**“Evaluation of R. B. Tone XT for the safety, efficacy, tolerability and pregnancy outcomes in the management of pregnancy anemia.”**

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**Abstract:**

**Objective:** The objective of the study was to evaluate the clinical benefits associated with R. B. Tone XT tablet (Medley pharmaceutical, Mumbai) containing ferrous ascorbate equivalent to elemental iron 100 mg + folic acid 1.5 mg + elemental zinc 22.5 mg, in pregnancy anemia in India.

**Material and Methods:** The post marketing surveillance study was an open label and non-comparative study. The drug R. B. Tone XT was administered to 15 anemic pregnant women in the age range of 22-32 years. Drug was administered from 13th week of pregnancy until delivery. Baseline haemogram was evaluated at 13th week of gestation before starting iron supplementation. Another haemogram was evaluated at one week prior to the predictable date of delivery to estimate increase in levels. Study included birth weight, gestational age and increase in haemoglobin level as therapeutic outcomes. Efficacy & tolerability was evaluated by the investigator. The subjective improvement of the clinical symptoms like fatigue, and breathlessness were evaluated on a predefined scale of Fatigue Severity Scale (FSS) and Breathless Severity Scale(BSS), respectively.

**Results:** All the patients completed the study. Haemoglobin level was increased by 10.80% from the base line. Mean birth weight of infants was found to be 2.93 ±0.07 kg. Mean gestational age at the time of delivery was 38.92 ± 0.38 weeks. Not a single case of preterm delivery was reported during the study. Efficacy and tolerability was rated by the investigator as excellent in 53.33% and good 26.66% of the patients. The study drug showed excellent GI tolerability with few (13.33%) incidence of gastritis & constipation. Patients reported with significant improvements in fatigue and breathlessness on FSS and BSS scale, respectively.

**Conclusion:** R. B. Tone XT has excellent efficacy, tolerability, & safety in pregnancy anemia with an excellent pregnancy outcome in terms of gestational age and birth weight.

**Keywords:** Pregnancy anaemia,ascorbate,gestational age.

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