For the use of only a registered medical practitioner or hospital or laboratory

Recombinant Human Erythropoietin Alpha Injection

ERYPRO™ - 2000 / 4000 / 10000 एरिप्रो - २०००/४०००/१००००

WARNINGS: INCREASED MORTALITY, SERIOUS CARDIOVASCULAR and THROMBOEMBOLIC EVENTS, and INCREASED RISK OF TUMOR PROGRESSION OR RECURRENCE
Renal failure: Patients experienced greater risks for death and serious cardiovascular events when administered erythropoiesis-stimulating agents (ESAs) to target higher versus lower hemoglobin levels (13.5 vs. 11.3 g/dL; 14 vs. 10 g/dL). Individualize dosing to achieve and maintain hemoglobin levels within the range of 10 to 12 g/dL.

Cancer:

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in some clinical studies in patients with breast, non-small cell lung, head an neck, lymphoid, and cervical cancers (see WARNINGS).
- To decrease these risks, as well as the risk of serious cardio and thrombovascular events, use the lowest dose needed to avoid red blood cell transfusion.
- Use ESAs only for treatment of anemia due to concomitant myelosuppressive chemotherapy.
- ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure.
- Discontinue following the completion of a chemotherapy course.

Perisurgery: ERYPRO™ increased the rate of deep venous thromboses in patients not receiving prophylactic anticoagulation. Consider deep venous thrombosis prophylaxis.
(See WARNINGS: Increased Mortality, Serious Cardiovascular and Thromboembolic Events,

WARNINGS: Increased Mortality and/or Increased Risk of Tumor Progression or Recurrence, INDICATIONS AND USAGE, and DOSAGE AND ADMINISTRATION.)

COMPOSITION:

ERYPRO™ 2000
Each 1ml vial contains:
Recombinant Human Erythropoietin Alpha : 2000 IU

ERYPRO™ 4000
Each 1ml vial contains:
Recombinant Human Erythropoietin Alpha : 4000 IU

ERYPRO™ 10000
Each 1ml vial contains:
Recombinant Human Erythropoietin Alpha : 10000 IU

DESCRIPTION
Erythropoietin is a glycoprotein which stimulates red blood cell production. It is produced in the kidney and stimulates the division and differentiation of committed erythroid progenitors in the bone marrow. Erythropoietin (Epoetin alfa), a 165 amino acid glycoprotein manufactured by recombinant DNA technology, has the same biological effects as endogenous Erythropoietin.

CLINICAL PHARMACOLOGY
Mechanism of action
Erythropoietin (EPO) is a glycoprotein that regulates the production of red blood cells by stimulating the division and differentiation of committed erythroid progenitor cells in the bone marrow. Recombinant Human Erythropoietin has the same biological activity as native EPO. In adults, almost 90% of EPO is produced in the kidney with the remainder produced by the liver. During fetal development, EPO is produced in the liver, and prior to birth at term, production is transferred to the kidney. Erythropoietin production in the kidney occurs in interstitial cells in the inner cortex that are in immediate proximity to the proximal tubules. More cells are activated as the hematocrit drops. Renal tubular cells may serve as oxygen sensors transmitting signals to the interstitial cells, possibly because they contain large amounts of heme protein that may function as an intracellular oxygen sensor and transducer.

Erythropoietin is required for the transformation of the most mature erythroid progenitor cell, erythroid colony-forming unit (CFU-E), to a proerythroblast. In the absence of EPO, this transformation cannot occur and the CFU-E will die. Erythropoietin activates the synthesis of haemoglobin and other proteins found in normal erythroblasts. Erythropoietin also causes a shift of marrow reticulocytes into the circulation. Due to the length of time required for erythropoiesis, a clinically significant increase in hematocrit is usually not observed in less than 2 weeks and may take up to 6 weeks in some patients. Erythropoietin has little effect on early erythroid progenitor cells, erythroid burst-forming units (BFU-E), whose growth is more dependent upon interleukin-3 and granulocyte-macrophage colony stimulating factor (GM-CSF). The production and activity of EPO is linked in a negative feedback loop, which maintains optimal red cell mass for oxygen transport. There appears to be a plateau of optimal oxygen transport to tissues occurring around hematocrit of 35-55% with significant decreases in oxygen transport above and below these values. Erythropoietin produces a dose-dependent increase in the hematocrit; an increase of 2% per week may be seen during the initial phase of therapy. The stimulation of erythropoiesis increases the demand for iron, making iron supplementation necessary for many patients.

