



PALDELA INJECTION

Ferric Carboxymaltose Injection 50 mg/ml (10 ml Vial)

PALDELATM INJECTION

Ferric Carboxymaltose Injection 50 mg/ml (10 ml Vial)

CLINICAL EVIDENCE-1:

1. Ferric carboxymaltose: A revolution in the treatment of postpartum anemia in Indian women

Study design : A Comparative study

No of Patients : 300

Three Groups:

Group A : Oral Iron(ferrous ascorbate) (100)

Group B : Iron Sucrose (100)

Group C : FCM (100)

Duration of study : 6 Weeks

Change in Hematological Parameters over 6 weeks.

Parameters	Oral Iron	Iron sucrose	FCM
Hb (g/dl)			
Baseline	8.23±1.01	8.05±1.07	7.71±1.17
6 Weeks	10.36±1.39	11.40±1.17	12.11±0.84
Serum Ferritin (ng/ml)			
Baseline	37.01±18.06	38.39±19.79	35.52±20.22
6 Weeks	51.20±21.49	102.32±48.73	142.22±58.74

FCM: Ferric carboxymaltose; Hb : Hemoglobin

Percentage of patients achieving a target Hb 12g /dl in 3 groups:

Mode of Treatment	At 6 weeks Hb n (%)	
	< 12 g/dl	≥12 g/dl
Oral Iron	88 (88)	12 (12)
Iron Sucrose	73 (73)	27 (27)
FCM	34 (34)	66 (66)
P< 0.0001, FCM: Ferric carboxymaltose; Hb : Hemoglobin		

Conclusion : In 6 weeks of study total 4.4 g/dl Hb is increased after giving 1000 mg FCM which is higher than other groups.

Ferric carboxymaltose elevates Hb level and restores iron stores faster than IV iron sucrose and oral iron, without any severe adverse reactions.

Reference: Int J Appl Basic Med Res. 2015 Jan-Apr; 5(1): 25–30.

CLINICAL EVIDENCE-2:

2. To evaluate safety and efficacy of intravenous ferric carboxymaltose (FCM) versus standard medical care (SMC) for iron-deficiency anemia (IDA) in postpartum women and women with heavy menstrual bleeding.

