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Farben: • Schwarz

Package leaflet: Information for the patient

### Abseamed 1 000 IU/0.5 mL solution for injection in a pre-filled syringe

### Abseamed 2 000 IU/1 mL solution for injection in a pre-filled syringe

### Abseamed 3 000 IU/0.3 mL solution for injection in a pre-filled syringe

### Abseamed 4 000 IU/0.4 mL solution for injection in a pre-filled syringe

### Abseamed 5 000 IU/0.5 mL solution for injection in a pre-filled syringe

### Abseamed 6 000 IU/0.6 mL solution for injection in a pre-filled syringe

### Abseamed 7 000 IU/0.7 mL solution for injection in a pre-filled syringe

### Abseamed 8 000 IU/0.8 mL solution for injection in a pre-filled syringe

### Abseamed 9 000 IU/0.9 mL solution for injection in a pre-filled syringe

### Abseamed 10 000 IU/1 mL solution for injection in a pre-filled syringe

### Abseamed 20 000 IU/0.5 mL solution for injection in a pre-filled syringe

### Abseamed 30 000 IU/0.75 mL solution for injection in a pre-filled syringe

### Abseamed 40 000 IU/1 mL solution for injection in a pre-filled syringe epoetin alfa

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Abseamed is and what it is used for

Abseamed contains the active substance epoetin alfa, a protein that stimulates the bone marrow to produce more red blood cells which carry haemoglobin (a substance that transports oxygen). Epoetin alfa is a copy of the human protein erythropoietin (ee-rith-roe-po-eh-tin) and acts in the same way.

#### Abseamed is used to treat 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). Abseamed is prescribed to stimulate your bone marrow to produce more red blood cells.

Abseamed 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. Abseamed can reduce the need for a blood transfusion in these patients.

Abseamed 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 Abseamed stimulates the production of red blood cells, doctors can take more blood from these people.

Abseamed 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.

Abseamed is used to treat anaemia in adults with a bone marrow disorder that causes a severe disruption in the creation of blood cells (myelodysplastic syndromes). Abseamed can reduce the need for a blood transfusion.

#### 2. What you need to know before you use Abseamed

##### Do not use Abseamed

- if you are allergic to epoetin alfa or any of the other ingredients of this medicine (listed in section 6).
- 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 Abseamed). See section 4.
- 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 have transfusions with your own blood during or after surgery.
- if you are due 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

Abseamed may not be suitable for you. Please discuss with your doctor. While on Abseamed, some people need medicines to reduce the risk of blood clots. If you can't take medicines that prevent blood clotting, you must not have Abseamed.

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Abseamed.

Abseamed and other products that stimulate red cell production may increase the risk of developing blood clots in all patients. This risk may be higher if 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 you are off your feet for a long time because of surgery or illness). Please tell your doctor about any of these things. Your doctor will help you to decide if Abseamed is suitable for you.

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

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 Abseamed, your doctor will check your dose of Abseamed because repeatedly increasing your dose of Abseamed 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 Abseamed) 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 Abseamed may be associated with shorter survival and a higher death rate in head and neck, and metastatic breast cancer patients who are receiving chemotherapy.

Serious skin reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in association with epoetin treatment.

SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-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 Abseamed and contact your doctor or seek medical attention immediately.

#### Take special care with other products that stimulate red blood cell production:

Abseamed is one of a group of products that stimulate the production of red blood cells like the human protein erythropoietin does. Your healthcare professional will always record the exact product you are using. If you are given a product in this group other than Abseamed during your treatment, speak to your doctor or pharmacist before using it.

#### Other medicines and Abseamed

Tell your doctor if you are taking, have recently taken or might take any other medicines.

#### 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. Abseamed is not approved in the management of anaemia associated with hepatitis C.

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

Iron supplements and other blood stimulants may increase the effectiveness of Abseamed. 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 Abseamed treatment. It may affect other treatments or test results.

#### Pregnancy, breast-feeding and fertility

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

- 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

#### No data on the effects of Abseamed on fertility are available

#### Abseamed contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".

#### 3. How to use Abseamed

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 Abseamed.

Abseamed may be given by injection:

- Either into a vein or a tube that goes into a vein (intravenously)
- Or under the skin (subcutaneously).

Your doctor will decide how Abseamed 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 Abseamed treatment, may later learn how to inject themselves under the skin: see *Instructions on how to inject Abseamed yourself at the end of the leaflet*.

Abseamed 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 Abseamed you receive is based on your body weight 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 Abseamed.