Pharmacokinetics
Recombinant Human Erythropoietin is administered intravenously or subcutaneously. The subcutaneous route produces peak plasma concentrations between 5-24 hours after administration. Although the IV route gives a more rapid peak, the delayed systemic absorption from the subcutaneous route gives a more sustained response. Subcutaneous administration can result in some drug accumulation because of delayed absorption. A dose-dependent response is seen with Erythropoietin doses of 50-300 units/kg three times a week; however, a greater response is not seen at doses > 300 units/kg three times a week. Other factors affecting response to therapy include iron stores, baseline hematocrit, and concurrent medical conditions. As with the endogenous Erythropoietin (EPO), Erythropoietin does not appear extravascularly in humans.
Whether the drug crosses the placenta or is distributed into breast milk has not been evaluated. Metabolism and elimination of endogenous EPO or Erythropoietin are not fully understood. Administered IV Erythropoietin is eliminated via first order kinetics with a circulating t ½approximately 4 to 13 hr. In healthy volunteers, the half-life of Erythropoietin is approximately 20% shorter than the half-life in patients with chronic renal failure.

Special Populations: Erythropoietin half-life in patients with chronic renal failure after IV administration is 4 to 13 hours. The drug is not removed by hemodialysis. The pharmacokinetic profile of Erythropoietin in children and adolescents appears to be similar to that of adults. Limited data are available for neonates. Relative to data obtained in 10 healthy adults, a study of 7 preterm very low birth weight neonates given IV Erythropoietin suggests that the volume of distribution and clearance are higher (1.5 to 2-fold and 3-fold, respectively) in preterm neonates.

INDICATIONS AND USAGE

Treatment of Anemia of Chronic Renal Failure Patients
Recombinant Human Erythropoietin is indicated for the treatment of anemia associated with CRF, including patients on dialysis (ESRD) and patients not on dialysis. Erythropoietin is indicated to elevate or maintain the red blood cell level (as manifested by the hematocrit or haemoglobin determinations) and to decrease the need for transfusions in these patients.
Treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.

Recombinant Human Erythropoietin should be administered under the guidance of a qualified physician.
Clinical effects of Erythropoietin
In CRF patients
In various clinical studies with starting dose of 50 – 150 IU/ Kg thrice in a week approximately 95% of all patients responded with a clinically significant increase in hematocrit. By the end of two months of therapy virtually all patients were transfusion independent

Adult patients on Dialysis
In largest clinical studies conducted in dialysis patients the median maintenance dose necessary to maintain the hematocrit between 30 – 36% was approximately 75IU/Kg given three times in a week. In another double blind, placebo controlled, multicentric trial clinically and statistically (p<0.05) significant improvement was shown in patients treated with Erythropoietin compared to placebo group.

CRF patients not requiring Dialysis
Clinical studies conducted in patients with CRF not on dialysis involving 181 patients treated with erythropoietin with average duration of therapy for nearly five months showed that these patients responded to erythropoietin therapy in a manner similar to that observed in patients on dialysis. Moreover, erythropoietin doses of 75- 150 IU/kg per week have been shown to maintain hematocrit of 36-38% for up to six months.

A phase IV open label multicentric trial with EPOCIM (Erypro in India) was studied in 98 anaemic cancer patients. Patients received treatment with EPOCIM, at doses of 10000 IU 3 times per week by subcutaneous (SC) administration during 8 weeks. At the 4th week of treatment EPOCIM dose was increased to 20000 IU by subcutaneous administration 3 times per week, if the hemoglobin value was not increased at least in 10 g/L in relation with the initial value.
The results of this clinical trial showed that 65.9 % of these patients increased the value of haemoglobin to 15 g/L or more (27/41 patients) at 8 weeks of treatment, in relation with the baseline value; and 46.3 % of patients showed an increase higher than 20 g/L in the same period of time (19/41 patients). The increase of the mean haemoglobin value in the patients treated with EPOCIM showed a significant increase as early as at 4 week of treatment, and at the end of the week 8. Initial mean haemoglobin value was 86.62 g/L, rising to 107.24 g/L at the 8 of weeks of treatment. Transfusion requirements in these patients treated with EPOCIM decreased in 29.3 % at 8 week of treatment in relation with the baseline number of required transfusions. In adult clinical trial EPOCIM has being very well tolerated, bone pain (20.7 %), fever 13.8 % and pain in the site of injection (8.6 %,) were the main adverse events reported, all of them classified as mild or moderate intensity according WHO criteria. This study suggests that patients with haematological malignance or solid tumours, who received several schedules and intensity chemotherapy or radiotherapy treatments, respond similarly to EPOCIM

