Survey Report

Perception mapping of Indian physicians on different oral iron preparation and strengths in the treatment of iron deficiency anemia

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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Table of Content

1	Introduction	2
2	Rationale of the study	3
3	Objectives	4
4	Methods	4
4	Results	5
5	Summary	. 20
6	Discussion	. 21
7	Clinical Recommendations	. 23
8	Consulting opinion	. 24
9	Market opportunities	. 25
10	Market positioning	. 26
11	References	. 27

1 INTRODUCTION

Iron deficiency occurs when there is an inadequate supply of iron to the body's cells, following the depletion of iron reserves. Key contributing factors include a diet low in absorbable iron, increased iron demands during pregnancy that are not met through diet, and iron loss due to parasitic infections, particularly hookworm, or other forms of blood loss [1]. This condition is most prevalent nutrient deficiency among pregnant women [2]. Persistent iron deficiency often progresses to iron-deficiency anemia (IDA). Although iron deficiency is the leading cause of anemia, other factors such as acute and chronic infections causing inflammation, deficiencies in folate, vitamins B2, B12, A, and C, as well as genetic conditions like thalassemia and sickle-cell anemia, can also contribute independently or in combination [3]. In 2011, the global prevalence of anemia among pregnant women was estimated at 38.2%.

Oral iron supplementation is a cheap and efficient way to treat ID in stable outpatients. Iron should be taken between meals, and iron absorption inhibitors (calciumcontaining foods including dairy, tea, and coffee) should be avoided when taking the iron supplement. Antacids and other medications that reduce gastric acidity may affect oral iron absorption and should be avoided. Oral iron combined with vitamin C (orange juice or ascorbic acid) can improve iron absorption [4]. Adverse effects of oral iron include nausea, constipation, diarrhea, vomiting, metallic taste, and black stool (fecal occult blood tests is unaffected), and are dose-dependent [5]. Efforts to minimize iron insufficiency should focus on increasing the availability and access to iron-rich foods. Non-animal foods include legumes, green leafy vegetables, nuts, oilseeds, jaggery, and dried fruits, as well as liver, meat, fish, and chicken. Generally, animal diets contain more iron than non-animal foods [6]. Pregnant lady should avoid foods that contain inhibitors of iron absorption with tea or milk at those meals that are inherently low in iron such as a breakfast of a low-iron cereal (eg, bread, cornflakes) [7]. Patients have generally been told to take iron in divided daily dosages to get 100 to 200 mg of elemental iron per day. Iron absorption and tolerability can be improved by using lower single daily dosages and every other day dosing. A study of 54 women with ID who did not have anemia found that larger and divided daily doses of iron raised hepcidin and resulted in less optimum iron absorption than lower and once-aday iron administration [8]. Two small open-label trials demonstrated that divided iron

dosages raised hepcidin levels but did not improve absorption [9]. Every other day dose resulted in better iron absorption than once-a-day administration, with a statistically nonsignificant trend toward reduced nausea [10].

Thus the survey was undertaken to get opinion of clinicians on different oral iron preparation and strengths in the treatment of IDA. This study employs a questionnairebased survey conducted among physicians across India to gather insights into their perspectives on the comparison of effectiveness and safety of the oral iron preparations and strenghts in IDA. By evaluating physicians' clinical experiences, patient outcomes, the study aims to provide valuable data that can inform clinical practice and guide treatment strategies tailored to the Indian population with iron deficiency during pregnancy.

2 RATIONALE OF THE STUDY

The rationale for this study was to gather comprehensive insights into oral iron preparations and their strengths in managing IDA. Understanding the prescribing patterns, treatment preferences, and perceived efficacy among physicians aided in optimizing therapeutic strategies and improving patient outcomes. The purpose of this study was to evaluate IDA in Indian patients. This investigation aimed to assess its efficacy in improving fertility, enhancing patient compliance, and determining its longterm safety profile.

The survey was designed to explore and map physicians' perceptions of oral iron supplements and their therapy indications. The rationale for conducting the survey included the management of conditions like IDA, the emergence of different oral iron preparations as a novel therapy, the need to understand the daily dosing of iron supplements, and the alignment of clinical guidelines with real-world practice. By assessing physician perspectives, the survey identified the indications influencing the strengths of oral iron as well as any barriers that hindered its wider application in clinical practice. This provided valuable insights into optimizing IDA management and improving patient outcomes.

