

EPOMAX® 2000 UI/ml - EPOMAX® 2000 UI/0.5 ml - EPOMAX® 4000UI/ml - EPOMAX® 10 000 UI/ml
Solution for injection
Recombinant human erythropoietin alpha

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has not been tested for use by children. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, nurse, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4, Possible side effects.

What is this leaflet:

1. What EPOMAX is and what it is used for
2. What you need to know before you use EPOMAX
3. How to use EPOMAX
4. Possible side effects
5. How to store EPOMAX
6. Contents of the pack and other information
7. What EPOMAX is what it is used for

Pharmaco-therapeutic class:
 This medicine belongs to the pharmacotherapeutic class of "other ANTI-ANEMIC / ERYTHROPOIETINE".

Therapeutic indications:

- EPOMAX is used to **relieve symptomatic anaemia caused by kidney disease**
 - in children on haemodialysis
 - in adults on haemodialysis or peritoneal dialysis
 - in severely anaemic adults not yet undergoing dialysis.
- If you have kidney disease, you may be short of red blood cells if your kidney does not produce enough erythropoietin (necessary for red cell production). EPOMAX is prescribed to stimulate your bone marrow to produce more red blood cells.
- EPOMAX is used to **treat anaemia in adults receiving chemotherapy for solid tumours**, malignant lymphoma or multiple myeloma (bone marrow cancer) who may have a need for a blood transfusion. EPOMAX can reduce the need for a blood transfusion.
- EPOMAX is used in **moderately anaemic adults who donate some of their blood before surgery**, so that it can be given back to them during or after the operation. Because EPOMAX stimulates the production of red blood cells, it is used to **reduce the need for a blood transfusion**.
- EPOMAX is used in **moderately anaemic adults about to have major orthopaedic surgery** (for example hip or knee replacement operations), to reduce the potential need for blood transfusions.
- EPOMAX is used to **treat anaemia in adults with myelodysplastic syndromes**. EPOMAX can reduce the need for a blood transfusion.

What you need to know before you use

Do not use EPOMAX

- If you are allergic (hypersensitive) to epoetin alfa or any of the other ingredients of EPOMAX (listed in section 4) or to any of the products of the same manufacturer.
- If you have been diagnosed with **Pure Red Cell Aplasia** (the bone marrow cannot produce enough red blood cells) after previous treatment with any product that stimulates red blood cell production (including EPOMAX).
- If you have **high blood pressure** not properly controlled with medicines.
- To stimulate the production of your red blood cells (so that doctors can take more blood from you) if you cannot tolerate a blood transfusion immediately after surgery.
- If you are to **have major elective orthopaedic surgery** (such as hip or knee surgery), and you:
 - have severe heart disease
 - have severe disorders of the veins and arteries
 - have recently had a heart attack or stroke
 - can't take medicines to thin the blood

Warnings and precautions

Take special care with EPOMAX

EPOMAX and other products that stimulate red cell production may increase the risk of developing blood clots in patients at higher risk. You have other risk factors for developing blood clots (for example, if you have had a blood clot in the past or are overweight, have diabetes, have heart disease or are off your feet for a long time after surgery or illness). Please tell your doctor about any of these things. Your doctor will advise you on the best way to reduce your EPOMAX risk for you.

It is important to tell your doctor if any of the following apply to you. You may still be able to use EPOMAX, but discuss this with your doctor before you start using it.

- If you **know you suffer**, or have suffered, from:
 - high blood pressure;
 - epileptic seizures or fits
 - liver disease
 - anaemia from other causes
 - porphyria (a rare blood disorder)
- If you are a patient with **chronic renal failure**, and particularly if you do not respond properly to EPOMAX, your doctor will check your dose of EPOMAX because repeatedly increasing your dose of EPOMAX 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.

If you are a cancer patient be aware that products that stimulate red blood cell production (like EPOMAX) may act as a growth factor and therefore in theory may affect the progression of your cancer. Depending on your individual situation a blood transfusion may be preferable. Please discuss this with your doctor.

If you are a cancer patient, be aware that use of EPOMAX may be associated with shorter survival and a higher death rate than if you are not receiving treatment or if you are receiving chemotherapy.