Study design : Open-label, multicenter randomized study

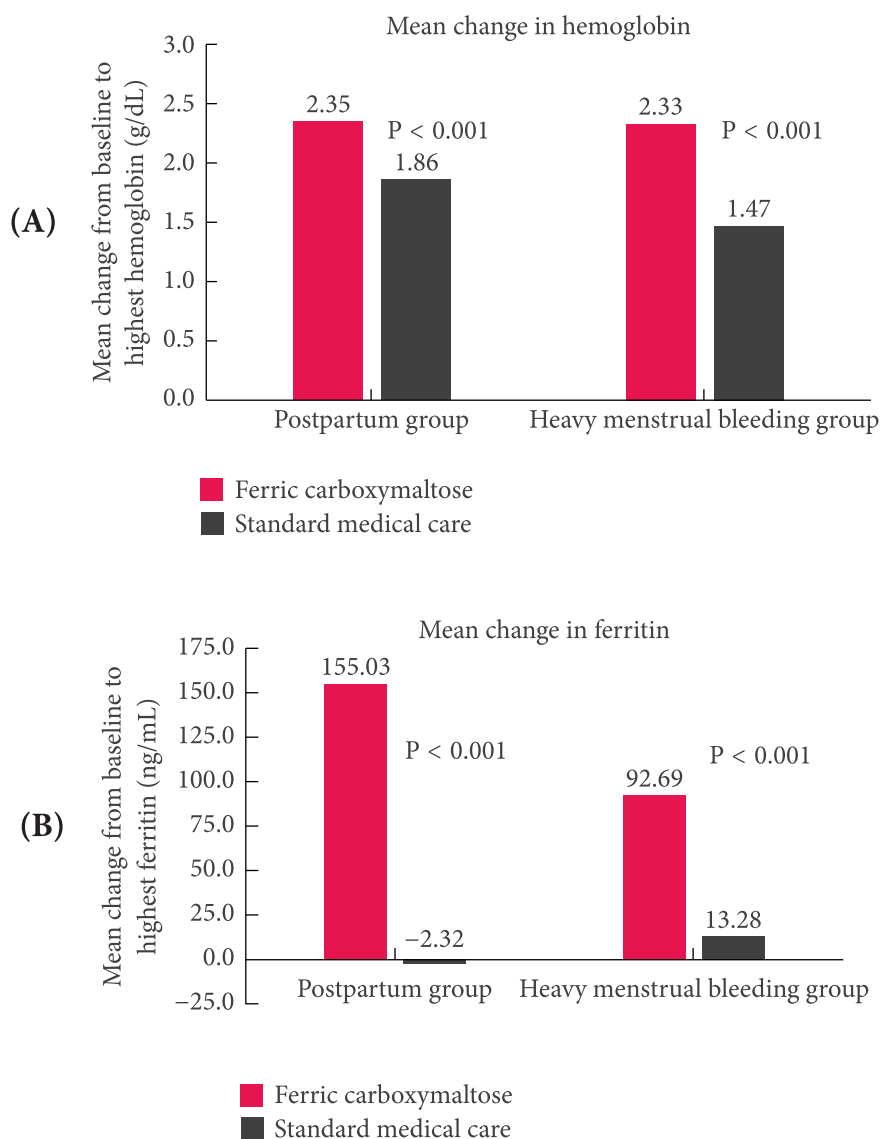
No of Patients : 2045

Three Groups:

Group A : Ferric carboxymaltose

Group B : Standard medical care (SMC)

Duration of study : 30 days



Conclusion: This study demonstrated that a single dose of FCM up to 1000mg, given by IV infusion, is safe and effective in the treatment of IDA in postpartum women and women with heavy menstrual bleeding.

FCM improves hemoglobin levels and replenishes iron stores more effectively than oral iron.

Reference : Melvin H. Seid et al ; "Ferric Carboxymaltose as Treatment in Women with Iron-Deficiency Anemia" hindawi journal; 2017; Article ID 9642027, 9 pages

PALDELATM INJECTION

Ferric Carboxymaltose Injection 50 mg/ml (10 ml Vial)

DESCRIPTION:

- **PALDELA** is an intravenous iron preparation, a medicine that is used in the treatment of iron deficiency conditions.
- It contains iron in the form of ferric carboxymaltose, an iron carbohydrate compound. Ferric carboxymaltose (FCM) is a new IV iron formulation. It is a polynuclear iron (III)-hydroxide carbohydrate complex designed to mimic physiologic ferritin. Half-life of Ferric carboxymaltose is 16 hrs.

INDICATION:

- For the treatment of Iron deficiency (ID) and iron deficiency anemia (IDA) in adults who have intolerance to oral iron or who have had unsatisfactory response to oral iron

DOSAGE & ADMINISTRATION:

- **PALDELA** (Ferric Carboxymaltose) must only be administered by the intravenous route: by injection, by infusion.
- Administer **PALDELA** intravenously, either as an undiluted slow intravenous push or by infusion. When administering as a slow intravenous push, give at the rate of approximately 100 mg (2 mL) per minute.
- When administered via infusion, dilute up to no more than 250 mL of sterile 0.9% sodium chloride injection, USP, such that the concentration of the infusion is not less than 2 mg of iron per mL and administer over at least 15 minutes.

Calculation of the cumulative iron dose:

- The cumulative dose for repletion of iron using ferric carboxymaltose is determined based on the patient's body weight and hemoglobin level and must not be exceeded. The following table should be used to determine the cumulative iron dose:

Cumulative iron dose for PALDELA:

Hb (g/dl)	Patients with body weight ≥ 35 kg and < 70 kg	Patients with body weight ≥ 70 kg
< 10	1500 mg	2000 mg
≥ 10	1000 mg	1500 mg

PRESENTATION:

- **PALDELA** is available as a Vial of 10 ml.
- Each 10 ml vial contains 500 mg of iron as ferric carboxymaltose

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