3 OBJECTIVES

To assess the perceptions, practice patterns, and clinical experiences of Indian physicians regarding the different oral iron preparations and strengths in the treatment of IDA.

4 METHODS

This study was a cross-sectional, questionnaire-based survey aimed at assessing the perceptions, practices, and clinical experiences of Indian physicians regarding the use of oral iron preparations and their indications in the management of IDA. The study involved the distribution of a structured questionnaire to a representative sample of physicians across various regions in India and general practitioners who encountered conditions such as acromegaly in their routine practice. The questionnaire was designed to capture data on the preparation and strengths of oral iron supplements, treatment protocols, efficacy, safety, and factors influencing their indication.

Physicians were identified and invited to participate through professional networks and medical associations. The 15-question survey was administered electronically. Responses were collected and securely stored. Statistical analysis was conducted to summarize findings and identify key trends. By utilizing a questionnaire-based approach, the study efficiently gathered a wide range of data from a diverse group of practitioners, ensuring that the findings were representative of the broader medical community in India. The target sample size for this study was 100 Indian physicians. This number was chosen to ensure a diverse and representative sample, allowing for meaningful statistical analysis of the survey data. The study adhered to the ethical principles outlined in the Declaration of Helsinki. Ethical approval was sought from an Independent Ethics Committee. Data were analyzed using descriptive and inferential statistics. Descriptive statistics summarized demographic information and response frequencies.

4 **RESULTS**

A total of 88 HCPs participated in the survey. Below is the summary of the responses.

Question 1: In your clinical practice anemia is common in which of the following

group?

- A. Pregnant women
- B. Non-pregnant women of reproductive age
- C. Children
- D. Elderly patients (>65 yrs)



- The majority (72.7%) of physicians reported that anemia was common in pregnant women during clinical practice.
- Anemia in non-pregnant women of reproductive age was reported by 18.2% of physicians.
- Approximately 9% of physicians reported that anemia was common in elderly patients during clinical practice.
- None of the physicians reported anemia in children.

Question 2: In a month what percent of women of reproductive age visit your clinic with iron deficiency anemia?

- A. <5%
- B. 5 <20%
- C. 20 <30%
- D. ≥ 35%



- A significant portion (36.4%) of physicians reported that 35% or more of women of reproductive age visited the clinic for deficiency anemia.
- Around 31.8% of physicians reported that 20% to less than 30% of women of reproductive age visited the clinic for deficiency anemia.
- Similarly, 31.8% of physicians reported that 20% to less than 30% of women of reproductive age visited the clinic for deficiency anemia.
- None of the physicians reported that less than 5% of women of reproductive age visited the clinic for deficiency anemia.

Question 3: In your clinical practice, the cut-off used for the diagnosis of anemia in pregnancy?

- A. Below 9 g/dl
- B. Below 10 g/dl
- C. Below 11 g/dl
- D. Below 12 g/dl



- A significant portion (40.9%) of physicians reported that a hemoglobin level below 10 g/dL was the cutoff used for the diagnosis of anemia in pregnancy.
- Around 31.8% of physicians reported that a hemoglobin level below 9 g/dL was the cutoff used for the diagnosis of anemia in pregnancy.
- A notable group (13.6%) of physicians reported that a hemoglobin level below 11 g/dL was the cutoff used for the diagnosis of anemia in pregnancy.
- Similarly, 13.6% of physicians reported that a hemoglobin level below 12 g/dL was the cutoff used for the diagnosis of anemia in pregnancy.

Question 4: What is the common cause of anemia in your clinical setting?

- A. Iron deficiency anemia
- B. Other nutritional deficiencies (vitamin B12, folate and vitamin A)
- C. Infectious diseases (malaria, helminth infections, tuberculosis)
- D. Hemoglobinopathies



- The majority (72.7%) of physicians reported that iron deficiency anemia was the most common cause of anemia during clinical practice.
- Other nutritional deficiencies (vitamin B12, folate, and vitamin A) were reported as the common cause of anemia by 13.6% of physicians.
- Approximately 9% of physicians reported that infectious diseases (malaria, helminth infections, tuberculosis) were the common cause of anemia during clinical practice.
- A small portion (4.5%) of physicians reported that hemoglobinopathies were the common cause of anemia during clinical practice.

