AMGEN Aranesp⁶

Package leaflet: Information for the user

Aranesp 10 micrograms solution for injection in pre-filled syringe Aranes p 10 micrograms solution for injection in pre-filled syrings Aranes p 20 micrograms solution for injection in pre-filled syrings Aranes p 30 micrograms solution for injection in pre-filled syrings aranes p 40 micrograms solution for injection in pre-filled syrings in the pre-filled syrings are pre-filled

- Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

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 The medicine has been prescribed for you only, Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

 If you get any side effects, talk to your doctor, pharmacoit or nurse. This includes any possible side reflects not listed in this intellect. See section 1.

- 1. What Aranesp is and what it is used for

- What you need to know before you use Aranesp
 How to use Aranesp
 Possible side effects
 How to tore Aranesp
 Contents of the pack and other information

1. What Aranesp is and what it is used for

Your doctor has given you Araneso (an anti-anaemic) to treat your anaemia. Anaemia is when your blood does not contain enough red blood cells and the symptoms may be fatigue, weakness and shortness of breath.

Erythropoietin is produced in your kidneys and encourages your bone marrow to produce more red blood cells. The active substance of Aranesp is darbepoetin alfa produced by gene-technology in Chinese Hamster Ovary Cells (CHO-K1).

Aranesp is used to treat symptomatic anaemia that is associated with chronic renal failure (kidney failure) in adults and children. In kidney failure, the kidney does not produce enough

Recause it will take your horly some time to make more red blood cells, it will be about four

Aranesp is used to treat symptomatic anaemia in adult cancer patients with non-bone marrow cancers (non-myeloid malignancies) who are receiving chemotherapy.

One of the main side effects of chemotherapy is that it stops the bone marrow producing enough blood cells. Towards the end of your chemotherapy course, particularly if you have had a lot of chemotherapy, your red blood cell count may fall making you anaemic.

2 What you need to know before you use Aranesn

Do not use Aranesp:

- if you are allergic to darbepoetin alfa or any of the other ingredients of this medicine (listed in section 6).
- if you have been diagnosed with high blood pressure which is not being controlled with other medicines prescribed by your doctor

Talk to your doctor, pharmacist or nurse before using Aranesp

- Please tell your doctor if you are **suffering** or **have suffered** from:

 high blood pressure which is being controlled with medicines presickle cell anaemia;

 epileptic fits (seizures); dicines prescribed by your doctor

- significant lack of response to medicines used to treat anaemia; an allergy to latex (the needle cap on the pre-filled syringe contains a derivative of latex); or

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, PRCA means that the body has stonged or reduced the production of red blood cells which causes severe anaemia. If you experience these symptoms you should contact your doctor who will determine the best course of action to treat your anaemia.

- Take special care with other products that stimulate red blood cell production: Aranesp is race special care with other products that stimulate the production of red blood cells like the human protein erythropoietin does. Your healthcare professional should always record the exact product you are using.
- If you are a patient with chronic renal failure, and particularly if you do not respond If you are a patient wint chronic renal faulure, and particularly if you do not respond properly to Arnaes, your doctor will check your dose of Araness pecuase repeatedly increasing your dose of Aranesp if you are not responding to treatment may increase the risk of having a problem of the heart or the blood vessels and could increase risk of myocardial infarction, stroke and death.
- Your doctor should try to keep your haemoglobin between 10 and 12 g/dl. Your doctor will check that your haemoglobin does not exceed a certain level, as high haemoglobin concentrations could put you at risk of having a problem of the heart or the blood vessels and could increase risk of myocardial inf
- If you have symptoms which include severe hearlache drowsiness confusion problems my our have symptoms which include severe heatacase, downsiness, contisions, problem with your eyesight, nausea, vomiting or fits (seizures), it could mean that you have very high blood pressure. If you experience these symptoms you should contact your doctor
- If you are a cancer natient you should be aware that Aranesp may act as a blood cell If you are a cancer patient you around be aware an alta values by may act as a bood coil growth factor and in some circumstances may have a negative impact on your cancer. Depending on your individual situation a blood transfusion may be preferable. Please discuss this with your doctor.
- Misuse by healthy people can cause life-threatening problems with the heart or blood vessels.
- Serious skin reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrotysis (TEI) have been reported in association with epodelin treatment. SJSTEN can appear initially as reddsh targed-like spots or circular patches often with central bisless on the trunk. Also, ubcers of mouth, throat, nose, gentlalist and eyes; dar and svoillen eyes; can cour. These serious skin raches are often precoded by fever and/or full-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications. If you develop a serious rash or another of these skin symptoms, stop taking Aranesp and contact your doctor or seek medical attention immediately

Other medicines and Arangen

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Tell your doctor or pharmacist if you are using, have recently used or might use any

Cyclosoprin and tarrollmus (medicines which suppress the immune system) may be affected by the number of red cells in your blood. It is important to tell your doctor if you are taking

Using Aranesp with food and drink

Food and drink do not affect Araneso

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Aranesp has not been tested in pregnant women. It is important to tell your doctor if you:

- are pregnant;
 think you may be pregnant; or
 plan to get pregnant.

