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Safety and Efficacy of Ayurvedic Formulations in Pregnancy: An Evidence-Based Review of Maternal and Fetal Outcomes

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Abstract: *Background: Ayurvedic literature describes pregnancy-specific dietary, behavioural and medicinal care, including Garbhini Paricharya and month-wise regimens. Herbal and traditional products are also used by pregnant women in many settings, often because they are perceived as natural. Natural origin, however, does not establish maternal or fetal safety.*
Objective: To critically examine classical Ayurvedic concepts relevant to pregnancy and appraise the available evidence on the efficacy, maternal safety and fetal safety of selected herbal interventions and Ayurvedic formulations.
Methods: This narrative review framework integrates classical Ayurvedic concepts with selected clinical reviews, pregnancy guidance, toxicological literature and Indian regulatory information. The final journal submission should include a reproducible search log documenting databases, search dates, terms, screening and selection. This manuscript does not claim to be a systematic review.
Results: Ayurveda offers a structured framework for maternal nourishment and antenatal care. Some individual herbal interventions, particularly ginger for early-pregnancy nausea, have been evaluated in clinical studies and are mentioned in WHO antenatal guidance, although certainty of evidence is limited. Evidence for many compound Ayurvedic formulations remains inadequate. Important concerns include ingredient variability, inadequate reproductive-toxicity data, herb–drug interactions, contamination and potential exposure to toxic metals.
Conclusion: The safety and efficacy of Ayurvedic formulations in pregnancy cannot be generalized across products. Assessment must be formulation-, dose-, route- and gestational-age-specific. Standardization, reproductive toxicology, well-designed clinical research and pharmacovigilance are essential before routine antenatal use..

Keywords: Ayurveda; pregnancy; Garbhini Paricharya; herbal medicines; maternal safety; fetal safety; teratogenicity; pharmacovigilance

Abbreviations: AYUSH, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy; GMP, good manufacturing practices; ICMJE, International Committee of Medical Journal Editors; RCT, randomized controlled trial

I. INTRODUCTION

Pregnancy is a dynamic physiological state in which maternal adaptations support placentation, embryonic development, fetal growth and preparation for childbirth. Medicines taken by the pregnant woman may affect maternal

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physiology and, depending on their properties and timing of exposure, may also reach the embryo or fetus. Therapeutic decisions therefore require consideration of both maternal benefit and potential fetal risk.

Traditional and complementary medicines are used during pregnancy in many countries. Herbal products may be chosen because they are culturally familiar, readily available or believed to be safer than conventional medicines. Such assumptions require caution: plants contain pharmacologically active chemicals, and the safety of a product depends on its exact species, plant part, preparation, dose, route, duration, contaminants and co-administered medicines.

Ayurveda describes pregnancy care through concepts such as Garbhini Paricharya, Masanumasika Paricharya and selected medicinal substances. These concepts provide a historical and clinical framework for maternal nourishment and care. Their modern evaluation requires a distinction between traditional indication, experimental pharmacology, clinical efficacy and demonstrated maternal–fetal safety.

This review considers Ayurvedic concepts alongside modern evidence and identifies the research and regulatory requirements necessary for responsible clinical integration. It does not recommend routine use of untested formulations in pregnancy.

II. AIM AND OBJECTIVES

Aim: To critically review the classical Ayurvedic concepts relevant to pregnancy and evaluate available evidence concerning the efficacy and maternal–fetal safety of Ayurvedic formulations and selected herbal interventions.

- To summarize classical concepts of Garbha, Garbhavakranti and Garbhini Paricharya.
- To describe categories of Ayurvedic preparations that may be encountered in pregnancy care.
- To appraise evidence for selected individual herbal interventions without extrapolating it to compound formulations.
- To discuss pharmacokinetic, placental, reproductive-toxicology and teratogenicity considerations.
- To examine product quality, contamination, herb – drug interactions and pharmacovigilance.
- To identify research gaps and propose safeguards for clinical practice.