Question 5: What is the preferred treatment strategy for the management of moderate anemia in the first trimester of pregnancy?

- A. Modification in diet
- B. Oral iron therapy
- C. Injectable iron
- D. Both A and B



- Both A and B (modification in diet and oral iron therapy) were the preferred treatment strategies for the management of moderate anemia in the first trimester of pregnancy, as reported by 77.3% of physicians.
- Modification in diet alone was the preferred treatment strategy for the management of moderate anemia in the first trimester of pregnancy, as reported by 9.1% of physicians.
- Similarly, 9.1% of physicians reported that oral iron therapy alone was the preferred treatment strategy for the management of moderate anemia in the first trimester of pregnancy.
- Injectable iron was the preferred treatment strategy for the management of moderate anemia in the first trimester of pregnancy, as reported by 4.5% of physicians.

Question 6: At what Hemoglobin level do you usually prefer oral Iron therapy in your clinical practice?

- A. Severe Anemia (6.5–7.9 g/dl)
- B. Moderate Anemia (8.0–10.0 g/dl)
- C. Mild Anemia (10 g/dl to levels within normal limits)



- Moderate anemia (8.0–10.0 g/dL) was the hemoglobin level usually treated with oral iron therapy, as reported by 45.5% of physicians in clinical practice.
- Similarly, mild anemia (10 g/dL to levels within the normal range) was the hemoglobin level usually treated with oral iron therapy, as reported by 45.5% of physicians.
- Around 9.1% of physicians reported that severe anemia (6.5–7.9 g/dL) was the hemoglobin level preferred for treatment with oral iron therapy.

Question 7: Which oral iron therapy do you prefer to use in your clinical setting for the treatment of anemia?

A. Ferrous sulphate

- B. Ferrous fumarate
- C. Ferrous ascorbate
- D. Ferric Pyrophosphate
- E. Bisglycinates



- The majority (86.4%) of physicians reported that ferrous ascorbate was the preferred iron therapy used in the treatment of anemia in clinical practice.
- Bisglycinate was the preferred iron therapy used in the treatment of anemia, as reported by 9.1% of physicians.
- Ferrous sulfate was the preferred iron therapy used in the treatment of anemia, as reported by 4.5% of physicians.
- None of the physicians reported ferrous fumarate or ferric pyrophosphate as the preferred iron therapy used in the treatment of anemia.

Question 8: GI intolerance due to oral iron is a major factor for decreased compliance.

A. Agree

B. Disagree



- The majority (86.4%) of physicians agreed that gastrointestinal (GI) intolerance caused by oral iron is a major factor for decreased compliance in clinical practice.
- A small portion (13.6%) of physicians disagreed that GI intolerance caused by oral iron is a major factor for decreased compliance in clinical practice.

Question 9: What factors influence your decision to switch from one iron preparation to other?

- A. Safety
- B. Elemental iron content
- C. High absorption rate
- D. Price
- E. Hb rise
- F. All of the above



- The majority (86.4%) of physicians reported that all of the above factors (safety, elemental iron content, high absorption rate, price, and hemoglobin [Hb] rise) influence the decision to switch from one iron preparation to another in clinical practice.
- Elemental iron content was reported as a factor influencing the decision to switch from one iron preparation to another by 4.5% of physicians.
- Similarly, a high absorption rate was reported as a factor influencing the decision to switch by 4.5% of physicians.
- Likewise, Hb rise was reported as a factor influencing the decision to switch by 4.5% of physicians.
- None of the physicians reported safety or price as factors influencing the decision to switch from one iron preparation to another.

Question 10: In your opinion what would be the utility of low dose iron

preparations?

- A. Prophylaxis of IDA in pregnancy
- B. Mild anemia
- C. Both A and B
- D. I generally do not prefer low dose iron



- A majority (42.9%) of physicians reported that they generally do not prefer lowdose iron in clinical practice.
- Similarly, 42.9% of physicians reported that low-dose iron preparations are useful for both the prophylaxis of iron deficiency anemia (IDA) in pregnancy and the treatment of mild anemia.
- The prophylaxis of IDA in pregnancy as a utility of low-dose iron preparations was reported by 9.5% of physicians.
- Around 4.8% of physicians reported that low-dose iron preparations were preferred for the treatment of mild anemia.

