, the pre-filled pen may not inject properly.
- Choose a site at least 5 cm away from the navel.
- Clean the site where the injection is to be made with an alcohol swab and allow the site to dry.
- Pinch the skin of the abdomen firmly between the thumb and fingers creating a space at least 3 cm wide (twice the width of the tip of the pre-filled pen). Maintain a firm skin pinch for the entire procedure.

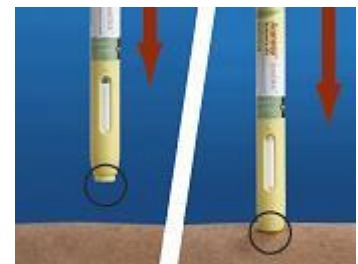


Step 1

Centre the pre-filled pen in the area of the pinched skin at a right angle (90 degrees) and push firmly against the skin. Hold down.



Press the pre-filled pen firmly enough against the skin so that the yellow safety cover is fully retracted. This will be possible without excessive pressure.



Step 2

Maintain a firm skin pinch use your thumb to (1) press - you will hear a "click" - and (2) release the red button on top.

Do not lift the pre-filled pen.

Do not keep your thumb on the red button after you have pressed it.

The Aranesp is now being injected under your skin.



Step 3

Count slowly to 15 (you may hear a second 'click' as the red button pops back up).



Check the inspection window. It should be yellow. Your Aranesp has now been fully injected. Lift the SureClick pen from the

injection site. Consult your doctor, nurse or pharmacist if you have any questions.

The yellow safety cover will move down over the needle and lock into place. The inspection window will be yellow, confirming the injection is complete.



Before use (with grey needle shield)	Just prior to use (without grey needle shield)	After use (yellow needle cover comes down)
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If you experience difficulties choose a more firm injection site.

If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues.

DO NOT rub the injection site. If needed, you may cover the injection site with a dressing.

You cannot reuse the Aranesp SureClick pre-filled pen.

Do not put the grey needle shield back on the used pre-filled pen.

Put the used pre-filled pen in the puncture-resistant sharps container.



How to inject into the thigh or back of the arm using Aranesp SureClick (pre-filled pen)

Remove the grey needle shield.



Step 1

Clean the site where the injection is to be made with an alcohol swab and allow the site to dry

Grasp the pre-filled pen in your hand, ensuring that you are holding it towards the upper half of the pen (see picture).

Place the pre-filled pen on the injection site at a right angle (90 degrees) and push firmly against the skin. Hold down (see picture).



Press the pre-filled pen firmly enough against the skin so that the yellow safety cover is fully retracted (see picture). This will be possible without excessive pressure.



Step 2

While holding the pre-filled pen in place, use your thumb to (1) press - you will hear a "click" - and (2) release the red button on top.

Do not keep your thumb on the red button after you have pressed it.

Do not lift the pre-filled pen.

The Aranesp is now being injected under your skin.



Step 3

Count slowly to 15 (you may hear a second 'click' as the red button pops back up).



Check the inspection window. It should be yellow. Your Aranesp has now been fully injected. Lift the SureClick pen from the injection site. Consult your doctor, nurse or pharmacist if you have any questions.

The yellow safety cover will move down over the needle and lock into place. The inspection window will be yellow, confirming the injection is complete.



Before use (with grey needle shield)	Just prior to use (without grey needle shield)	After use (yellow needle cover comes down)
--------------------------------------	--	--

If you experience difficulties choose a more firm injection site.

If you notice a spot of blood at the injection site, dab away with a cotton ball or tissues.

DO NOT rub the injection site. If needed, you may cover the injection site with a dressing.

You cannot reuse the Aranesp SureClick pre-filled pen.

Do not put the grey needle shield back on the used pre-filled pen.

If there are any problems with administering the product, place

the product back into original packaging and contact a pharmacy.

Put the used pre-filled pen in the puncture-resistant sharps container.



How to inject Aranesp using a pre-filled syringe with an automatic needle guard

Important

Before you use Aranesp pre-filled syringe with automatic needle guard, read this important information:

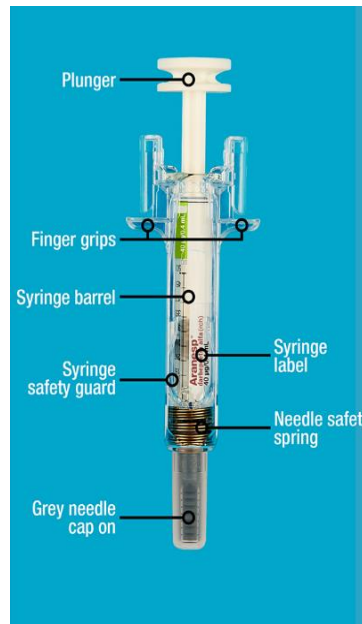
- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Aranesp is given as an injection into the tissue just under the skin (subcutaneous injection).
- Tell your doctor if you have an allergy to latex. The needle cover on the pre-filled syringe contains a derivative of latex and may cause severe allergic reactions.
- DO NOT remove the grey needle cap from the pre-filled syringe until you are ready to inject.
- DO NOT use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.
- DO NOT attempt to activate the pre-filled syringe prior to injection.

