Renegy Product Sheet

1. **General Product Information**
    - Generic name: Ferric Carboxymaltose
    - Pharmaceutical form: Solution
    - Presentation: 1 Box, 1 Ampoule, 10 ml 1 Box, 5 Ampoules, 10 ml
    - Formula: The ampoule contains: Ferric carboxymaltose equivalent to 500 mg of elemental iron Vehicle q.s. 10 ml.
2. **Indications**
    - RENEGY® is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.
    - The therapeutic indication should always be accompanied by relevant laboratory tests (e.g., serum ferritin test and transferrin saturation).
    - In cases of acute iron deficiency anemia (e.g., postoperative or postpartum hemorrhage, upper or lower gastrointestinal bleeding, etc.), RENEGY® can be used as a central or concomitant therapy depending on the diagnosis and its severity.
    - RENEGY® is useful for treating chronic iron deficiency anemia caused by diseases such as chronic renal failure, erosive acid-peptic diseases, inflammatory bowel diseases (Crohn's disease, chronic nonspecific ulcerative colitis [CUCI]), celiac disease, menstrual disorders (e.g., hyperpolymenorrhea), oncological diseases, intestinal parasitosis, etc. It can also be used concomitantly with erythropoiesis-stimulating agents.
3. **Usage (Dosage)**
    - Route of administration: Intravenous
    - Maximum single tolerated dose: A single dose of ferric carboxymaltose should not exceed 1,000 mg of iron (20 mL) per day or 20 mg of iron (0.4 mL) per kg of body weight. Do not administer 1,000 mg of iron (20 mL) more than once a week.
    - The use of iron by the parenteral (intravenous) route must always be indicated and calculated individually for each patient by the treating physician. Regardless of the case, the recommended maximum weekly doses should always be considered: a) Direct intravenous bolus administration. b) Direct administration at the venous end of the dialyzer during hemodialysis. c) Continuous intravenous infusion.

- As with any other iron preparation, special care should be taken with parenteral administration to avoid paravenous application or extravasation due to the potential for local irritation.
- Intravenous bolus injection: Ferric carboxymaltose can be administered by intravenous injection using an undiluted solution of up to 1,000 mg of iron. For doses up to 200 mg of iron, there is no prescribed administration time. For doses greater than 200 and up to 500 mg of iron, ferric carboxymaltose should be administered at a rate of up to 100 mg of iron/min. For doses greater than 500 and up to 1,000 mg of iron, ferric carboxymaltose should be administered over 15 minutes.
- Injection at the venous end of the hemodialysis dialyzer: During the hemodialysis session, administer undiluted, directly into the dialysis catheter end.
- Intravenous drip infusion: Ferric carboxymaltose can be administered by intravenous infusion up to a single maximum dose of 1,000 mg of iron (20 mL).
- In the case of infusion with ferric carboxymaltose solution, it should only be diluted in 0.9% sterile sodium chloride solution.

4. **Mode of Action (Pharmacodynamics)**
    - RENEGY® is a ferric carboxymaltose solution that provides iron in a stable ferric state (Fe3+) as a non-dextran iron complex. This complex, similar in structure to the core of ferritin, is designed to deliver iron in a controlled and usable manner by the body. After intravenous administration, RENEGY® is distributed in the reticuloendothelial system, where it is phagocytized by macrophages and deposited in lysosomes. There, ferric iron (Fe3+) is converted to ferrous iron (Fe2+) and released into the macrophage cytoplasm, where it can be transported out of the cell via ferroportin or stored in ferritin. Subsequently, ferrous iron is captured by transferrin and transported throughout the body, particularly to cells with high iron demand, such as erythroblasts, where it is used in hemoglobin synthesis.

Questions to Understand the Doctor's Needs:

- Have you treated iron deficiency before?
- How often do you prescribe intravenous treatments?
- How do you evaluate the effectiveness of oral iron treatments?
- In what cases do you prefer to prescribe intravenous treatments?
- How do you determine the dose and frequency of administration for iron deficiency treatments?

Value Dialogue Against the Competition: Of course, I understand your interest in exploring more options for your patients. Renegy stands out for its ferric carboxymaltose formulation, the only one available in Mexico, providing iron in a controlled and usable manner by the body. Our intravenous solution is an effective and safe option for treating iron deficiency, especially in cases where oral preparations are insufficient. Additionally, we offer flexibility in dosing and administration. We are committed to the health and well-being of your patients.