Question 11: In pregnancy when do you start oral iron supplementation?

- A. First trimester
- B. Second trimester
- C. Can be started at any point of time



- A significant portion (47.6%) of physicians reported starting oral iron supplementation in the second trimester.
- A notable group (33.3%) of physicians reported that oral iron supplementation can be started at any point in time.
- A small portion (19.0%) of physicians reported starting oral iron supplementation in the first trimester.

Question 12: Adding folic acid to iron helps in

- A. Preventing neural tube defects in babies
- B. Treating a folate deficiency
- C. All of the above



- The majority (86.4%) of physicians reported that all of the above (preventing neural tube defects in babies, treating a folate deficiency) were reasons to add folic acid to iron.
- Adding folic acid to iron helped treat folate deficiency, as reported by 13.6% of physicians.
- None of the physicians reported that preventing neural tube defects in babies was a reason to add folic acid to iron.

Question 13: In how many days do you observe improvement in Hb with Ferrous ascorbate in pregnant women suffering from iron deficiency anemia?

- A. 10 days
- B. 15 days
- C. 20 days
- D. 25 days



- A significant portion (36.4%) of physicians reported that improvement in Hb was observed after 25 days of using ferrous ascorbate in pregnant women suffering from iron deficiency anemia.
- A notable portion (31.8%) of physicians reported that improvement in Hb was observed after 20 days of using ferrous ascorbate in pregnant women suffering from iron deficiency anemia.
- Around 27.8% of physicians reported that improvement in Hb was observed after 15 days of using ferrous ascorbate in pregnant women suffering from iron deficiency anemia.
- A small portion (4.5%) of physicians reported that improvement in Hb was observed after 10 days of using ferrous ascorbate in pregnant women suffering from iron deficiency anemia.

Question 14: In your experience, how often have you observed adverse events with ferrous ascorbate?

- A. Very rarely
- B. Rarely
- C. Uncommonly
- D. Commonly



- The majority (52.4%) of physicians reported that they rarely observed adverse events with ferrous ascorbate.
- A notable group (23.8%) of physicians reported that they very rarely observed adverse events with ferrous ascorbate.
- Around 14.3% of physicians reported that they uncommonly observed adverse events with ferrous ascorbate.
- A small portion (9.5%) of physicians reported that they commonly observed adverse events with ferrous ascorbate.

Question 15: What is your assessment regarding efficacy of ferrous ascorbate?

- A. Very good
- B. Good
- C. Average
- D. Poor



- A majority (47.6%) of physicians reported that ferrous ascorbate had very good efficacy during clinical practice.
- Around 42.6% of physicians reported that ferrous ascorbate had good efficacy during clinical practice.
- A notable group (4.8%) of physicians reported that ferrous ascorbate had average efficacy during clinical practice.
- Similarly, 4.8% of physicians reported that ferrous ascorbate had poor efficacy during clinical practice.

5 SUMMARY

The data highlights physicians' insights on anemia management in clinical practice. The majority (72.7%) reported anemia as most common in pregnant women, with iron deficiency being the leading cause (72.7%). Cutoffs for diagnosing anemia in pregnancy varied, with 40.9% using <10 g/dL as the threshold. Oral iron therapy was a common treatment for moderate anemia (8–10 g/dL), preferred by 77.3% of physicians in the first trimester, often paired with dietary modifications. Ferrous ascorbate was the most favored iron preparation (86.4%), recognized for its very good efficacy by 47.6% of physicians, though GI intolerance reduced compliance for some.

Improvement in hemoglobin levels with ferrous ascorbate was noted after 25 days by 36.4% of physicians, with adverse events rarely observed by 52.4%. For folic acid supplementation, 86.4% cited both preventing neural tube defects and treating folate deficiency as reasons. Regarding low-dose iron, 42.9% valued it for prophylaxis of iron deficiency anemia (IDA) and mild anemia, but 42.9% generally did not prefer its use. Decisions to switch iron preparations were influenced by factors like safety, elemental iron content, absorption rate, price, and hemoglobin rise. In clinical settings, anemia in non-pregnant women of reproductive age (18.2%), elderly patients (9%), and rarely in children were also noted. Additionally, 47.6% initiated iron supplementation in the second trimester, while 33.3% felt it could begin anytime. This data underscores the varied approaches physicians adopt for anemia diagnosis, treatment, and management in clinical practice.

