

For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

Erythropoietin Injection B.P.

REPOITIN

FOR S.C./I.V. INJECTION

PHARMACOLOGICAL CHARACTERISTICS
INDICATIONS
CONTRAINDICATIONS
PRECAUTIONS
Formulation of REPOITIN (Erythropoietin) in vials/ampoules

1. Erythropoietin B.P. 3000 IU/5 mL	2. Erythropoietin B.P. 3000 IU/10 mL	3. Erythropoietin B.P. 4000 IU/4 mL	4. Erythropoietin B.P. 5000 IU/5 mL
5. Erythropoietin B.P. 6000 IU/6 mL	6. Erythropoietin B.P. 8000 IU/8 mL	7. Erythropoietin B.P. 10000 IU/10 mL	8. Erythropoietin B.P. 10000 IU/20 mL

GENERAL PRECAUTIONS
Precautions of Use
Pharmacokinetics
Pharmacodynamics
Pharmacology
Pharmacokinetics
Pharmacodynamics
Pharmacology
Pharmacokinetics
Pharmacodynamics
Pharmacology

Para el uso exclusivo de un Médico Registrado o Hospital o Laboratorio

Eritropoyetina Inyección B.P.

REPOITIN

PARA LA INYECCIÓN S.C./I.V.

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CONTRAINDICACIONES
PRECAUCIONES
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Formulación de REPOITIN (Eritropoyetina) en viales/ampollas

À usage uniquement de médecins autorisés ou hôpitaux ou de Laboratoire

Injection Erythropoïétine B.P.

REPOITIN

Pour Injections S.C./I.V.

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INDICATIONS
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Formulation of REPOITIN (Erythropoietin) in vials/ampoules

Reason for issue: NEW	Specification: Printed in 2 colour on Bible paper not less than 40 gsm.
Customer: REPOITIN	
Product: REPOITIN	
Item Code Number: 20011307/0	Specification No.: /
Supersedes Item Code:	Dimensions: 370 x 352 mm

PACKAGING DEVELOPMENT

QUALITY ASSURANCE

REGULATORY AFFAIRS

MEDICAL DEPARTMENT

QUALITY ASSURANCE

File Name: E:\Packaging artwork as on 080212\Arwoks 140212\insert3 language insert\NEW_B1 SED\Repoitin Insert as per BP 080317\repoitin PFS for exports 080313.doc Date: 08.03.13 035 52095/4/F3

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Patient Information Leaflet for **REPOITIN** (Patient's awareness program)

This Patient Information Leaflet contains information and directions for patients (and their caregivers) whose Doctor has determined that they (patient) should receive REPOITIN in their home. Please read this Patient Information Leaflet carefully. This Patient Information Leaflet does not include all information about REPOITIN and does not replace talking with your Doctor. You should discuss any questions about treatment with REPOITIN with your Doctor.

Only your Doctor can prescribe REPOITIN and determine if it is right for you.

Please read carefully the Questions and Answers given below:

What does REPOITIN contain?

Each Vial / Pre Filled Syringe contains 2000, 3000, 4000, 5000, 6000, 8000 OR 10,000 International Units of recombinant human erythropoietin in a sterile solution. It also contains a small amount of human serum albumin and other inactive ingredients: sodium chloride, Disodium Hydrogen Phosphate.12H₂O; Sodium Dihydrogen Phosphate, H₂O Preservative-free.

REPOITIN is available in following strengths & pack :

- REPOITIN 2000 Vials / PFS
- REPOITIN 3000 PFS
- REPOITIN 4000 Vials / PFS
- REPOITIN 5000 Vials / PFS
- REPOITIN 6000 Vials / PFS
- REPOITIN 8000 Vials / PFS
- REPOITIN 10000 Vials / PFS

What are the effects of REPOITIN injections?

The human body produces (mainly in the kidney) a substance called Erythropoietin. REPOITIN contains recombinant human Erythropoietin which is almost identical to the Erythropoietin produced in the body. Erythropoietin stimulates the bone marrow to produce Red Blood Cells (RBC) and Haemoglobin (Hb) (Shortage of RBC and / or haemoglobin results in anaemia with symptoms such as tiredness, weakness, paleness and dizziness).