Clinical efficacy of Erythropoietin in Indian patients

A multicentric phase III open label prospective study was conducted on Indian patients to evaluate the efficacy and safety of rHuEPO (Erypro) in patients either on dialysis or non dialysis for management of anemia in CKD. The study was conducted on 42 patients (32 patients completed the study) with baseline hematocrit of ≤ 20% and Hb 9.5 gm/dl. The study period was for 12 weeks and the dosage ranged from 50 – 100IU/ kg thrice in a week (TIW). There was a steady rise in Hb through out the study period with mean rise of Hb 3.5 gm/dl at the end of study period which was statistically highly significant(p value < 0.0001). The mean hematocrit also showed a significant rise from 22% to 34% which was statistically significant (p value < 0.0001). All the known adverse events of erythropoietin like hypotension, headache, muscle cramps, fever, vomiting, cough occurred in more than 5% of patients. Hypertension a known adverse effect with erythropoietin occurred in less than 5% of patients. The study concluded that rHuEPO (Erypro) was able to correct the absolute and functional deficiency of iron and hence anemia of CKD and eliminated the need for blood transfusions. Erypro was effective, safe and well tolerated comparable to other recombinant human erythropoietin as reported in medical literature.

CONTRAINDICATIONS

Erythropoietin is contraindicated in patients with:
1. Uncontrolled hypertension.
2. Known hypersensitivity to mammalian cell-derived products.
3. Known hypersensitivity to Albumin (Human).

WARNINGS

Adults
Pure Red Cell Aplasia
Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to Erythropoietin, have been reported in patients treated with Erythropoietin. This has been reported predominantly in patients with CRF receiving Erythropoietin by subcutaneous administration.

Albumin (Human)
Recombinant Human Erythropoietin contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

Chronic Renal Failure Patients
Hypertension: Patients with uncontrolled hypertension should not be treated with Erythropoietin; blood pressure should be controlled adequately before initiation of therapy. Up to 80% of patients with CRF have a history of hypertension. Although there does not appear to be any direct pressor effects of Erythropoietin, blood pressure may rise during Erythropoietin therapy. During the early phase of treatment when the hematocrit is increasing, approximately 25% of patients on dialysis may require initiation of, or increases in, antihypertensive therapy. Hypertensive encephalopathy and seizures have been observed in patients with CRF treated with Erythropoietin.
It is recommended that the dose of Erythropoietin be decreased if the haemoglobin increase exceeds 1 g/dl in any 2-week period, because of the possible association of excessive rate of rise of haemoglobin with an exacerbation of hypertension. In CRF patients on hemodialysis with clinically evident ischemic heart disease or congestive heart failure, the haemoglobin should be managed carefully, not to exceed 12 g/dL .
Seizures: Seizures have occurred in patients with CRF participating in Erythropoietin clinical trials. In adult patients on dialysis, there was a higher incidence of seizures during the first 90 days of therapy (occurring in approximately 2.5% of patients) as compared with later time points. Given the potential for an increased risk of seizures during the first 90 days of therapy, blood pressure and the presence of premonitory neurological symptoms should be monitored closely. Patients should be cautioned to avoid potentially hazardous activities such as driving or operating heavy machinery during this period.While the relationship between seizures and the rate of rise of haemoglobin is uncertain, it is recommended that the dose of Erythropoietin be decreased if the haemoglobin increase exceeds 1 g/dL in any 2-week period.