Take special care with other products that stimulate red blood cell production:
 EPOMAX is one of a group of products that stimulate the production of red blood cells like the human protein erythropoietin. Your healthcare professional will also record the exact product you are using. If you are given a product in this group other than EPOMAX during your treatment, speak to your doctor or pharmacist before using another product.

Other medicines and EPOMAX

EPOMAX does not normally react with other medicines but please tell your doctor if you are using (or have recently used) any other medicines – including medicines obtained without a prescription.

If you are taking a drug called cyclosporin (used e.g. after kidney transplants), your doctor may order blood tests to check the level of cyclosporin while you are taking EPOMAX.

Iron supplements and iron tablets may increase the effectiveness of EPOMAX. Your doctor will decide if it is right for you to take them.

If you visit a hospital, clinic or family doctor, tell them you are having EPOMAX treatment. It may affect other treatments or test results.

Interactions with food and drinks

Not applicable.

Interactions with herbal products or alternative therapies

Not applicable.

Pregnancy and breast-feeding

It is important to tell your doctor if any of the following apply to you. You may still be able to use EPOMAX, but discuss it with your doctor first.

- If you are pregnant, or think you may be pregnant.
- If you are breast feeding.

How to use EPOMAX

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

Your doctor has carried out blood tests and decided you need EPOMAX. EPOMAX may be given by injection:

- Either into a vein or a tube that goes into a vein (intravenously)
- Or into the skin (subcutaneously) to make it more effective.

Your doctor will decide how EPOMAX will be injected. Usually the injections will be given to you by a doctor, nurse or other health care professional. Some people, depending on why they need EPOMAX treatment, may later learn to inject themselves under the skin. See instructions on how to inject EPOMAX yourself.

EPOMAX should not be used:

- After the expiry date on the label and outer carton
- If you know, or think that it may have been accidentally frozen, or
- If there has been a refrigerator failure.

The dose of EPOMAX you receive is based on your bodyweight in kilograms. The cause of your anaemia is also a factor in your doctor deciding the correct dose.

Your doctor will monitor your blood pressure regularly while you are using EPOMAX.

People with kidney disease

Your doctor will maintain your haemoglobin level between 10 and 12 g/dL, as a high haemoglobin level may increase the risk of blood clots and death.

The usual starting dose of EPOMAX for adults and children is 50 International Units (IU) per kilogram (kg) of bodyweight given three times a week.

For patients on peritoneal dialysis EPOMAX may be given twice a week.

For adults and children EPOMAX is given as an injection either into a vein or a tube that goes into a vein. When this excess (via a vein or tube) is not readily available, your doctor may decide that EPOMAX should be injected under the skin (subcutaneously). This includes patients on dialysis and patients not yet on dialysis.

Your doctor will order blood tests to see how your anaemia is responding and may adjust the dose, usually no more frequently than every four weeks.

Once your anaemia has been corrected, your doctor will continue to check your blood regularly.

Your doctor will monitor your iron levels. Iron supplements may be further adjusted to maintain your response to treatment. Your doctor will use the lowest effective dose to control the symptoms of your anaemia.

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

If you are on a more extended dosing interval (greater than once weekly) of EPOMAX, you may not maintain adequate haemoglobin levels and you may require an increase in EPOMAX dose or frequency of administration.

Do not use this medicine more often than EPOMAX treatment. Your doctor may decide that EPOMAX should be used to adjust your dialysis treatment when you begin treatment with EPOMAX, your dialysis regime may need to be adjusted. Your doctor will decide this.

Adults on chemotherapy

Your doctor may initiate treatment with EPOMAX if your haemoglobin is 10 g/dL or less.

Your doctor will maintain your haemoglobin level between 10 and 12 g/dL, as a high haemoglobin level may increase the risk of blood clots and death.

The starting dose is either 150 IU per kilogram bodyweight three times a week or 450 IU per kilogram bodyweight once a week.

EPOMAX is given by injection under the skin.

Your doctor will order blood tests, and may adjust the dose, depending on how your anaemia responds to EPOMAX treatment.

You may be given iron supplements before and during EPOMAX treatment to make it more effective.

You will usually continue EPOMAX treatment for one month after the end of chemotherapy.