What are REPOITIN injections used for?

To treat and correct anaemia.
(There are various types of anaemia with different causes; not all types respond to REPOITIN treatment).

- Chronic Kidney Failure
- Chemotherapy used to treat cancer or if you are at risk for significant blood loss).
- HIV and taking a medicine called Zidovudine (AZT)

How are the injections given?

REPOITIN Can be given through Intravenous (IV) or Subcutaneous (SC) route. Make sure you discuss with your doctor and understand which way is best for you. In patients on hemodialysis, the IV route is recommended.

A. Intravenous (IV) Route :

A single intravenous injection is given three times a week. In patients undergoing dialysis, it may be given via the dialysis tubing or via the arteriovenous fistula after dialysis. The dose will depend on the weight of the patient and on the response to treatment. The dose is adapted individually so as to be correct for each patient.

B. Subcutaneous (SC) Route :

REPOITIN injections may be given under the skin when the correct dosage for a patient has been established. When receiving subcutaneous injections, always change the site for each injection as directed by your doctor. You may wish to record and track the site where you have injected. Do not inject REPOITIN into an area that is tender, red, bruised, hard, or has scars or stretch marks. Recommended sites for injection are presented in the figure below, including the outer area of the upper arm, the abdomen (except for the two inch area around the navel), the front of the middle thighs, and the outer area of the buttocks.

How to Use the subcutaneous route:

1. With one hand, hold the area surrounding the cleaned skin either by spreading it or by pinching up a large area. Do not touch the cleansed area.
2. Double-check that the correct amount of REPOITIN is in the syringe.
3. Hold the syringe with the other hand, as you would a pencil, insert the needle into the skin at a 45-degree angle. Let go of the skin and pull the plunger back slightly. If blood comes into the syringe, do not inject REPOITIN, as the needle has entered a blood vessel; withdraw the syringe, clean a new area, follow steps 1 and 2 and inject at a different site. If blood does not enter the syringe, inject the REPOITIN by pushing the plunger all the way down.
4. Pull the needle straight out of the skin and immediately press the antiseptic swab over the injection site for several seconds.
5. Always keep a spare syringe and needle on hand.

Always use the correct syringe:

Your doctor has REPOITIN/ demonstrated to you on how to give yourself the correct dosage of REPOITIN. This dosage can usually be measured in Units per milliliter or cc's. It is important to use a syringe that is marked in units of milliliters (for example, 0.2 mL or cc). Using the wrong syringe can lead to a mistake in your dose, and you

may receive too much or too little REPOITIN. Too little REPOITIN may not be effective in increasing the number of red blood cells. Too much REPOITIN may lead to serious problems because too many red blood cells are being produced (a haemoglobin or hematocrit that is too high).

What to observe while taking REPOITIN inj.?

Be sure that you and the person who will be giving the injections read the manufacturer's information for the patient that comes with REPOITIN before you use it for the first time at home.

When you receive your REPOITIN from the dialysis center, doctor's office or pharmacy, always check to see that:

1. The name REPOITIN appears on the carton and vial / PFS label.
2. The Expiry date and batch Number are present on the carton / labels of REPOITIN.

The REPOITIN solution in the vial / PFS should always be clear and colorless.

Do not use REPOITIN if the contents of the vial / PFS appear discolored or cloudy, or if the vial / PFS appears to contain lumps, flakes, or particles. If the vial has been shaken vigorously, the solution may appear to be frothy and should not be used. Care should be taken not to shake the REPOITIN vial / PFS before use. Write down the date, time, dose of REPOITIN, and the spot where you injected your dose in a record book. Always follow the instructions of your Doctor concerning the Dose, how to administer and how to administer REPOITIN. Ask your Doctor what to do if you miss a Dose of REPOITIN.

What to do in case of emergency/overdose?

In case of overdose, call your local poison control center. If the victim has collapsed or is not breathing, call local emergency services. Contact immediately your Doctor/Hospital.