Thrombotic Events: During hemodialysis, patients treated with Erythropoietin may require increased anticoagulation with heparin to prevent clotting of the artificial kidney. Other thrombotic events (eg, myocardial infarction, cerebrovascular accident, transient ischemic attack) have occurred in clinical trials at an annualized rate of less than 0.04 events per patient year of Erythropoietin therapy.

PRECAUTIONS
The parenteral administration of any biologic product should be attended by appropriate precautions in case allergic or other untoward reactions occur clinical trials, while transient rashes were occasionally observed concurrently with Erythropoietin therapy, no serious allergic or anaphylactic reactions were reported.
The safety and efficacy of Erythropoietin therapy have not been established in patients with a known history of a seizure disorder or underlying hematologic disease (eg, sickle cell anemia, myelodysplastic syndromes, or hypercoagulable disorders). In some female patients, menses have resumed following Erythropoietin therapy; the possibility of pregnancy should be discussed and the need for contraception evaluated.

Hematology
Exacerbation of porphyria has been observed rarely in patients with CRF treated with Erythropoietin. However,

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Erythropoietin has not caused increased urinary excretion of porphyrin metabolites in normal volunteers, even in the presence of a rapid erythropoietic response. Nevertheless, Erythropoietin should be used with caution in patients with known porphyria.
Bone marrow fibrosis is a known complication of CRF in humans and may be related to secondary hyper-parathyroidism or unknown factors. The incidence of bone marrow fibrosis was not increased in a study of adult patients on dialysis who were treated with Erythropoietin for 12 to 19 months, compared to the incidence of bone marrow fibrosis in a matched group of patients who had not been treated with Erythropoietin . Haemoglobin in CRF patients should be measured twice a week.

Lack or Loss of Response
If the patient fails to respond or to maintain a response to doses within the recommended dosing range, the following etiologies should be considered and evaluated:
1. Iron deficiency: Virtually all patients will eventually require supplemental iron therapy.
2. Underlying infectious, inflammatory, or malignant processes.
3. Occult blood loss.
4. Underlying hematologic diseases (ie, thalassemia, refractory anemia, etc).
5. Vitamin deficiencies: Folic acid or vitamin B12.
6. Hemolysis.
7. Aluminium intoxication.
8. Osteitis fibrosacystica.
9. Pure Red Cell Aplasia (PRCA) or anti-Erythropoietin antibody-associated anemia: In the absence of another etiology, the patient should be evaluated for evidence of PRCA and sera should be tested for the presence of antibodies to Erythropoietin.

Iron Evaluation
During Erythropoietin therapy, absolute or functional iron deficiency may develop. Functional iron deficiency, with normal ferritin levels but low transferrin saturation, is presumably due to the inability to mobilize iron stores rapidly enough to support increased erythropoiesis. Transferrin saturation should be at least 20% and ferritin should be at least 100 mg/ml.
Prior to and during Erythropoietin therapy, the patient's iron status, including transferrin saturation (serum iron divided by iron binding capacity) and serum ferritin, should be evaluated. Virtually all patients will eventually require supplemental iron to increase or maintain transferrin saturation to levels which will adequately support erythropoiesis stimulated by Erythropoietin. All surgery patients being treated with Erythropoietin should receive adequate iron supplementation throughout the course of therapy in order to support erythropoiesis and avoid depletion of iron stores.

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Carcinogenic potential of Erythropoietin has not been evaluated. Erythropoietin does not induce bacterial gene mutation (Ames Test), chromosomal aberrations in mammalian cells, micronuclei in mice, or gene mutation at the HGPRT locus. In female rats treated IV with Erythropoietin, there was a trend for slightly increased fetal wastage at doses of 100 and 500 Units/kg.

Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Erythropoietin should be used during pregnancy only if potential benefit justifies the potential risk to the fetus.

Nursing Mothers
It is not known whether Erythropoietin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Erythropoietin is administered to a nursing woman.

Pediatric Use
Pediatric Patients on Dialysis: The safety data from literature show that there is no increased risk to pediatric CRF patients on dialysis when compared to the safety profile of Erythropoietin in adult CRF patients. Published literature provides supportive evidence of the safety and effectiveness of Erythropoietin in pediatric CRF patients on dialysis.

