

# ABPEG-10000™

Erythropoietin Injection 10000 IU/1.0 ml

## Description

Ebpeg 1000 injection is used to treat anemia in patients with chronic kidney disease (CKD) who may or may not be on dialysis. This medicine may also be used to prevent or treat anemia that is caused by surgery or medicines (eg, zidovudine) that are used for other conditions, such as HIV or cancer.

Ebpeg 1000 injection is a man-made version of human erythropoietin (EPO). EPO is produced naturally in the body, mostly by the kidneys. It causes the bone marrow to produce red blood cells. If the body does not produce enough red blood cells, severe anemia can occur. This often occurs in people with chronic kidney failure whose kidneys are not working properly. This medicine is available only with your doctor's prescription.

This product is available in the following dosage forms:

- Solution

## Before Using

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

## Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

## Pediatric

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of Ebpeg 1000 injection in children 1 month of age and older. Safety and efficacy have not been established in children younger than 1 month of age with chronic kidney disease who are on dialysis, in children younger than 5 years of age with cancer, and in children with chronic kidney disease who are not on dialysis or with HIV infection.

## Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of Ebpeg 1000 injection in the elderly.

## Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

## Drug Interactions

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your healthcare professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine.

## Other Interactions

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

## Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any

other medical problems, especially:

- Aluminum poisoning, severe or
- Bleeding, severe or
- Blood disorders (eg, thalassemia, myelodysplastic syndrome) or
- Bone problems or
- Folic acid, iron, or vitamin B12 deficiencies or
- Infection, inflammation, or cancer or
- Porphyrin (red blood cell pigment) metabolism disorder or
- Sickle cell anemia—Eprex 1000 may not work properly.
- Blood clots (history of) or other problems with the blood or
- Cancer, active or
- Congestive heart failure or
- Heart attack, history of or
- Heart bypass surgery or
- Heart or blood vessel disease or
- Seizures, history of or
- Stroke, history of or
- Thrombosis, at risk for—The chance of side effects may be increased.
- Cancer, history of—May cause some tumors to progress or come back.
- Hypertension (high blood pressure), uncontrolled or
- Pure red cell aplasia (rare bone marrow disease)—Should not be used in patients with these conditions.

### **Proper Use**

This medicine is usually given by your doctor. However, medicines given by injection are sometimes used at home. If you will be using this medicine at home, your doctor will teach you how the injections are to be given. Be sure you understand exactly how the medicine is to be injected.

This medicine may be given as a shot under your skin (usually in the buttocks, upper arms, thighs, or stomach) or into a vein. If your doctor tells you to inject it in a certain way, follow your doctor's instructions.

This medicine comes with a Medication Guide and patient instructions. Read and follow these instructions carefully. Ask your doctor if you have any questions.

If you are using this medicine at home:

- Use a new needle and syringe each time you inject your medicine.
- Do not use more medicine or use it more often than your doctor tells you to.
- You will be shown the body areas where this shot can be given. Use a different body area each time you give yourself a shot. Do not inject into areas that are tender, red, bruised, hard, or have scars, or stretch marks. Keep track of where you give each shot to make sure you rotate body areas. This will help prevent skin problems from the injections.
- Do not shake the vial before using it. Do not use this medicine if it has been frozen.
- Check the liquid in the vial. It should be clear and colorless. Do not use if it is cloudy, discolored, or has lumps, flakes, or particles in it.
- If you use the vials that have one dose, you might not use all of the medicine in each vial. Use each vial only once and throw any extra medicine away. Do not save an opened vial.
- If you use the vial that has enough medicine for more than one dose, put it back in the refrigerator after use. Write the date on the vial that you first used it and throw away any unused medicine after 21 days.

In addition to this medicine, your body needs iron and vitamins to make red blood cells. Your doctor may direct you to take iron or vitamin supplements. Be sure to follow your doctor's orders carefully.

### **Dosing**

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label.

The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For injection dosage form:
  - For anemia from chemotherapy:

- Adults—Dose is based on body weight and must be determined by your doctor. The starting dose is 150 units per kilogram (kg) injected under the skin 3 times a week or 40,000 units injected under the skin once a week. Your doctor may adjust the dose as needed.
  - Children 5 years of age and older—Dose is based on body weight and must be determined by your doctor. The starting dose is 600 units per kg injected into a vein once a week. Your doctor may adjust the dose as needed.
  - Children younger than 5 years of age—Use and dose must be determined by your doctor.
- For anemia from chronic kidney disease not on dialysis:
  - Adults—Dose is based on body weight and must be determined by your doctor. The starting dose is 50 to 100 units per kilogram (kg) injected into a vein or under the skin 3 times a week. Your doctor may adjust the dose as needed.
  - Children—Use and dose must be determined by your doctor.
- For anemia from chronic kidney disease on dialysis:
  - Adults—Dose is based on body weight and must be determined by your doctor. The starting dose is 50 to 100 units per kilogram (kg) injected into a vein or under the skin 3 times a week. Your doctor may adjust the dose as needed.
  - Children 1 month to 16 years of age—Dose is based on body weight and must be determined by your doctor. The starting dose is 50 units per kg injected into a vein or under the skin 3 times a week. Your doctor may adjust the dose as needed.
  - Children younger than 1 month of age—Use and dose must be determined by your doctor.
- For anemia from HIV therapy:
  - Adults—Dose is based on body weight and must be determined by your doctor. The starting dose is 100 units per kilogram (kg) injected into a vein or under the skin 3 times a week for 8 weeks. Your doctor may adjust the dose as needed.
  - Children—Use and dose must be determined by your doctor.
- For anemia from surgery:
  - Adults—Dose is based on body weight and must be determined by your doctor. The starting dose is 300 units per kilogram (kg) injected under the skin for 10 days before the surgery, on the day of the surgery, and for 4 days after surgery.
  - Children—Use and dose must be determined by your doctor.