Symptoms of overdose may include pain, tenderness, redness, warmth, and/or swelling in the legs; chest pain, squeezing pressure, or tightness; discomfort or pain in the arms, shoulder, neck, jaw, or back; fast or irregular heartbeat; shortness of breath; cough that won't go away or coughing up blood; swelling of the hands, feet, or ankles; blue-grey color or darkening around mouth or nails; Excessive sweating; dizziness or lightheadedness; fainting or loss of consciousness; sudden trouble seeing in one or both eyes; sudden confusion; sudden trouble speaking or understanding speech; sudden weakness or numbness of an arm or leg, especially on one side of the body) or face; sudden trouble walking or loss of balance or coordination; sudden severe headache; extreme tiredness or weakness; seizure; increased blood pressure; blood clot in hemodialysis port

What should I do if I forget a dose?

Call your Doctor, to ask what to do, if you miss a dose of REPOITIN. Do not use a double dose to make up for a missed one.

Who should not receive REPOITIN injections?

- Patients with high blood pressure not under control with medication Allergies to REPOITIN or any other brand of Erythropoietins.
- Patients who are allergic to human serum albumin (HSA).
- Previous allergic reactions to any of the ingredients in REPOITIN.
- Patients who have developed types of tumours.
- Patients who have certain types of tumours.
- Stopped production of Red Blood Cell following treatment with any Patients who do not receive treatment for prevention for blood clots.
- Patients having coronary heart disease.
- Patients having surgery, including dental surgery.

Talk to your doctor if you are not sure if you have these conditions or if you have any questions about this information.

What information Should I share with my Doctor, before taking REPOITIN?

The doctor must know if a patient:

- Has Heart Disease.
- Has high blood pressure and receives medication.
- Develops high blood pressure during treatment.
- Suffers from seizures or ever had a seizure.
- Has narrowed arteries or vascular disease.
- Is allergic to this type of product.
- Blood disorders (such as Sickle Cell anemia, clotting disorders)
- Pregnant or nursing.

Tell your doctor about all your health conditions and all the medicines you take including prescription and over the counter medicines, Vitamins, Supplements, and Herbal.

The following warnings are for patients who undergo dialysis :

It is extremely important to follow all the doctor's instructions carefully especially regarding medicines and diet. Take all medicines as prescribed, especially medicines for high blood pressure and iron supplements. The injections will not be effective if a shortage of iron exists. If anaemia is corrected, a feeling of well being may result and you may be tempted not to keep to dietary prescriptions and this may cause complications with dialysis. Only in very exceptional cases, severe high blood pressure has developed during treatment. This requires intensive medical care. The symptoms resemble those of brain disease (nausea and confusion). If you experience any unusual symptom, you must immediately notify your doctor.

What special dietary instructions should I follow?

If you are following a prescribed special diet because you have kidney disease or high blood pressure, follow it carefully, even if you feel better while using REPOITIN. REPOITIN will not work unless your body has enough iron. Your doctor or dietitian will probably tell you to eat foods that are rich in iron. If you cannot get enough iron from your diet, your doctor may prescribe an iron supplement. Take this supplement exactly as directed.

What are the side-effects of REPOITIN?

Not all side-effects reported for the medicine are included in this leaflet. If your general state of health worsens while taking this medicine, please consult with your doctor.

The more common side-effects are : Transient flu-like symptoms, including headaches, chills, muscle and joint pains. Dizziness, increase in blood pressure, itching and allergic-skin reactions may also occur. Pain and discomfort may occur at the subcutaneous injection site. For serious side-effects, see under "Warnings" above.

Reason for issue: TEXT REVISED		Specification: Printed on bible paper 40 gsm.	
Customer: EXPORTS		Colour: Pantome Blue & Red	
Product: REPOITIN		Specification No.:	
Item Code number: 20010040/1		Artwork made to: 100%	
Supersedes Item Code: 20010040/0		Dimensions: 201 x 287 mm	
PACKAGING DEVELOPMENT		MEDICAL DEPARTMENT	
QUALITY CONTROL		QUALITY ASSURANCE	

If you are on hemodialysis, there is a risk of blood clots forming at your vascular access. Call your doctor or dialysis center if you think your access is blocked. Some patients may have an increased risk of blood clots forming in blood vessels, especially in the leg veins (venous thrombosis). In some patients, pieces of blood clot may travel to the lungs and block the blood circulation in the lungs (pulmonary embolism).

Call your doctor if you experience chest pain, shortness of breath, or pain in the legs with or without swelling.