- DO NOT attempt to remove the peelable label on the pre-filled syringe barrel before administering your injection.
- DO NOT attempt to remove the clear pre-filled syringe safety guard from the pre-filled syringe.

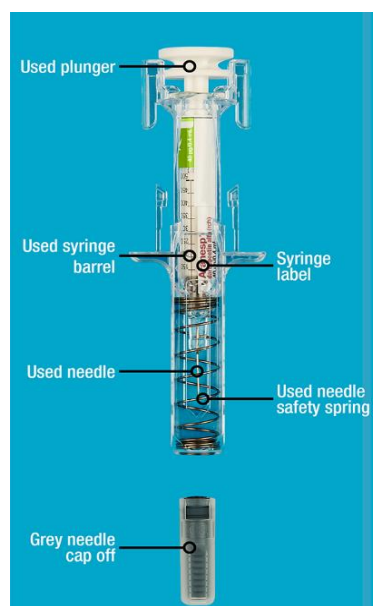
Call your doctor or healthcare provider if you have any questions.

Guide to parts

Before use



After use



How to use the Aranesp pre-filled syringe with automatic needle guard?

Things to do before you inject

A. Remove the pre-filled syringe tray from the package and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a dressing and a sharps disposal container (may be included).

Put the original package with any unused syringes back in the refrigerator.

For a more comfortable injection, leave the pre-filled syringe at room temperature for about 30 minutes before injecting. Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the new pre-filled syringe and the other supplies.

- DO NOT try to warm the syringe by using a heat source such as hot water or microwave
- DO NOT leave the pre-filled syringe exposed to direct sunlight
- DO NOT shake the pre-filled syringe
- **Keep pre-filled syringes out of the sight and reach of children**

B. Open the tray, peeling away the cover. Grab the pre-filled syringe safety guard to remove the pre-filled syringe from the tray.



For safety reasons:

- DO NOT grasp the plunger
- DO NOT grasp the grey needle cap

C. Inspect the medicine and pre-filled syringe.

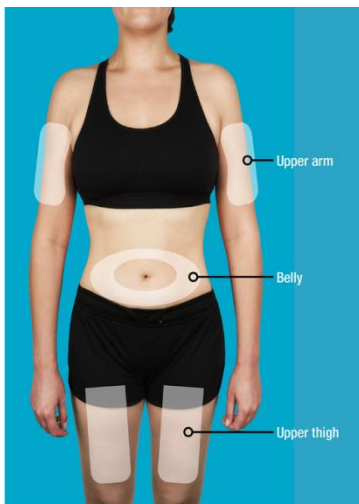


- **DO NOT use the pre-filled syringe if:**
 - The medicine is cloudy or there are particles in it. It must be a clear and colourless liquid.
 - Any part appears cracked or broken.
 - The grey needle cap is missing or not securely attached.
 - The expiry date printed on the label has passed the last day of the month shown.

In all cases, call your doctor or healthcare provider.

Where to inject

- A. Wash hands thoroughly. Prepare and clean your injection site.**



You can use:

- Upper part of your thigh
- Belly, except for a 5 cm (2-inch) area right around your belly button
- Outer area of upper arm (only if someone else is giving you the injection)

Clean the injection site with an alcohol wipe. Let your skin dry.

- DO NOT touch the injection site before injecting
 - Choose a different site each time you give yourself an injection. If you need to use the same injection site, just make sure it is not the same spot on that site you used last time.
 - DO NOT inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- B. Carefully pull the grey needle cap straight out and away from your body.**



- C. Pinch your injection site to create a firm surface.**



- It is important to keep the skin pinched when injecting.

How to inject

- A. Hold the pinch. INSERT needle into skin.**



- DO NOT touch the cleaned area of the skin
- B. PUSH the plunger with slow and constant pressure until you feel or hear a "snap". Push all the way down through the snap.**



- It is important to push down through the "snap" to deliver your full dose.

- C. RELEASE your thumb. Then LIFT the syringe off skin.**



After releasing the plunger, the pre-filled syringe safety guard will safely cover the injection needle.

