NUTRITION & BLOOD

1. Haematinic Agents

1.1. HAEMOLYTIC, HYPOPLASTIC, RENAL ANAEMIAS

EPOTIN

Presentation

Vials: Pack of 1 or 10 vials.

Composition

Each vial contains: Recombinant human erythropoietin 2,000 IU, 4,000 IU, or 10000 IU.
(Host: CHO cell, Vector: SV40)

Indications

- Treatment of Anaemia of Chronic Renal Failure Patients

For the treatment of anaemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. **Epotin** elevates or maintains the red blood cell level and decreases the need for transfusions.

- Treatment of Anaemia in Cancer Patients on Chemotherapy

Epotin is indicated to elevate the red blood cell level to donate autologous blood. **Epotin** is also indicated to prevent from reduction of haemoglobin for the patients scheduled to major surgery who are not able to participate in an autologous blood donation program as in the following conditions:

1. Patients with low haemoglobin concentration.
2. Patients scheduled to major surgery, female needs more than 4 units of blood or male needs more than 5 units of blood.
3. In case of short time before surgery to donate autologous blood.

Dosage and Administration

- Chronic Renal Failure (CRF) Patients

Epotin is administered intravenously at an initial dose of 50 IU/kg for 1 - 2 minutes 3 times a week. It can be given by either an intravenous or subcutaneous route for patients with CRF not on dialysis. The dose increase is dependent upon the initial response. The dose can be increased, if necessary, by 25 IU/kg in a 4-week period. If haemoglobin is increased more than 2g/dl at a dose of 50 IU/kg, the frequency should be reduced to 2 times a week. To correct the anaemia, the target concentration of haemoglobin is 10g/dl (30% as haematocrit). When the anaemia is corrected, **Epotin** is given as a maintenance dose of 25 - 50 IU/kg 2 - 3 times a week. The target range of haemoglobin is 10 - 12g/dl. The patients with pretreatment haemoglobin < 6g/dl need higher maintenance dose than the patients with pretreatment haemoglobin > 8g/dl. the dose may be adjusted according to the age of the patient. The unit dose of **Epotin** should not exceed 200 IU/kg, and the frequency should not be more than 3 times a week. Prior to initiation of therapy or during the therapy, the patient's iron stores should be evaluated, if necessary, iron should

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be supplied. If the patients are in aluminum intoxication or infected, delayed or diminished responses may be occurred. In patients with CRF not on dialysis, the maintenance dose must also be individualized according to the severity of anaemia or age, however, the dose of 70 - 150 IU/kg per week have been shown to maintain 36 - 38% of haematocrit for more than six months.

- Cancer patients on chemotherapy

The recommended initial dose of **Epotin** is 150 IU/kg as a subcutaneous injection three times a week. If the response is unsatisfactory after 8 weeks of therapy, the dose can be increased up to 300 IU/kg three times a week. If patients have not responded satisfactorily to an Epotin dose of 300 IU/kg 3 times a week, it is unlikely that they will respond to higher doses of **Epotin**. If the haematocrit exceeds 40%, the dose of **Epotin** should be withheld until it falls to 36%. The dose of **Epotin** should be reduced by 25% when treatment is resumed or the dose is titrated to maintain the desired haematocrit. If the initial dose of Epotin includes a very rapid haematocrit response (e.g., an increase of more than 4% points in any 2-week period), the dose should be reduced. In general, patients with lower baseline serum erythropoietin level responded more vigorously to **Epotin** than patients with higher erythropoietin levels. Although no specific serum erythropoietin level can be stipulated above which patients would be unlikely to respond to **Epotin** therapy, treatment of patients with grossly elevated serum erythropoietin levels higher than 200mU/mL is not recommended. The haematocrit should be monitored on a weekly basis in patients receiving **Epotin** therapy until haematocrit becomes stable.