Talk to your doctor for more information about side effects.

Make sure to report any side effects to your doctor.

Are there any special precautions with the use of REPOITIN

Avoid potentially hazardous activities such as driving or operating heavy machinery at the beginning of the treatment.

Your doctor should be told if you have or develop an infection or inflammation as this may reduce the effect of the injection.

If you suffer from high blood pressure, it must be under control before and during treatment with REPOITIN and it must therefore be measured regularly during treatment.

The dose of your blood pressure medications may have to be increased or additional medications may have to be prescribed to keep your blood pressure under control. Be sure to take these medicines exactly as prescribed.

The haemoglobin in your blood will be measured regularly as this gives a good indication of how effective the treatment is.

The dosage of REPOITIN will then be adjusted carefully (increased or decreased) according to the change in haemoglobin concentration in the blood.

Is REPOITIN safe for pregnant women?

Safety in pregnancy has not been established.

Does REPOITIN interact with other medicines?

Inform your doctor if you are taking any other medicines regularly. Concomitant use of various medicines may cause undesirable interaction. Do not share medicine prescribed for you with others.

What are Storage and Disposal Conditions?

- Store refrigerated between 2 – 8 °C.
- Do not freeze.
- Do not shake the Vial / PFS.
- Keep out of reach of children.
- Use a disposable syringe or needle only one time.
- Discard any unused medicine solution in Vial / PFS immediately.
- Return unused and expired medicines to your pharmacist for disposal.
- Do not use a vial / PFS that has been frozen.
- Do not leave the vial/PFS in direct sunlight.
- Throw away used syringes in a puncture-resistant container, out of the reach of children.
- Talk to your doctor or pharmacist about how to throw away the puncture-resistant container.
- Do not throw the container in your household trash.
- There may be special state and local laws for throwing away used needles and syringes.

If you have any questions about REPOITIN, that has been exposed to temperature extremes, be sure to check with your doctor.

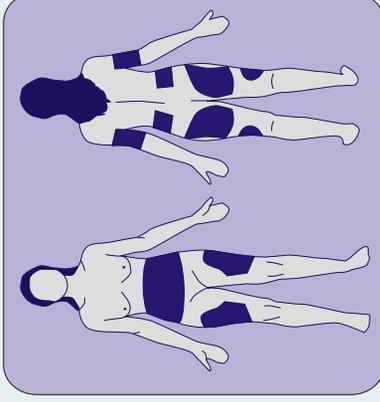
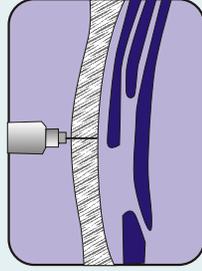
When traveling, transport REPOITIN in its original carton in an insulated container with a coolant such as blue ice. To avoid freezing, make sure the REPOITIN vial / PFS does not touch the coolant. Once you arrive, your REPOITIN should be placed in a refrigerator as soon as possible.

For further information please contact your doctor.

REPOITIN is Manufactured & Marketed by:
Serum Institute of India Ltd.
 21/2/ Haddapsar, Pune-411 028, INDIA.
 TEL: +91-20-26993900/04,
 FAX: +91-20-26993924 / 26993921,

Website : www.seruminstitute.com.

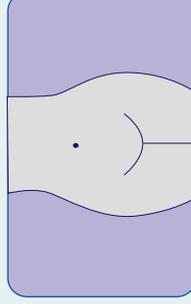
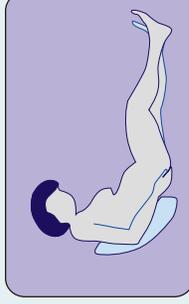
HOW TO INJECT REPOITIN



Subcutaneous injection sites in body

Follow the following steps to inject Repoitin properly:

1. Wash your hands well with soap and water. Dry your hands.
2. Sit or lie in a comfortable position so that you can easily see the area of your abdomen where you will be injecting.
3. Select an area on the right or left side of your abdomen, at least 5 centimeters from your belly button.



Do not inject within 5 centimeters of your belly button or around existing injury. Alternate the site of injection between the left and right sides of the abdomen.

4. Clean the area you have selected for your injection and allow the area to dry.

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