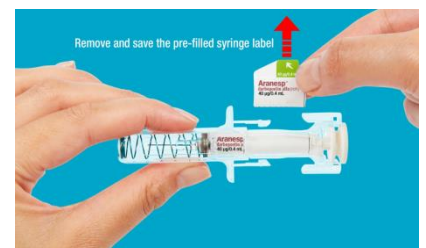
- DO NOT put the grey needle cap back on used pre-filled syringes.

How to remove the detachable label

Healthcare providers only

- DO NOT attempt to remove the peelable label on the pre-filled syringe barrel before administering your injection.

The trade name of the administered product should be clearly recorded in the patient file.



Turn the plunger to move the label into a position where you can remove the syringe label.

Disposing

- A. Discard the used pre-filled syringe and other supplies in a sharps disposal container.**



Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Keep the syringe and sharps disposal container out of sight and reach of children.

- DO NOT reuse the pre-filled syringe
- DO NOT recycle pre-filled syringes or throw them into household waste

B. Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. DO NOT rub the injection site. Apply a dressing if needed.

How to inject using the Aranesp pre-filled syringe

This section contains information on how to give yourself an injection of Aranesp using the pre-filled syringe.

It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. If you are not sure about giving the injection or you have any questions, please ask your doctor or nurse for help.

Things to do before you inject:

To give yourself a subcutaneous injection you will need:

- a new pre-filled syringe.

- a puncture-resistant sharps container.
- an alcohol swab.

Follow these instructions exactly to help avoid contamination and possible infection:

1. Find a comfortable, well-lit, clean surface and put all the equipment you need within reach.
2. Remove the pre-filled syringe from the refrigerator.
3. DO NOT shake the pre-filled syringe.
4. DO NOT remove the needle cover from the pre-filled syringe until you are ready to inject.
5. Check that it is the correct strength that your doctor has prescribed.
6. Check the expiry date on the pre-filled syringe label (Exp.). DO NOT use it if the date has passed the last day of the month shown.
7. Check the appearance of Aranesp. It must be a clear, colourless liquid. If it is cloudy or there are particles in it, you must not use it.
8. For a more comfortable injection, leave at room temperature for approximately 30 minutes. DO NOT warm Aranesp in any other way (for example, DO NOT warm it in a microwave or in hot water). DO NOT leave the pre-filled syringe exposed to direct sunlight.
9. Wash and dry your hands.

Where to inject

The best injection sites (see picture) are:

- your abdomen, except for the area around the navel (belly button) or
- the top and side of your thighs.

Change the place that you inject each time so you do not become sore in one area. If someone else is injecting for you, they can also use the back of your arms.



How to inject

1. Clean the site where the injection is to be made with an alcohol swab and allow the site to dry
2. To avoid bending the needle, firmly pull the cover from the needle straight off. DO NOT touch the needle or plunger.



3. You may notice a small air bubble in the pre-filled syringe. You do not have to remove the air bubble before injecting. Injecting the solution with the air bubble is harmless.
4. Pinch the skin between your thumb and forefinger, without squeezing it.





- Put the needle fully into the skin at an angle of about 45 degrees to 90 degrees (up to right angle).



- Push the plunger with a slow constant pressure, always keeping your skin pinched. Push the plunger all the way down as far as it will go to inject all the liquid.
- After injecting the liquid, remove the needle and let go of your skin.
- If you notice a spot of blood at the injection site dab away with a cotton ball or tissues. **DO NOT** rub the injection site. If needed, you may cover the injection site with a dressing.

DO NOT reuse the Aranesp pre-filled syringe.

DO NOT put the grey needle cover back on the used pre-filled syringe. Put the used pre-filled syringe in the puncture-resistant sharps container.



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 two weeks or once a month. 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 kidney failure 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 and go straight to the hospital, as you may need urgent medical attention:

- Serious allergic reaction:
 - 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
- 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.
- Pain in the legs or arms, with or without swelling.

These 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:

- Redness, swelling, pain or itching at the site of injection.
- Swelling of the arms, feet and legs.
- Tiredness, fever, flu-like feeling.
- Bleeding, infection or clotting in your shunt (a channel that bypasses normal blood circulation) if you are receiving haemodialysis.
- Light-headedness.
- Diarrhoea, vomiting, nausea (feeling sick), stomach pain, constipation.
- Muscle or joint aches, pain in arms, legs or back.
- Chest or throat infection, difficulty breathing, cough.
- Itching.

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.

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.

After using it

Storage

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

Do not shake. Protect from light.

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

Aranesp® is a registered trademark of Amgen.

SureClick® is a registered trademark of Amgen.

This leaflet was prepared in June 2017.