Adults donating their own blood

- The usual dose is 600 IU per kilogram bodyweight twice a week.
- EPOMAX is given by injection into a vein immediately after you have donated blood for 3 weeks before your surgery.
- You may be given iron supplements before and during EPOMAX treatment to make it more effective.
- Adults scheduled for elective orthopaedic surgery:
 - The recommended dose is 600 IU per kilogram bodyweight once a week.
 - EPOMAX is given by injection under the skin each week for three weeks before surgery and on the day of surgery.
 - If there is a medical need to reduce the time before your operation, you will be given a daily dose of 500 IU/kg up to ten days before surgery, on the day of surgery, and for four days immediately afterwards.
 - If blood tests show your haemoglobin is too high before the operation, the treatment will be stopped.
 - You may be given iron supplements before and during EPOMAX treatment to make it more effective.

Instructions on how to inject EPOMAX yourself

When treatment starts, EPOMAX is usually injected by medical or nursing staff. Later, your doctor may suggest that you or your caregiver learn how to inject EPOMAX under the skin (subcutaneously) yourself.

• Do not attempt to inject yourself unless you have been trained to do so by your doctor or nurse.

• Always use EPOMAX exactly as instructed by your doctor or nurse.

• Only use EPOMAX if it has been stored correctly – see section 5, How to store EPOMAX.

• Before use, leave the EPOMAX syringe to stand until it reaches room temperature. This usually takes between 15 and 30 minutes. You can use the vial within 3 days of being taken out of the refrigerator as much as possible.

Use only one dose of EPOMAX per vial

If EPOMAX is injected under the skin (subcutaneously), the amount injected is usually not greater than one millilitre (1 ml) for a single injection.

EPOMAX is administered alone and is not mixed with other fluids to be injected.

Do not shake the vials of EPOMAX.

Vigorous and prolonged agitation may deteriorate the product.

If the product has been vigorously agitated, do not use it.

How to self-inject the product using injection prepared from a vial:

• Wash your hands thoroughly.

• Take a vial out of the refrigerator and check to make sure that the expiry date has not passed, that the vial is unopened and that the liquid is clear and not frozen.

• Remove the cap from the bottle but not the rubber stopper. Clean the rubber stopper with an antiseptic swab.

• Remove the needle cap from the syringe. Pull on the plunger of the syringe to fill the syringe with an amount of air equal to the volume of liquid to be injected.

• Place the vial on a flat surface and push the needle of the syringe through the rubber stopper. Push the plunger of the syringe to introduce the air into the vial.

• Turn the vial and syringe upside down. Pull on the plunger of the syringe to fill the syringe with the correct amount of fluid from the vial. It is important that the needle is always in the liquid to prevent the formation of air bubbles in the syringe.

• Remove the syringe and needle from the vial. Hold the syringe with the needle pointing upwards to see if there are any air bubbles inside. If there are air bubbles, gently push the plunger until the air (but not the liquid) is gone.

• Inject the injection site are at the top of the thigh and on the abdomen, but away from the belly button. Clean your syringe site from one day to the next.

• Clean the skin at the injection site with an antiseptic swab.

• Insert the needle quickly and firmly into the skin gently. Inject the EPOMAX solution as shown by your doctor. If you do not, consult your doctor or pharmacist.

• When the liquid has been injected, remove the needle and release the skin. Press the injection site with a dry, sterile swab.

• Dispose of your used syringe in a container designed for this purpose. If any fluid remains in the vial after injection, the vial should be discarded appropriately and not reused (see How to store EPOMAX).

If you use more EPOMAX than you should

Tell the doctor or nurse immediately if you think too much EPOMAX has been injected. Side effects from an overdose of EPOMAX are unlikely.

If you forget to use EPOMAX

Make the next injection as soon as you remember. If you are within a day of your next injection, forget the missed one and carry on with your normal schedule. Do not double up the injections.

If you are a patient with hepatitis C and you receive interferon and ribavirin

You should discuss this with your doctor because a combination of epoetin alfa with interferon and ribavirin has led to a loss of effect and development of a condition called pure red cell aplasia (PRCA), a severe form of anaemia, in rare cases. EPOMAX is not approved in the management of anaemia associated with hepatitis C.

If you have any further questions about the use of this product, ask your doctor, nurse or pharmacist.