III. REVIEW APPROACH AND LITERATURE IDENTIFICATION

This manuscript is structured as a narrative review. Relevant literature should be identified from PubMed/MEDLINE, Cochrane Library, Google Scholar, WHO publications, Ministry of AYUSH resources and official Indian regulatory sources. Suggested search strings include: (Ayurveda OR Ayurvedic OR traditional medicine) AND (pregnancy OR antenatal OR maternal); (herbal medicine OR medicinal plants) AND (pregnancy AND safety); (herbal medicine AND teratogenicity); and (Ayurvedic medicine AND pharmacovigilance). Classical sources should be consulted in identifiable editions and cited with text, section, chapter and verse.

For a transparent submission, authors should record the date of each search, database, complete search string, language limits, inclusion criteria and the process used to select sources. This draft does not provide a fabricated search yield or claim exhaustive retrieval. If the authors conduct a formal systematic review, the methods and reporting should be redesigned in accordance with PRISMA 2020 rather than retaining a narrative-review label.

Suggested eligibility: classical Ayurvedic sources relevant to pregnancy; human clinical trials and observational studies of herbal products in pregnancy; systematic reviews; pharmacological and reproductive-toxicology studies; and authoritative clinical or regulatory guidance. Exclude untraceable claims, duplicate reports and sources that do not identify the intervention sufficiently for interpretation.

IV. CLASSICAL AYURVEDIC CONCEPTS RELEVANT TO PREGNANCY

4.1 Garbha and Garbhavakranti

Classical Ayurvedic descriptions discuss Garbha formation in relation to reproductive elements, the maternal reproductive environment and the presence of life. Concepts such as Ritu, Kshetra, Ambu and Beeja are frequently discussed in relation to conception and the conditions required for development. Garbhavakranti refers to the

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development of the embryo and fetus in the uterus. These concepts may be discussed alongside fertilization, implantation, embryogenesis, placentation and fetal development as historical or conceptual parallels; they should not be presented as exact equivalents of modern embryological mechanisms.

4.2 Garbhini Paricharya

Garbhini Paricharya denotes the regimen described for a pregnant woman, including diet, behaviour and selected therapeutic measures. Its broad aims include maternal well-being, nourishment, support of fetal development and preparation for childbirth. Classical recommendations emphasize suitable, nourishing and digestible food and adaptation of care to the progress of pregnancy. In contemporary interpretation, these themes can be discussed in relation to nutritional adequacy, antenatal surveillance, physical well-being and individualized care.

4.3 Masanumasika Garbhini Paricharya

Masanumasika Paricharya refers to month-wise recommendations. Different classical texts describe variations in dietary and therapeutic regimens. The recommendations are traditionally interpreted as adapting nourishment and care to the changing needs of pregnancy. They should be reported from a specified classical edition and not converted directly into a modern prescription schedule. A classical recommendation is not, by itself, evidence that a medicinal ingredient is safe for the embryo or fetus.

Pregnancy period	Broad classical emphasis	Modern interpretive caution
First trimester	Nourishing, readily digestible dietary preparations are emphasized in classical descriptions.	Avoid assuming that a food-based recommendation validates concentrated medicinal extracts.
Second trimester	Continued nourishment with month-specific dietary descriptions.	Assess nutritional adequacy and avoid unverified claims of fetal-growth enhancement.
Third trimester	Continued maternal support and selected preparations described in classical texts.	Any intervention intended to affect labour or uterine activity requires obstetric assessment.

4.4 Garbhasthapaka Dravya

Garbhasthapaka is a classical term used for substances described in relation to supporting or maintaining pregnancy. It must not be equated automatically with a modern, clinically proven treatment for threatened miscarriage, recurrent pregnancy loss or prevention of preterm birth. The identity of each drug, textual context, preparation and intended indication should be verified, followed by independent pharmacological and clinical assessment.

4.5 Classical knowledge and evidence hierarchy

Classical textual evidence is valuable for documenting historical use and generating research questions. It does not replace analytical identification, toxicology or controlled clinical evidence. A sound review should keep four levels distinct: textual indication; traditional clinical experience; experimental pharmacological findings; and human clinical evidence for a defined product and outcome.

V. AYURVEDIC PREPARATION TYPES AND PRODUCT COMPLEXITY

Ayurvedic preparations may include single-herb products, polyherbal mixtures, food-like preparations, lipid-based formulations, fermented products and preparations containing mineral or metal-derived ingredients. The pharmaceutical form alone does not establish safety. The exact ingredient list, botanical identity, plant part, processing method, concentration, dose, route and duration must be known.