Pediatric Patients Not Requiring Dialysis: Published literature has reported the use of Erythropoietin in 133 pediatric patients with anemia associated with CRF not requiring dialysis, ages 3 months to 20 years, treated with 50 to 250 Units/kg SC or IV TIW. Dose-dependent increases in haemoglobin and hematocrit were observed with reductions in transfusion requirements.

Geriatric Use
No overall differences in safety or effectiveness were observed between geriatric and younger patients. Dose selection and adjustment for an elderly patient should be individualized to achieve and maintain the target hematocrit.

Chronic Renal Failure Patients
Patients with CRF Not Requiring Dialysis
Blood pressure and haemoglobin should be monitored no less frequently than for patients maintained on dialysis. Renal function and fluid and electrolyte balance should be closely monitored, as an improved sense of well-being may obscure the need to initiate dialysis in some patients.

Hematology
Sufficient time should be allowed to determine a patient's responsiveness to a dosage of Erythropoietin before adjusting the dose. Because of the time required for erythropoiesis and the red cell half-life, an interval of 2 to 6 weeks may occur between the time of a dose adjustment (initiation, increase, decrease, or discontinuation) and a significant change in haemoglobin.In order to avoid reaching the suggested target haemoglobin too rapidly, or exceeding the suggested target range (haemoglobin of 10 g/dl to 12 g/dl), the guidelines for dose and frequency of dose adjustments should be followed.
For patients who respond to Erythropoietin with a rapid increase in haemoglobin (eg, more than 1 g/dl in any 2-week period), the dose of Erythropoietin should be reduced because of the possible association of excessive rate of rise of haemoglobin with an exacerbation of hypertension.The elevated bleeding time characteristic of CRF decreases toward normal after correction of anemia in adult patients treated with Erythropoietin. Reduction of bleeding time also occurs after correction of anemia by transfusion.

Laboratory Monitoring
The haemoglobin should be determined twice a week until it has stabilized in the suggested target range and the maintenance dose has been established. After any dose adjustment, the haemoglobin should also be determined twice weekly for at least 2 to 6 weeks until it has been determined that the haemoglobin has stabilized in response to the dose change. The haemoglobin should then be monitored at regular intervals. A complete blood count with differential and platelet count should be performed regularly. During clinical trials, modest increases were seen in platelets and white blood cell counts. While these changes were statistically significant, they were not clinically significant and the values remained within normal ranges.
In patients with CRF, serum chemistry values (including blood urea nitrogen [BUN], uric acid, creatinine, phosphorus, and potassium) should be monitored regularly. In some adult patients with CRF not on dialysis treated with Erythropoietin, modest increases in serum uric acid and phosphorus were observed. While changes were statistically significant, the values remained within the ranges normally seen in patients with CRF.

Diet
As the haemoglobin increases and patients experience an improved sense of well-being and quality of life, the importance of compliance with dietary and dialysis prescriptions should be reinforced. In particular, hyperkalemia is not uncommon in patients with CRF.

Dialysis Management
Therapy with Erythropoietin results in an increase in hematocrit and a decrease in plasma volume which could affect dialysis efficiency. In studies to date, the resulting increase in hematocrit did not appear to adversely affect dialyzer function or the efficiency of high flux hemodialysis. During hemodialysis, patients treated with Erythropoietin may require increased anticoagulation with heparin to prevent clotting of the artificial kidney. Patients who are marginally dialyzed may require adjustments in their dialysis prescription. As with all patients on dialysis, the serum chemistry values (including BUN, creatinine, phosphorus, and potassium) in patients treated with Erythropoietin should be monitored regularly to assure the adequacy of the dialysis prescription.

Renal Function
In adult patients with CRF not on dialysis, renal function and fluid and electrolyte balance should be closely monitored, as an improved sense of well-being may obscure the need to initiate dialysis in some patients. In patients with CRF not on dialysis, placebo-controlled studies of progression of renal dysfunction over periods of greater than 1 year have not been completed. In shorter term trials in adult patients with CRF not on dialysis, changes in creatinine and creatinine clearance were not significantly different in patients treated with Erythropoietin compared with placebo-treated patients.