#### 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. In children the haemoglobin level should be maintained between 9.5 and 11 g/dL.
- The usual starting dose of Abseamed for adults and children is 50 International Units (IU) per kilogram (/kg) of body weight given three times a week. For patients on peritoneal dialysis Abseamed may be given twice a week.
- For adults and children Abseamed is given as an injection either into a vein (intravenously) or a tube that goes into a vein. When this access (via a vein or tube) is not readily available, your doctor may decide that Abseamed should be injected under the skin (subcutaneously). This includes patients on dialysis and patients not yet on dialysis.
- Your doctor will order regular blood tests to see how your anaemia is responding and may adjust the dose, usually no more frequently than every four weeks. A rise in haemoglobin of greater than 2 g/dL over a four week period should be avoided.
- Once your anaemia has been corrected, your doctor will continue to check your blood regularly. Your Abseamed dose and frequency of administration 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 Abseamed, your doctor will check your dose and will inform you if you need to change doses of Abseamed.
- If you are on a more extended dosing interval (greater than once weekly) of Abseamed, you may not maintain adequate haemoglobin levels and you may require an increase in Abseamed dose or frequency of administration.
- You may be given iron supplements before and during Abseamed treatment to make it more effective.
- If you are having dialysis treatment when you begin treatment with Abseamed, your dialysis regime may need to be adjusted. Your doctor will decide this.

#### Adults on chemotherapy

- Your doctor may initiate treatment with Abseamed 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 body weight three times a week or 450 IU per kilogram body weight once a week.
- Abseamed 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 Abseamed treatment.
- You may be given iron supplements before and during Abseamed treatment to make it more effective.
- You will usually continue Abseamed treatment for one month after the end of chemotherapy.

#### Adults donating their own blood

- The usual dose is 600 IU per kilogram body weight twice a week.
- Abseamed 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 Abseamed treatment to make it more effective.

#### Adults scheduled for major orthopaedic surgery

- The recommended dose is 600 IU per kilogram body weight once a week.
- Abseamed 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 300 IU/kg for 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 Abseamed treatment to make it more effective.

#### Adults with myelodysplastic syndrome

- Your doctor may initiate treatment with Abseamed if your haemoglobin is 10 g/dL or less. The aim of treatment is to maintain your haemoglobin level between 10 and 12 g/dL as a higher haemoglobin level may increase the risk of blood clots and death.
- Abseamed is given by injection under the skin.
- The starting dose is 450 IU per kilogram bodyweight once a week.
- Your doctor will order blood tests, and may adjust the dose, depending on how your anaemia responds to Abseamed treatment.

#### Instructions on how to inject Abseamed yourself

When treatment starts, Abseamed is usually injected by a medical professional or a nurse. Later, your doctor may suggest that you or your caregiver learn how to inject Abseamed 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 Abseamed exactly as instructed by your doctor or nurse.
- Ensure that you only inject the amount of liquid as instructed by your doctor or nurse.
- Only use Abseamed if it has been stored correctly – see section 5, *How to store Abseamed*.
- Before use, leave the Abseamed syringe to stand until it reaches room temperature. This usually takes between 15 and 30 minutes. Use the syringe within 3 days of taking it out of the refrigerator.

#### Only take one dose of Abseamed from each syringe.

If Abseamed is injected under the skin (subcutaneously), the amount injected is not normally more than one millilitre (1 mL) in a single injection.

Abseamed is given alone and not mixed with other liquids for injection.

Do not shake Abseamed syringes. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it.

Instructions on how to inject yourself with Abseamed can be found at the end of this leaflet.

#### If you use more Abseamed than you should

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



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Farben: • Schwarz

#### If you forget to use Abseamed

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 take a double dose to make up for a forgotten dose.

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

#### 4. Possible side effects

Like all medicines, this medicine 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.

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

##### Very common side effects

These may affect more than 1 in 10 people.

- **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.

##### Common side effects

These may affect up to 1 in 10 people.

- **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 medicines (or adjustment to any medicines you already take for high blood pressure).
- **Blood clots** (including deep vein thrombosis and embolism) that may require urgent treatment. You may have **chest pain, breathlessness, and painful swelling and redness, usually in the leg** as symptoms.
- **Cough.**
- **Skin rashes, which may result from an allergic reaction.**
- **Bone or muscle pain.**
- **Flu-like symptoms**, such as headache, aches and pains in the joints, feeling of weakness, chills, tiredness and dizziness. These may be more common at the start of treatment. If you have these symptoms during injection into the vein, a slower delivery of the injection may help to avoid them in the future.
- **Redness, burning and pain at the site of injection.**
- **Swelling of the ankles, feet or fingers.**
- **Arm or leg pain.**

##### Uncommon side effects

These may affect up to 1 in 100 people.

- **High levels of blood potassium** which can cause abnormal heart rhythm (this is a very common side effect in patients on dialysis).
- **Fits.**
- **Nose or airway congestion.**
- **Allergic reaction.**
- **Hives.**

##### Rare side effects

These may affect up to 1 in 1 000 people.

- **Symptoms of pure red cell aplasia (PRCA)**

PRCA 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 epoetin alfa 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.
- Severe allergic reaction that may include:
  - a swollen face, lips, mouth, tongue or throat,
  - difficulty swallowing or breathing,
  - itchy rash (hives).

- Problem with the blood that may cause pain, dark coloured urine or increased sensitivity of the skin to sunlight (porphyria).

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.