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Preparation category	Examples of form	Key pregnancy-safety questions
Herbal preparations	Churna, kwatha, swarasa, kalka, vati/gutika	Are species and plant parts authenticated? What is the dose and systemic exposure?
Lipid-based preparations	Ghrita, taila	Which ingredients are extracted into the lipid phase? Is the preparation oral or topical?
Fermented preparations	Asava, arishta	What are the alcohol content, fermentation products, ingredients and dose?
Mineral/metal-containing preparations	Rasaushadhi and related products	Are metals intentionally present? Are speciation, content and toxicological risks characterized?

A product marketed under a familiar classical name may differ between manufacturers or batches. The published evidence for one standardized preparation should not be transferred to another product without demonstrating comparability.

VI. MODERN PRINCIPLES OF MEDICINAL SAFETY IN PREGNANCY

6.1 Pregnancy-related pharmacokinetic changes

Pregnancy changes drug absorption, distribution, metabolism and excretion. Gastrointestinal motility and gastric conditions may change; plasma volume and total body water increase; albumin concentrations may decrease; hepatic enzyme activity changes in an enzyme-specific manner; and renal blood flow and glomerular filtration generally increase. These changes can alter exposure to active constituents and metabolites. The direction and clinical significance are compound-specific, and cannot be predicted reliably from the traditional category of a formulation.

6.2 Placental transfer

The placenta is a selective interface rather than an absolute barrier. Transfer depends on molecular size, lipid solubility, ionization, protein binding, concentration gradients, transporter activity, placental metabolism and gestational age. Some plant-derived constituents and metabolites may cross the placenta. Maternal tolerability therefore does not prove fetal safety.

6.3 Timing of exposure and developmental toxicity

The pre-implantation period, embryonic organogenesis and fetal period have different patterns of susceptibility. Exposure during organogenesis may interfere with structural development, while later exposure may affect growth or functional maturation. The often-used 'all-or-none' description for very early exposure is a simplified principle and should not be treated as an absolute prediction for an individual pregnancy.

Developmental period	Approximate timing after fertilization	Potential concern
Pre-implantation	First 2 weeks	Severe exposure may result in embryonic loss; outcome is not universally predictable.
Embryonic period	Weeks 3–8	Major organogenesis; heightened concern for structural malformations.
Fetal period	Week 9 to birth	Growth, maturation and functional development may be affected.

Obstetric gestational age is conventionally calculated from the first day of the last menstrual period and is approximately two weeks greater than age counted from fertilization. Authors should specify which dating convention is used.

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VII. EVIDENCE FOR SELECTED HERBAL INTERVENTIONS

Evidence concerning individual herbs must not be presented as evidence for all Ayurvedic products or for compound formulations. The following examples illustrate how a review can distinguish traditional use, clinical evidence and uncertainty.

7.1 Ginger (Zingiber officinale; Ardraka/Shunthi)

Ginger is used traditionally for digestive complaints and has been investigated for nausea and vomiting in early pregnancy. WHO antenatal guidance includes ginger among options that may be offered for relief of nausea in early pregnancy, according to the woman's preferences and available options. WHO notes that the evidence is of low certainty for ginger and is based on small studies. This supports a limited, indication-specific discussion; it does not establish the safety of high-dose extracts, essential oils or multi-ingredient products containing ginger.

Potential adverse effects reported in clinical literature include heartburn, reflux and gastrointestinal discomfort. Formulation and dose differ across studies. The clinician should also consider the severity of nausea and vomiting and ensure that dehydration, hyperemesis gravidarum or another diagnosis is not overlooked.

7.2 Yashtimadhu/licorice (Glycyrrhiza glabra)

Licorice contains glycyrrhizin and related constituents. Heavy licorice consumption has been associated in observational pregnancy literature with early preterm birth. Such associations do not prove causation and may be affected by exposure measurement and confounding, but they justify caution. Excessive glycyrrhizin exposure can also produce mineralocorticoid-like effects, including sodium retention, hypertension and hypokalaemia. Medicinal-dose licorice should not be assumed safe because it has a traditional indication.