ADVERSE EFFECTS
Erythropoietin is generally well tolerated. In a multicentric phase III open label prospective study conducted on Indian patients to evaluate the efficacy and safety of rHuEPO (Erypro) in patients either on dialysis or non dialysis for management of anemia in CKD a total 154 adverse events were reported in the study with hypotension, headache, muscle cramps, fever, vomiting and cough in the descending order of frequency. All these events occurred in greater than five percent subjects in the study.
Though the rHuEPO is known to increase the blood pressure or cause hypertension when used in CKD patients, the same occurred in less than five percent study subjects. This was also corroborated by the baseline and end of study blood pressure values which remained near their original values at the end of the study. Most of the adverse events reported i.e, 93% of them were mild in severity with 86% being reported as very unlikely to be related to the study drug, while only 2% of them were reported to be probably related to rHuEPO. All the events were managed by established standard of care defined in the medical literature.

OVERDOSAGE
The maximum amount of Recombinant Human Erythropoietin that can be safely administered in single or multiple doses has not been determined. Doses of up to 1500 Units/kg TIW for 3 to 4 weeks have been administered to adults without any direct toxic effects of Erythropoietin itself. Therapy with Erythropoietin can result in polycythemia if the haemoglobin is not carefully monitored and the dose appropriately adjusted. If the suggested target range is exceeded, Erythropoietin may be temporarily withheld until the haemoglobin returns to the suggested target range; Erythropoietin therapy may then be resumed using a lower dose (see DOSAGE AND ADMINISTRATION). If polycythemia is of concern, phlebotomy may be indicated to decrease the haemoglobin.

DOSAGE AND ADMINISTRATION

Chronic Renal Failure patients
Adults
IV/Subcutaneous **Initial dose:** 50 to 100 units/kg 3 times/wk.
Maintenance: Individually titrate.

Children (1 mo of age and older)
IV/Subcutaneous 50 units/kg 3 times/wk.

Dose adjustment
Do not adjust dose more frequently than once monthly, unless clinically indicated. After any dose adjustment, determine the Hct twice weekly for at least 2 to 6 wk. If the Hb is increasing and approaching 12 g/dL, reduce the dose approximately 25%. If Hb continues to increase, temporarily withhold the dose until Hb begins to decrease, at which point therapy should be reinitiated at a dose approximately 25% below the previous dose. If Hb increases by more than 1 g/dL in a 2-wk period, decrease the dose by about 25%. If the increase in Hb is less than 1 g/dL over 4 wk and iron stores are adequate, increase the dose by approximately 25% of the previous dose. Further increase may be made at 4-wk intervals until the specified Hb is obtained. Suggested target Hb range is 10 to 12 g/dL.

Cancer Patients
Adults Three times/wk dosing
Subcutaneous 150 units/kg 3 times/wk. Reduce dose when Hb approaches 12 g/dL or Hb increases by more than 1 g/dL in any 2-wk period. Withhold dose when Hb exceeds 13 g/dL, until the Hb falls to 12 g/dL, then restart dose at 25% below the previous dose. Increase dose to 300 units/kg 3 times/wk if response is not satisfactory (no reduction in transfusion requirements or rise in Hb) after 8 wk. Suggested target Hb range is 10 to 12 g/dL.

Weekly dosing
Subcutaneous 40,000 units/wk. If after 4 wk of therapy the Hb has not increased by 1 g/dL or more, in the absence of RBC transfusion; increase dose to 60,000 units/wk. If there is no satisfactory response to a dose of 60,000 units/wk after 4 wk, it is unlikely the patient will respond to higher doses. Withhold dose if Hb exceeds 13 g/dL, and when Hb falls to less than 12 g/dL, restart dose 25% below the previous dose. Reduce dose when treatment produces a very rapid Hb response (eg, Hb increases more than 1 g/dL in any 2-wk period).

Presentation

ERYPRO™ is supplied in the following packages:
Each 1ml vial : 2000 IU
Each 1ml vial : 4000 IU
Each 1ml vial : 10000 IU

STORAGE
Store at temperature between 2°C- 8°C.
Protect from light, do not freeze or shake.
Keep out of reach of children.

SHELF LIFE: Please refer to carton/label.

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Marketed by:
Biocon Biologics India Limited
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Electronics City, Phase - II,
Bengaluru - 560 100, India.

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To report adverse events and/or product complaints visit our website **www.biocon.com** or call toll free number: **1800 102 9465** or e-mail us at **DrugSafety@biocon.com.**