6 **DISCUSSION**

The data provides valuable insights into physicians' practices and preferences in diagnosing and managing anemia, particularly in pregnant women. Anemia is most commonly reported among pregnant women (72.7%), emphasizing its significance as a public health concern during pregnancy. Non-pregnant women of reproductive age (18.2%) and elderly patients (9%) also experience anemia, but children are rarely reported as affected, reflecting differences in population vulnerabilities. Iron deficiency anemia (IDA) emerged as the most prevalent cause (72.7%), consistent with global trends. Other nutritional deficiencies, including vitamin B12, folate, and vitamin A, accounted for 13.6% of cases, while infectious diseases (9%) and hemoglobinopathies (4.5%) were less commonly identified causes. These findings suggest a need for diverse diagnostic and management approaches tailored to underlying causes.

Diagnosis cutoffs for anemia in pregnancy varied among physicians, with 40.9% using a hemoglobin threshold below 10 g/dL. Other thresholds included <9 g/dL (31.8%), <11 g/dL (13.6%), and <12 g/dL (13.6%), indicating differences in clinical criteria and practices. Regarding treatment strategies, 77.3% of physicians preferred a combination of dietary modifications and oral iron therapy for managing moderate anemia in the first trimester, reflecting a comprehensive approach to addressing both nutritional deficiencies and iron supplementation. Injectable iron was less favored (4.5%), likely due to cost and invasive administration. Ferrous ascorbate was the most preferred oral iron therapy (86.4%), with its efficacy rated as very good by 47.6% and good by 42.6% of physicians. This preference highlights its effectiveness and patient tolerance compared to alternatives like bisglycinate (9.1%) and ferrous sulfate (4.5%).

Improvements in hemoglobin levels with ferrous ascorbate were reported after varying durations, with 36.4% observing changes by 25 days, 31.8% by 20 days, and 27.8% by 15 days. Adverse events were rarely (52.4%) or very rarely (23.8%) observed, affirming its tolerability. However, gastrointestinal (GI) intolerance was acknowledged as a major factor in decreased compliance by 86.4% of physicians. This finding underscores the need for strategies to manage side effects to ensure adherence. Supplementing iron with folic acid was commonly practiced, with 86.4% citing both

preventing neural tube defects and treating folate deficiency as reasons. This aligns with established guidelines for maternal and fetal health. Low-dose iron preparations were generally not preferred (42.9%), though their utility for IDA prophylaxis and mild anemia was recognized by 42.9%. These findings suggest that while low-dose iron may have specific applications, standard-dose formulations remain the norm for managing more severe cases.

The timing of oral iron supplementation was varied, with 47.6% initiating it in the second trimester and 33.3% suggesting it could start anytime, reflecting diverse clinical approaches. Decision-making on switching iron preparations was multifactorial, influenced by safety, absorption rate, elemental iron content, price, and hemoglobin response. In conclusion, this data highlights anemia as a critical concern during pregnancy, with IDA being the predominant cause. Physicians favor evidence-based therapies like ferrous ascorbate, emphasizing efficacy, safety, and patient adherence. Despite common practices, variations in diagnostic cutoffs, treatment preferences, and supplementation timing suggest opportunities for standardization and education to optimize anemia management.

7 CLINICAL RECOMMENDATIONS

- Routine anemia screening should be prioritized in pregnant women, nonpregnant women of reproductive age, and the elderly. Uniform diagnostic cutoffs, such as hemoglobin levels below 10 g/dL during pregnancy, could enhance consistency in diagnosing anemia.
- Ferrous ascorbate is recommended as the first-line oral iron therapy due to its efficacy and tolerability. Monitoring hemoglobin levels after 20–25 days of treatment can help assess therapeutic response.
- Dietary modifications alongside oral iron therapy should be considered for moderate anemia, especially in the first trimester. Injectable iron may be reserved for severe anemia or cases with poor oral tolerance.
- Use low-dose iron selectively for prophylaxis of iron deficiency anemia (IDA) in pregnancy and mild anemia.
- GI intolerance proactively to improve compliance. Strategies include dietary adjustments, splitting doses, or considering alternative formulations with fewer side effects.
- Combine folic acid with iron therapy to prevent neural tube defects and treat folate deficiencies in pregnant women.
- Begin iron supplementation early, ideally in the first or second trimester, depending on individual patient needs.
- Address other causes of anemia, including nutritional deficiencies and infectious diseases, through tailored interventions.