7.3 Shatavari (Asparagus racemosus)

Shatavari has a traditional place in women's health and contains steroidal saponins and other phytochemicals investigated in experimental research. However, high-quality pregnancy-specific human evidence is insufficient to establish its safety for miscarriage, congenital anomalies, fetal growth or neonatal outcomes. Traditional use in reproductive health should not be represented as proof of pregnancy-maintaining efficacy.

7.4 Amalaki (Phyllanthus emblica)

Amalaki is described as a Rasayana in Ayurveda and contains polyphenols and other phytochemicals. Experimental antioxidant findings and its use as a food are not equivalent to evidence for concentrated extracts during pregnancy. Dietary intake and medicinal-dose supplementation should be distinguished.

7.5 Eranda Taila/castor oil (Ricinus communis)

Castor oil contains ricinoleic acid and has been investigated as a labour-related intervention. It may cause gastrointestinal cramps, nausea and diarrhoea, with potential dehydration. Evidence on labour induction and maternal–fetal outcomes is inconsistent. It should not be self-administered to induce labour; any decision about induction must follow obstetric assessment and established clinical protocols.

7.6 Other products requiring caution

Senna-containing preparations may cause diarrhoea and electrolyte disturbance when used excessively. Oral aloe latex has potent laxative effects. Medicinal-dose fenugreek and concentrated essential oils have insufficient or product-specific pregnancy safety evidence. These examples are not a complete list of contraindications; species, part, preparation, dose and route matter.

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VIII. MATERNAL AND FETAL SAFETY CONCERNS

8.1 Maternal adverse effects

Potential adverse effects include gastrointestinal symptoms, dehydration, allergic reactions, blood-pressure changes, glucose disturbances, electrolyte abnormalities, hepatotoxicity and nephrotoxicity. These are possible categories of harm, not a claim that every Ayurvedic formulation causes them. The risk must be linked to the specific ingredients, dose, route, product quality and patient context.

8.2 Fetal and neonatal outcomes

Relevant outcomes for safety research include miscarriage, congenital anomalies, fetal growth restriction, preterm birth, stillbirth, neonatal morbidity and longer-term neurodevelopment. A study reporting no statistically significant difference in a small sample cannot establish absence of risk. Rare outcomes require large datasets and careful control of confounding.

8.3 Heavy metals and contamination

Lead, mercury, arsenic and cadmium may be present as contaminants or, in some products, as intentional ingredients. Their presence, chemical form, bioavailability and dose determine toxicological risk. In a 2004 study of 70 Ayurvedic products purchased in the Boston area, 14 products (20%) contained detectable lead, mercury or arsenic. The sample was geographically and temporally limited and should not be generalized to all Ayurvedic products; nevertheless, it demonstrates why independent batch testing is important.

Quality assessment should consider elemental analysis using validated methods, microbial contamination, pesticide residues, aflatoxins, identity testing, stability and compliance with applicable pharmacopoeial specifications. A manufacturer's claim of traditional purification does not replace analytical verification.

8.4 Herb–drug interactions

Concurrent use of herbal products and prescribed medicines may create pharmacokinetic or pharmacodynamic interactions. Potential mechanisms include altered drug-metabolizing enzymes or transporters, changes in absorption or renal clearance, additive glucose-lowering or sedative effects, and effects on coagulation. Interaction claims should be graded by evidence: human clinical interaction data are stronger than in-vitro or theoretical mechanisms. Clinicians should ask specifically about teas, powders, tablets, oils and products recommended by family or traditional practitioners.

8.5 Product variability and self-medication

Variation in botanical species, plant parts, growing conditions, storage, processing, concentration and manufacturing can produce batch-to-batch differences. Unlabelled mixtures and products with incomplete ingredient disclosure make risk assessment difficult. Self-medication may also delay diagnosis or proven treatment of obstetric complications.

IX. HOW TO EVALUATE A FORMULATION

A practical evidence pathway is summarized below. Each stage should be documented before a formulation is considered for pregnancy research or clinical use.