- Patients to be participated in autologous blood donation program

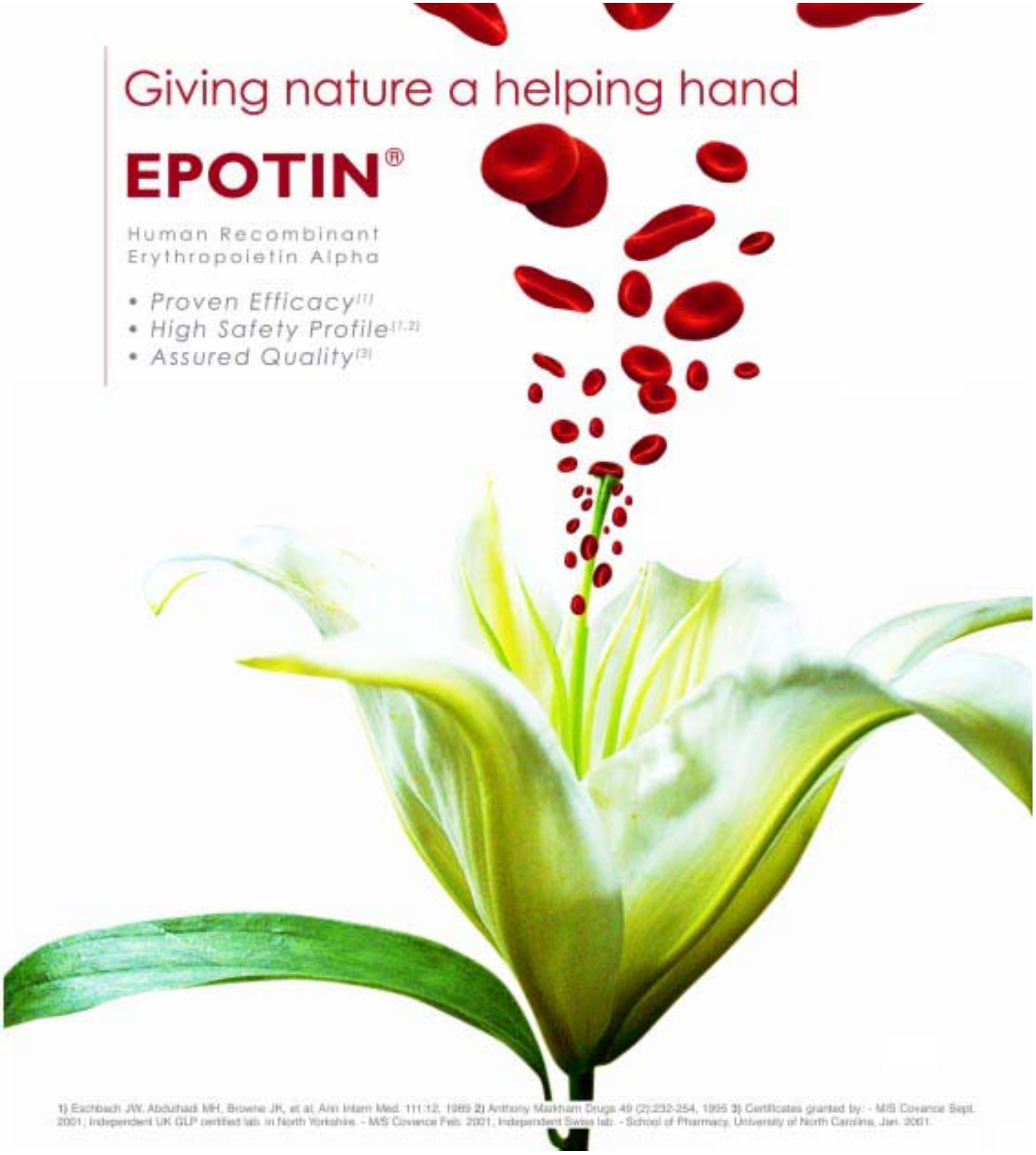
Prior to major surgery, it is recommended to take autologous blood two times a week for 3 weeks. Based on previous studies, **Epotin** can be given intravenously at a dose of 150 - 300 IU/kg, 2 times a week for 3 weeks to elevate the red blood cell levels. The recommended maximum dose to promote erythropoiesis is 600 IU/kg, two times a week for 3 weeks intravenously. The concentration of haemoglobin should be controlled weekly for the patients who are expected to require > 4 units of blood with pretreatment of haemoglobin > 11g/dl (Hb < 6.8 mmol/L), the patients require > 5 units of blood with pretreatment haemoglobin > 11g/dl (Hb < 6.8mmol/L), or the patients to be scheduled to surgery within 1-3 weeks. Iron supplementation: All surgery patients being treated with **Epotin** should receive adequate iron supplementation (e.g., 200mg of iron preparations per day, P.O) throughout the course of therapy in order to support erythropoiesis and avoid depletion of iron stores. Iron supplementation should be initiated as soon as possible, several weeks before taking blood.

Giving nature a helping hand

EPOTIN®

Human Recombinant
Erythropoietin Alpha

- *Proven Efficacy*[1]
- *High Safety Profile*[1,2]
- *Assured Quality*[3]



1) Eschbach JW, Abdulhadi MH, Browne JK, et al. Ann Intern Med. 111:12, 1989 2) Anthony Markham Drugs 49 (2):232-254, 1995 3) Certificates granted by: - M/S Covance Sept. 2001; Independent UK GLP certified lab. in North Yorkshire. - M/S Covance Feb. 2001, Independent Swiss lab. - School of Pharmacy, University of North Carolina, Jan. 2001.