8 CONSULTING OPINION

Anemia remains a significant public health concern, especially in pregnant women, as highlighted by the data. The prevalence of anemia in this group demands prioritization of early diagnosis and intervention to ensure maternal and fetal health. Iron deficiency anemia (IDA) is the most common cause, emphasizing the need for routine screening and effective management strategies. Diagnostic cutoffs for hemoglobin levels should be standardized to enhance uniformity in identifying anemia across clinical settings, with levels below 10 g/dL serving as a practical benchmark during pregnancy.

Ferrous ascorbate emerges as the preferred oral iron therapy due to its proven efficacy, rapid improvement in hemoglobin levels, and favorable tolerability profile. While gastrointestinal intolerance remains a barrier to adherence, proactive management through dose adjustments or alternative formulations can help mitigate these challenges. Combining dietary modifications with oral iron therapy is recommended for managing moderate anemia, particularly in the first trimester, while injectable iron may be reserved for severe cases or those intolerant to oral formulations. Adding folic acid to iron therapy is critical for preventing neural tube defects and addressing folate deficiencies, reaffirming its role as a standard component of prenatal care. Low-dose iron preparations, although less preferred for moderate and severe anemia, can be effectively utilized for prophylaxis in pregnancy and mild anemia cases.

The timing of intervention also plays a vital role. Initiating oral iron supplementation in the first or second trimester, as indicated by individual patient needs, can optimize outcomes. Additionally, addressing other causes of anemia, such as nutritional deficiencies and infections, through comprehensive care is essential. Overall, these findings underline the importance of an evidence-based, patient-centered approach to anemia management, prioritizing efficacy, safety, and compliance to improve outcomes for women of reproductive age and pregnant patients.

9 MARKET OPPORTUNITIES

The increasing prevalence of anemia, particularly among pregnant women and women of reproductive age, presents significant market opportunities for innovative healthcare solutions. The data highlights iron deficiency anemia (IDA) as the most common cause, creating a strong demand for effective iron supplements. Ferrous ascorbate, given its superior efficacy and tolerability, dominates the market, but there is potential for developing alternative formulations with fewer gastrointestinal side effects to improve compliance further. Low-dose iron preparations, though currently underutilized, present an opportunity for expansion in prophylaxis and mild anemia management, especially in prenatal care. Additionally, combining iron with folic acid to prevent neural tube defects and treat folate deficiencies offers a dual-benefit product line that caters to the needs of both physicians and patients.

The unmet need for personalized treatment strategies, such as dietary modification plans integrated with supplementation, offers opportunities for nutraceutical companies. Injectable iron products also hold potential in the severe anemia segment, particularly in hospital-based care or among patients with oral iron intolerance. In emerging markets, increasing awareness, accessibility, and affordability of anemia management solutions can drive growth. Companies investing in education, outreach programs, and partnerships with healthcare providers are well-positioned to capture this growing market. The evolving focus on maternal and child health further reinforces these opportunities.

10 MARKET POSITIONING

To establish a strong market presence in anemia management, products must be positioned as effective, safe, and tailored solutions for diverse patient needs. Iron supplements should emphasize their efficacy in rapidly improving hemoglobin levels, with products like ferrous ascorbate positioned as the gold standard due to their superior absorption rates and minimal gastrointestinal side effects. Highlighting these benefits can build trust among healthcare providers and patients alike. Low-dose iron formulations can be positioned as preventive solutions for iron deficiency anemia (IDA) in pregnancy and mild anemia, catering to patients seeking well-tolerated options for long-term use. Similarly, injectable iron products should target the niche market of severe anemia management, positioning them as critical tools for rapid hemoglobin correction, particularly in hospital settings or for patients intolerant to oral therapies. Combination supplements of iron and folic acid offer dual benefits, addressing both anemia and folate deficiency, making them an ideal choice for prenatal care. These can be marketed as comprehensive maternal health solutions, emphasizing their role in preventing neural tube defects.

Educational campaigns highlighting the importance of compliance and personalized anemia management, paired with affordability and accessibility, can enhance market penetration, particularly in underserved regions. This patient-centric approach can strengthen brand loyalty and expand market reach.

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