Stage	Required assessment	Examples of documentation
1. Classical identity	Exact textual reference and traditional indication	Text, edition, Sthana, Adhyaya, verse; ingredients and proportions
2. Product identity	Botanical and chemical authentication	Species, plant part, voucher specimen, batch and manufacturer

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3. Quality	Purity, consistency and stability	Fingerprinting, marker compounds, metals, microbes, pesticides, aflatoxins
4. Preclinical safety	Relevant toxicology, including reproductive and developmental toxicity	Dose, route, exposure window, maternal toxicity and embryo-fetal outcomes
5. Clinical evidence	Defined indication and patient-relevant outcomes	Comparator, dose, gestational age, maternal and fetal outcomes, adverse events
6. Post-market monitoring	Detection and reporting of suspected harms	Product/batch details, exposure timing, outcome and causality assessment

9.1 Pharmaceutical standardization

A pregnancy-relevant dossier should identify all ingredients and excipients, authenticate botanicals, quantify appropriate marker compounds, describe manufacturing and processing, and report batch-specific tests for contaminants and stability. Where metals are expected as part of a product, total concentration alone may be insufficient; chemical speciation and bioavailability may also be relevant.

9.2 Preclinical reproductive and developmental toxicology

The testing strategy should be scientifically justified and aligned with applicable regulatory guidance. Depending on the intended use and available data, it may include acute and repeated-dose toxicity, genotoxicity, fertility and early embryonic development, embryo-fetal development and pre-/postnatal development. Maternal toxicity must be distinguished from direct embryo-fetal toxicity. Animal data can inform risk but do not, by themselves, establish human pregnancy safety.

9.3 Clinical study outcomes

Studies should define a specific clinical indication, product and dose. Maternal outcomes may include symptom scores, blood pressure, glucose, laboratory markers and adverse events. Fetal and neonatal outcomes may include growth, congenital anomalies, gestational age at delivery, birth weight, stillbirth, neonatal morbidity and longer-term follow-up. Trials involving pregnant participants require a compelling scientific rationale, independent ethical review, informed consent and risk minimization.

X. PHARMACOVIGILANCE AND REGULATION IN INDIA

Pharmacovigilance is the detection, assessment, understanding and prevention of suspected adverse effects associated with medicinal products. For traditional medicines, reporting should include the product name, manufacturer, batch number, complete ingredients if available, dose, route, dates of exposure, gestational age, concomitant medicines and maternal or fetal outcome. Suspected adverse reactions should be reported through the appropriate national or institutional pathway.

In India, Ayurvedic, Siddha and Unani medicines fall within the framework of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Relevant provisions include manufacturing and labelling requirements, Schedule T good manufacturing practices and Rule 158B requirements concerning licensing and evidence of safety and effectiveness for applicable categories. Official government information describes requirements for GMP and quality standards. Regulatory compliance is important but should not be interpreted as proof that every product is suitable for pregnancy.

Authors should check the latest consolidated legislation, rules, amendments and Ministry of AYUSH notices at the time of submission. Regulatory requirements can change, and a manuscript should cite the current official source rather than rely solely on secondary summaries.

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XI. COMPARATIVE PERSPECTIVE: AYURVEDA AND MODERN ANTENATAL CARE

Ayurvedic concept	Potential area of contemporary discussion	Evidence interpretation
Garbhini Paricharya	Antenatal nutrition, rest, lifestyle and maternal support	Conceptual relevance; individual practices require evaluation.
Masanumasika Paricharya	Changing nutritional and care needs across gestation	Not a substitute for evidence-based trimester-specific antenatal care.
Garbhasthapaka Dravya	Traditional claims related to pregnancy maintenance	Not equivalent to proven miscarriage prevention.
Rasayana	Nourishment and restorative claims	Requires ingredient-specific efficacy and safety evidence.
Deepana/Pachana	Digestive symptom management	A traditional rationale does not establish clinical benefit.

The comparison should remain respectful and analytically precise. Classical terminology can guide research questions, but modern biomedical mechanisms should not be attributed to Ayurvedic concepts unless supported by direct evidence. Conversely, lack of modern evidence should be described as uncertainty rather than proof of ineffectiveness.