It is not known whether darbepoetin alfa is excreted in human milk. You must stop breast-feeding

Aranesp should not affect your ability to drive or use machinery.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e.

3 How to use Aranesn

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sun

Following blood tests, your doctor has decided you need Aranesp as your haemoglobin level is 10 g/dl or less. Your doctor will tell you how much and how often you must take Aranesp in order to maintain a haemoglobin level between 10 and 12 g/dl. This may vary depending on whether you are an adult or a child.

Your doctor may decide that it is best for you or a carer to inject Aranesp. Your doctor, nurse or pharmacist will show you how to inject yourself with the pre-filled syringe. Do not try to inject yourself if you have not been trained. Never inject Aranesp into a vein yourself.

If you have chronic renal failure

For all adult and paediatric patients ≥ 1 year of age with chronic renal failure, Aranesp is given as a single injection, either under your skin (subcutaneous) or into a vein (intrayeno

- In order to correct your anaemia, your initial dose of Aranesp per kilogram of your body
- weight will be either:

 0.75 micrograms once every two weeks, or
- 0.45 micrograms once weekly.
 For adult patients not on dialysis, 1.5 micrograms/kg once monthly may also be used as the
- For all adult and paediatric patients > 1 year of age with chronic renal failure, once your

For all adults and paediatic parties 2 1 year or age was 1 was a single injection, either once a week or once every two weeks. For all adults and paediatric patients ≥ 11 years of not on dialysis, Aranesp could also be given as an injection once monthly

Your doctor will take regular blood samples to measure how your anaemia is responding and may adjust your dose once every four weeks as necessary in order to maintain long-ter control of your anaemia

Your doctor will use the lowest effective dose to control the symptoms of your anaemia

If you do not respond adequately to Aranesp, your doctor will check your dose and will inform you if you need to change doses of Araneso.

Your blood pressure will also be checked regularly, particularly at the beginning of your treatment.

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

Your doctor may decide to change the way that your injection is given (either under the skin or into a vein). If this changes you will start on the same dose as you have been receiving and your doctor will take blood samples to make sure that your anaemia is still being managed correctly.

If your doctor has decided to change your treatment from r-HuEPO (erythropoietin produced In your octor has becaute the lange you the deather in the International Control of the your framesp, they will choose whether you should receive your Aranesp injection once weekly or once every two weeks. The route of injection is the same as with r-HuEPO but your doctor will tell you how much you should take, and when, and may adjust

Aranesp is given as a single injection, either once a week or once every three weeks, under

- In order to correct your anaemia, your initial dose will be
- 500 micrograms once every three weeks (6.75 micrograms of Aranesp per kilogram of your hody weight) or
- 2.25 micrograms (once weekly) of Araneso per kilogram of your body weight

Your doctor will take regular blood samples to measure how your anaemia is responding and may adjust your dose as necessary. Your treatment will continue until approximately four weeks after the end of your chemotherapy. Your doctor will tell you exectly when to stop taking Aranesy.

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

You could have serious problems if you use more Aranesp than you need, such as very high blood pressure. You should contact your doctor, purse or pharmacist if this does hannen. If you feel unwell in any way you should contact your doctor, nurse or pharmacist immediately

If you forget to use Aranesn

If you use more Araneso than you should

Do not use a double dose to make up for a forgotten dose.

If you have forgotten a dose of Aranesp, you should contact your doctor to discuss when you

If you want to stop using Aranesp, you should discuss it with your doctor first.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them

The following side effects have been experienced by some patients taking Ara

Chronic renal failure patients

Very common: may affect more than 1 in 10 people

High blood pressure (hypertension) Allergic reactions

Common: may affect up to 1 in 10 people

- Pain around the area injected.
- may affect up to 1 in 100 people
- Convulsions (fits and seizures)

. Pure red cell aplasia (PRCA) - (anaemia, unusual tiredness, lack of energy)

Cancer patients

Very common: may affect more than 1 in 10 neonle

- Allergic reactions Fluid retention (oedema)
- Common: may affect up to 1 in 10 peopl
- High blood pressure (hypertension) Blood clots (thrombosis) Pain around the area injected
- · Rash and/or redness of the skir nmon: may affect up to 1 in 100 people

Convulsions (fits and seizures)

All patients

- Southern Trequency calmide the standards in our available data
 Ferious altergic reactions which may include:
 Sudden life-threatening allergic reactions (anaphylaxis)
 Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in equalizations or breathing foreigned
- swallowing or breathing (angioedema) Shortness of breath (allergic bronchospasm)
- Hives (urticaria)
- Serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in association with epoetin treatment. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of mouth, throat, nose, genitals and eyes and can be preceded by fever
- and not mee symptoms.