### **Missed Dose**

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

### **Storage**

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store in the refrigerator. Do not freeze.

Protect the medicine from bright light. Keep your medicine in the original package until you are ready to use it.

Throw away used needles in a hard, closed container that the needles cannot poke through (puncture-resistant). Keep this container away from children and pets.

### **Precautions**

**It is very important that your doctor check your or your child's progress regularly** while you or your child are using this medicine. Blood tests are needed to check for unwanted effects. You may also need to monitor your blood pressure at home. If you notice any changes to your normal blood pressure, call your doctor right away. .

This medicine may increase your risk of having a heart attack, stroke, congestive heart failure, and blood clotting problems. Check with your doctor right away if you start having dizziness, fainting spells, severe tiredness, chest pain, trouble breathing, sudden or severe headache, or problems with vision, speech, or walking.

Do not use this medicine if you or your child have had an allergic reaction to albumin or products derived from human or animal cells.

This medicine contains benzyl alcohol which may cause serious reactions to newborn or premature infants. Discuss this with your doctor if you have concerns.

This medicine may increase the risk of convulsions (seizures) during the first few months of treatment. Talk with your doctor

if you have concerns.

People with severe anemia usually feel very tired and sick. When Ebpeg 1000 begins to work, usually in about 6 weeks, most people start to feel better. Some people are able to be more active. However, Ebpeg 1000 only corrects anemia. It has no effect on kidney disease, cancer, or any other medical problem that needs regular medical attention. Even if you or your child are feeling much better, **it is very important that you do not miss any appointments with your doctor or any dialysis treatments.** .

This medicine may increase your risk of having blood clots. This is more likely in patients who use high doses of this medicine, or who use this medicine before a major surgery. Call your doctor right away if you have chest pain, trouble breathing, or pain, redness, or swelling in your legs while using this medicine. If you are getting dialysis treatments, tell your doctor right away if you notice blood clots at the injection site. Your doctor may give you a blood thinner before surgery to help prevent blood clots.

This medicine may cause blood clots to form in the access port (A-V shunt) for patients with chronic kidney disease who receive dialysis treatments. This would cause the access port to stop working. Tell your doctor right away if you or your child see blood clots forming in the access port.

When used in patients with certain types of cancer (eg, breast, cervix, lymphoid, lung, head, or neck cancer), this medicine has shortened survival time and worsened the tumor or cancer in some patients. If you or your child are concerned about this, talk with your doctor.

This medicine may cause serious allergic reactions, including anaphylaxis and angioedema, which can be life-threatening and require immediate medical attention. Tell your doctor right away if you have a rash, itching, hoarseness, trouble breathing, trouble swallowing, or any swelling of your hands, face, or mouth after using this medicine.

Serious skin reactions (eg, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis) can occur with this medicine. Check with your doctor right away if you have blistering, peeling, or loosening of the skin, chills, cough, diarrhea, itching, joint or muscle pain, red irritated eyes, red skin lesions, often with a purple center, sore throat, sores, ulcers, or white spots in the mouth or on the lips, or unusual tiredness or weakness.

Ebpeg 1000 is made from donated human blood. Some human blood products have transmitted certain viruses to people who have received them, although the risk is low. Human donors and donated blood are both tested for viruses to keep the transmission risk low. Talk with your doctor if you have concerns.

Many people with kidney problems need to be on a special diet. Also, people with high blood pressure (which may be caused by kidney disease or by Ebpeg 1000 treatment) may need to be on a special diet or to take medicine to keep their blood pressure under control. After their anemia has been corrected, some people feel so much better that they want to eat more than before. To keep your kidney disease or your high blood pressure from getting worse, it is very important that you or your child follow your special diet and take your medicines regularly, even if you are feeling better.

### **Side Effects**

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

**Check with your doctor immediately** if any of the following side effects occur:

#### **More common**

- Chest pain
- fever
- headache
- increased blood pressure
- swelling of the face, fingers, ankles, feet, or lower legs
- weight gain

#### **Less common**

- Anxiety
- blurred vision
- change in skin color
- change in vision
- cough
- dizziness or lightheadedness
- double vision
- fainting
- fast heartbeat

- migraine headache
- nausea
- pain or discomfort in the arms, jaw, back, or neck
- pain, tenderness, or swelling of the foot or leg
- pain in the chest, groin, or legs, especially calves of the legs
- pale skin
- partial or complete loss of vision in the eye
- seizures
- severe headache of sudden onset
- skin rash or hives
- slurred speech
- sore throat
- sudden and severe inability to speak
- sudden loss of coordination
- sweating
- temporary blindness
- tenderness, pain, swelling, warmth, or skin discoloration at the injection site
- unusual bleeding or bruising
- unusual tiredness or weakness
- vision problems
- vomiting
- weakness in the arm or leg on one side of the body, sudden and severe

**Incidence not known**

- Blistering, peeling, or loosening of the skin
- chills
- diarrhea
- itching
- joint or muscle pain
- red, irritated eyes
- red skin lesions, often with a purple center
- sore throat
- sores, ulcers, or white spots in the mouth or on the lips

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

**More common**

- Bone or joint pain
- constipation
- general feeling of tiredness or weakness
- heartburn or belching
- itching or stinging at the injection site
- loss of strength or energy
- muscle aches or weakness
- shivering
- skin pain
- stomach discomfort, upset, pain, or swelling
- weight loss

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.