XII. RESEARCH GAPS AND FUTURE DIRECTIONS

- Few well-powered pregnancy-specific studies evaluate complete, authenticated Ayurvedic formulations with transparent ingredient and dose information.
- Reproductive and developmental toxicology is lacking for many products used in traditional practice.
- Placental transfer and maternal–fetal pharmacokinetics of many active constituents and metabolites remain poorly characterized.
- Herb–drug interactions are under-investigated, particularly in women receiving medicines for diabetes, hypertension, thyroid disease, epilepsy or thrombosis.
- Quality-control and batch-comparability data are not consistently available in clinical publications.
- Pregnancy registries and longitudinal mother–child follow-up could improve detection of uncommon or delayed outcomes.
- Research should prioritize clearly defined clinical indications and outcomes rather than broad claims of general pregnancy benefit.

A staged research agenda is preferable: authenticate and standardize the formulation; conduct appropriate toxicological studies; establish exposure and interaction profiles; review existing human data; and only then consider ethically justified clinical studies. Observational pregnancy registries can complement, but not replace, controlled evidence.

XIII. RECOMMENDATIONS FOR CLINICAL PRACTICE

- Ask pregnant patients non-judgmentally about all traditional medicines, supplements, teas, powders and topical products.
- Identify the exact product, ingredients, manufacturer, batch, dose, route and duration; do not assess an unknown mixture as though it were a known single herb.
- Avoid products with undisclosed ingredients, uncertain identity, unverified quality or suspected contamination.
- Exercise particular caution with metal- or mineral-containing preparations and products intended to alter

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uterine activity or induce labour.

- Review potential interactions with prescribed medicines and assess the patient's obstetric condition before any intervention.
- Do not delay or replace proven treatment for pre-eclampsia, gestational diabetes, anaemia, infection, threatened preterm labour or other complications.
- Document suspected adverse events and report them through the appropriate pharmacovigilance pathway.

XIV. LIMITATIONS

This is a narrative review framework and not a systematic review or meta-analysis. The evidence base is heterogeneous in product composition, dose, route, timing and outcome definitions. Some studies concern individual herbs rather than Ayurvedic compound formulations, limiting direct applicability. Observational associations may be affected by confounding, exposure misclassification and recall bias. Absence of a reported adverse event does not establish safety, especially for rare outcomes. Classical textual descriptions also vary by source and edition; exact citations must be verified against the editions used by the authors.

XV. DISCUSSION

The central finding of this review is that the evidence does not support a single safety conclusion for all Ayurvedic formulations in pregnancy. Ayurvedic texts offer a structured approach to maternal care, particularly through dietary and behavioural regimens. This traditional framework may contribute to patient-centred antenatal counselling and generate testable research questions. However, medicinal formulations require separate evaluation.

Evidence for selected interventions is indication-specific. Ginger is mentioned in WHO antenatal guidance as an option for nausea in early pregnancy, but the evidence is of low certainty and cannot be extrapolated to concentrated extracts or polyherbal preparations. Conversely, observational findings concerning heavy licorice consumption and early preterm birth illustrate why traditional use and perceived naturalness cannot substitute for safety assessment. Such associations should be interpreted cautiously, not treated as definitive proof of causality.

The product-quality dimension is particularly important for complex traditional preparations. The study by Saper and colleagues detected lead, mercury or arsenic in a subset of products purchased in a defined US setting. Its results should not be generalized to all products or manufacturers, but they establish a public-health rationale for validated testing and transparent labelling. Pregnancy heightens the importance of preventing avoidable toxic exposures.

A scientifically defensible approach is neither to presume that all Ayurvedic medicines are safe nor to dismiss all traditional products as harmful. Instead, the formulation, intended indication, exposure window, product quality and available evidence should be evaluated individually. This approach respects classical knowledge while protecting maternal and fetal health.

XVI. CONCLUSION

Ayurveda provides a comprehensive traditional framework for pregnancy care through Garbhini Paricharya, Masanumasika Paricharya and selected medicinal preparations. These concepts are relevant to scholarly discussion of maternal nourishment and antenatal care. Nevertheless, the safety and efficacy of Ayurvedic formulations during pregnancy cannot be generalized across products. Evidence for many compound preparations is insufficient, and potential concerns include maternal adverse effects, placental transfer, developmental toxicity, herb–drug interactions, contamination and product variability. Formulation-specific standardization, reproductive toxicology, carefully designed clinical research and active pharmacovigilance are essential before routine use can be supported. Integration into contemporary antenatal care should be guided by evidence, transparent communication and the overriding priority of maternal and fetal safety.

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