**Tell your doctor or nurse immediately** if you are aware of any of these effects, or if you notice any other effects while you are receiving treatment with Abseamed.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

#### 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. You can also report side effects in the United Kingdom via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in Google play or Apple App store, and in Ireland via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tel: + 353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Abseamed

- 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 label and carton after EXP. The expiry date refers to the last day of that month.
- Store and transport refrigerated (2 °C-8 °C).
- You may take Abseamed out of the refrigerator and keep it at room temperature (up to 25 °C) for no longer than 3 days. Once a syringe has been removed from the refrigerator and has reached room temperature (up to 25 °C) it must either be used within 3 days or disposed of.
- Do not freeze or shake.
- Store in the original package in order to protect from light.

Do not use this medicine if you notice that

- it may have been accidentally frozen, or
- if there has been a refrigerator failure,
- the liquid is coloured or you can see particles floating in it,
- the seal is broken.

#### Do not throw away any medicines via wastewater.

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 Abseamed contains

- **The active substance is:** epoetin alfa (for quantity see the table below).
- **The other ingredients are:** sodium dihydrogen phosphate dihydrate, disodium phosphate dihydrate, sodium chloride, glycine, polysorbate 80, hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment), and water for injections.

##### What Abseamed looks like and contents of the pack

Abseamed is presented as a clear, colourless solution for injection in a pre-filled syringe. The syringes are sealed in a blister.

Presentation	Corresponding Presentations in Quantity/Volume for each Strength	Amount of epoetin alfa
Pre-filled syringes*	<b>2 000 IU/mL:</b>	
	1 000 IU/0.5 mL	8.4 micrograms
	2 000 IU/1 mL	16.8 micrograms
	<b>10 000 IU/mL:</b>	
	3 000 IU/0.3 mL	25.2 micrograms
	4 000 IU/0.4 mL	33.6 micrograms
	5 000 IU/0.5 mL	42.0 micrograms
	6 000 IU/0.6 mL	50.4 micrograms
	7 000 IU/0.7 mL	58.8 micrograms
	8 000 IU/0.8 mL	67.2 micrograms
	9 000 IU/0.9 mL	75.6 micrograms
	10 000 IU/1 mL	84.0 micrograms
	<b>40 000 IU/mL:</b>	
	20 000 IU/0.5 mL	168.0 micrograms
30 000 IU/0.75 mL	252.0 micrograms	
40 000 IU/1 mL	336.0 micrograms	

\*Pack size of 1, 4 or 6 pre-filled syringe(s) with or without a needle safety guard. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

MEDICE Arzneimittel Pütter GmbH & Co. KG  
Kuhloweg 37  
58638 Iserlohn  
Germany

#### Manufacturer

Sandoz GmbH  
Biochemiestr. 10  
6250 Kundl  
Austria

This leaflet was last revised in 08/2025.

#### Instructions on how to inject yourself (for patients with symptomatic anaemia caused by kidney disease, for adult patients receiving chemotherapy, adult patients scheduled for orthopaedic surgery, or adult patients with myelodysplastic syndromes only)

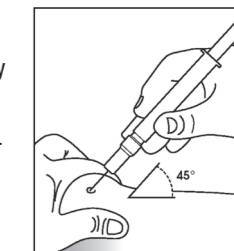
This section contains information on how to give yourself an injection of Abseamed. **It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse.** Abseamed is provided with or without a needle safety guard and you will be shown how to use this by 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.

**WARNING:** Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap. Do not use the Abseamed pre-filled syringe if it is broken. Return the pre-filled syringe and the package it came in to the pharmacy.

1. Wash your hands.
2. Remove one syringe from the pack and remove the protective cap from the injection needle. Syringes are embossed with graduation rings in order to enable partial use if required. Each graduation ring corresponds to a volume of 0.1 mL. If partial use of a syringe is required, remove unwanted solution before injection.
3. Clean the skin at the injection site using an alcohol wipe.
4. Form a skin fold by pinching the skin between thumb and forefinger.
5. Insert the needle into the skin fold with a quick, firm action. Inject the Abseamed solution as you have been shown by your doctor. You should check with your doctor or pharmacist if you are not sure.

##### Pre-filled syringe without needle safety guard

6. Always keeping your skin pinched, depress the plunger slowly and evenly.
7. After injecting the liquid, remove the needle and let go of your skin. Apply pressure over the injection site with a dry, sterile pad.
8. Discard any unused product or waste material. Only use each syringe for one injection.



##### Pre-filled syringe with needle safety guard

6. Always keeping your skin pinched, depress the plunger slowly and evenly until the entire dose has been given and the plunger cannot be depressed any further. Do not release the pressure on the plunger!
7. After injecting the liquid, remove the needle while maintaining pressure on the plunger and then let go of your skin. Apply pressure over the injection site with a dry, sterile pad.
8. Let go of the plunger. The needle safety guard will rapidly move to cover the needle.
9. Discard any unused product or waste material. Only use each syringe for one injection.