 Stop using Aranesp if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Aranesn

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton and on the pre-filled syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Do not use Aranesp if you think it has Keep the pre-filled syringe in the outer carton in order to protect from light.

When your syringe has been removed from the refrigerator and left at room temperature (up to 30°C) for approximately 30 minutes before injection it must either be used within 7 days Do not use this medicine if you notice the pre-filled syringe contents are cloudy or there are

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.

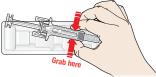
6. Contents of the pack and other information

What Aranesp contains

- and gather the supplies needed for your injection: alcohol wipes, a cotton ball or gauze pad, a plaster and a sharps disposal container (not included)

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

- X Do not try to warm the syringe by using a heat source such as hot water or microwave
- X Do not leave the pre-filled syringe exposed to direct sunlight
- Keep pre-filled syringes out of the sight and reach of children
- 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 X Do not grasp the plunger

- ✓ Do not grash the grey needle can
- Inspect the medicine and pre-filled syringe.



- X Do not use the pre-filled syringe if:
- 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

Step 2: Get ready

Wash your hands thoroughly. Prepare and clean



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

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.



Pinch your injection site to create a firm surface.



Hold the pinch, INSERT the needle into skin. X Do not touch the cleaned area of the skin

Step 3: Inject

PUSH the plunger with slow and constant pressure until you feel or hear a "snap". Push all the way down through the snap.





After releasing the plunger, the pre-filled syringe safety guard will safely cover th

Healthcare Providers only



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

Y Do not reuse the pre-filled syringe

Examine the injection site.

If there is blood press a cotton ball or nauze pad on your injection site. Do not rub the

Before you use an Aranesp pre-filled syringe with automatic needle guard, read

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider. Araneso is given as an injection into the tissue just under the skin
- Tell your doctor if you have an allergy to latex. The needle can on the pre-filled
- 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 provide x 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 Call your doctor or healthcare provider if you have any questions.

- The active substance is darhencetin affa. r.-HuEPO (enthronoietin produced by gene-technology) The pre-filled syringe contains either 10, 20, 30, 40, 50, 60, 80, 100, 150, 300 or 500 micro; of darbencetin alfa.
- to darbepoeur and.

 The other ingredients are sodium phosphate monobasic, sodium phosphate dibasic, sodium chloride, polysorbate 80 and water for injections.

What Aranesp looks like and contents of the pack

Aranesp is a clear, colourless or slightly pearly solution for injection in a pre-filled syringe.

Aranesp is available in packs of 1 or 4 pre-filled syringes with automatic needle guard in a blister wranning. Not all pack sizes may be marketed. Not all concentrations may be marketed

Site of Manufacture of the Drug Product:

Amgen Manufacturing Limited State Road 31 Kilometer 24.6 Puerto Rico USA

Marketing Authorisation Holder and Manufacturer

Amgen Furgne R V NI -4817 7K Breda

Other sources of information

http://www.ema.europa.eu

For any information about this medicine, please contact the local representative of the

This leaflet was last revised in August 2017.

Detailed information on this medicine is available on the European Medicines Agency web site:

This leaflet is available in all EU/EEA languages on the European Medicines Agency website

THIS MEDICINE ls a product, which affects your health, and its consumption contrary to instructions is

dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.

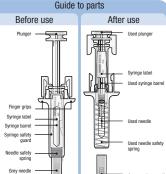
The doctor and the pharmacist are the experts in medicines, their benefits and risks.

Do not by yourself interrupt the period of treatment prescribed.

Do not repeat the same prescription without consulting your doctor. Keen all medicines out of reach of children

Council of Arab Health Ministers

Instructions for use:



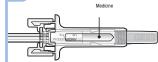
- X Do not remove the grey needle cap from the pre-filled syringe until you are ready
- Do not attempt to remove the clear pre-filled syringe safety guard from the

Step 1: Prepare Remove the pre-filled syringe tray from the package

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

- For a more comfortable injection, leave the pre-filled syringe at room temperature (up to 30°C) for about 30 minutes before injecting. Wash your hands thoroughly with soap and w
- Y Do not shake the pre-filled syringe





 The medicine is cloudy or there are particles in it. It must be a clear and colourless liquid. Any part appears cracked or broken.





- ✗ Do not touch the injection site before injecting
- Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.





Carefully pull the grey needle cap straight out and Grey needle cap o



It is important to keep the skin pinched when injecting.



Do not put the grey needle cap back on used pre-filled syringes



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

Step 4: Finish



Keen the syringe and charge disposal container out of sight and reach of children

X Do not recycle pre-filled syringes or throw them into household waste