4. Possible side effects

All medicines, EPOMAX can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of the effects in this list. **Very common side effects**

- Headache
- Diarrhoea
- Feeling sick in your stomach
- Vomiting
- Fever
- Respiratory tract congestion, such as stuffy nose and sore throat, has been reported in patients with kidney disease not yet on dialysis.

These may affect up to 1 in 10 people using EPOMAX.

Increased blood pressure. Headaches, particularly sudden, stabbing migraine-like headaches, feeling confused or having fits may be signs of a sudden increase in blood pressure. This requires urgent treatment. Raised blood pressure may require treatment with drugs (or adjustment to any drugs you already take for high blood pressure).

Blood clots (including deep vein thrombosis and embolisms) that may require urgent treatment. You may have swollen, painful, red, hot, and tender areas on your legs or arms.

Skin rashes, which may result from an allergic reaction.

Bone or muscle pain. Such as headache, aches and pains in the joints, feeling of weakness, chills, tiredness and dizziness.

Redness, burning and pain at the site of injection

An increase in levels of small blood cells (called platelets), which are normally involved in the formation of a blood clot may occur, particularly when starting treatment. Your doctor will check on this.

Uncommon side effects

These may affect up to 1 in 100 people using EPOMAX.

High levels of blood potassium which can cause abnormal heart rhythm (this is a very common side effect in patients on dialysis).

seizures

Nose or airway congestion

Rare side effects

These may affect up to 1 in 1,000 people using EPOMAX.

Symptoms of pure red cell aplasia (PRCA)

EPOMAX means the bone marrow does not make enough red blood cells. PRCA causes sudden and severe anaemia.

The symptoms are:

- unusual tiredness,
- feeling dizzy,
- breathlessness.

PRCA has been very rarely reported mostly in patients with kidney disease after months to years of treatment with EPOMAX and other products that stimulate red blood cell production.

An increase in levels of small blood cells (called platelets), which are normally involved in the formation of a blood clot may occur, particularly when starting treatment. Your doctor will check on this.

If you are receiving haemodialysis:

Blood clots (thrombosis) may form in your dialysis shunt. This is more likely if you have low blood pressure or if your fistula has complications.

Blood clots may also form in your haemodialysis system. Your doctor may decide to increase your heparin dose during dialysis.

5. How to store EPOMAX

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 box and on the label after the letters EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°-8°C). These temperature limits must be respected until administration to the patient. Do not freeze or shake.

Store in the original package in order to protect from light.

Do not use this medicine if you see that the seal is broken or if the liquid is coloured or you can see particles floating in it. In the event of either being observed, discard the medicinal product.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer wish to help protect the environment.

6. Contents of the pack and other information

What EPOMAX contains:

	EPOMAX 2000 UI/ml	EPOMAX 2000 UI/0.5 ml	EPOMAX 4000 UI/ml	EPOMAX 10 000 UI/ml
Active substance : Recombinant human erythropoietin alpha (epoetin alfa)	2000 IU	2000 IU	4000 IU	10 000 IU
Excipients:				
Human albumin, Disodium phosphate dihydrate, Sodium phosphate dihydrate, sodium chloride, Hydrochloric acid or Sodium hydroxide, Water for injections.				

What EPOMAX looks like and contents of the pack and MARKETING AUTHORISATION NUMBERS:
 EPOMAX 2000 UI/ml solution for injection in vial of 1 ml in pack of 1 or 10 vials - pack of 1 vial AMM N° 9233681H
 EPOMAX 2000 UI/0.5 ml solution for injection in pre-filled syringe of 0.5 ml in pack of 2 or 10 syringes AMM N° 9233682H

EPOMAX 4000 UI/ml solution for injection in vial of 1 ml in pack of 1 vial. AMM N° 9233684H
 EPOMAX 10 000 UI/ml solution for injection in vial of 1 ml in pack of 1 vial. AMM N° 9233685H

Delivery conditions: list I

Marketing authorisation holder and manufacturer:

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This is a drug

- A drug is a product but it is different from the other products.
- A drug is a product which acts on your health and its non appropriate consumption can expose you to danger.
- Rigorously respect your doctor's prescription and the mode of administration he prescribed. Follow your pharmacist's advices.
- Your doctor and your pharmacist know drugs, their indications and contra-indications.
- Do not stop on your own initiative the treatment during the prescribed period
- Do not retake, do not increase doses without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.

