

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF SIKANJABEEN LEMOONI IN MANAGEMENT OF PREGNANCY INDUCED NAUSEA AND VOMITING (QAY-AL-HAMAL)-A REVIEW ARTICLE

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ABSTRACT

Qay'al-Haml (Nausea and vomiting in pregnancy) is defined as the symptom of nausea and/or vomiting during early pregnancy. It occurs in up to 80% of pregnant. The physical problems of coping with qay'al-haml can lead to emotional problems, which can in turn exacerbate the physical problems, having a significant reduction in quality of life. Nausea and vomiting (Qay'al-haml) are considered atypical and almost inevitable feature of pregnancy. Concern about the harmful effect of medication on the fetus may cause many women not to seek treatment or to try alternative therapies for nausea and vomiting. The classical Unani sources viz., Al-Qanun fi'l Tibb (Canon of Medicine), Iksir-i-A'zam, Al Hawi fi'l Tibb (Continens Liber), Tarjuma Kamil al-Sana'a al-Tibbiyya, Dhakhira Khawarizm Shahi, and Tibbi-Akbar were reviewed. Further, different search engines were also browsed on the website to explore recent studies. Various Unani drugs are mentioned for the treatment of qay'al-haml including gulqand, sikanjabeen sada, sharbat anar sheerin, sikanjabeen lemooni, jawarish anarain, mastagi, ilaichi etc. The aim of the study is to evaluate the efficacy of sikanjabeen lemooni in qay'al-haml.

KEYWORDS: qay'al-haml, sikanjabeen lemooni.

I. INTRODUCTION OF NAUSEA VOMITING IN PREGNANCY

Nausea and vomiting in pregnancy is used to describe a wide spectrum of symptoms; at one end of the spectrum is the common, mild to moderate nausea and vomiting that is usually limited to the first trimester & at the other end are the intractable, severe symptoms of hyperemesis gravidarum (HG) that is associated with weight loss, dehydration, electrolyte imbalance and hospitalisation.^[1] Whether symptoms are mild, moderate, or severe, they can have a negative effect on the pregnant woman's quality of life.^[2] It is the most common complication affecting women in the first trimester,^[3] occurring in 44% to 89% of pregnant women.^[4] The Pregnancy Unique Quantification of Emesis (PUQE) score was used to assess the severity of NVP, as well as to follow the response to treatment and improvement over time,^[5] QOL was measured with the only existing NVP-specific QOL questionnaire.^[2]



Fig. 1: Nausea and Vomiting during.

Nausea and vomiting often pose a significant problem because they last longer and are more distressing than is generally understood. Uncertainty about how long it

will take for symptoms to resolve may lead women to feel disorganized and even to lose control over themselves, their families, and their work.^[6] Concern about the harmful effect of medication on the fetus may cause many women not to seek treatment or to try alternative therapies for nausea and vomiting. The only medicine that is FDA-approved for NVP is doxylamine pyridoxine combination; although effective has reported side effects like somnolence, headache, dizziness, dry mouth, and hypersensitivity.^[7] Pregnancy and childbirth are basic life events vital to the maintenance of humankind and thus are considered physiological processes. The most common complication affecting women in the first trimester is nausea and vomiting of pregnancy (NVP),^[1] occurring in 44% to 89% of pregnant women.^[2] Nausea and vomiting in pregnancy is defined as the symptom of nausea and/or vomiting during early pregnancy when no other cause is responsible for it,^[3] with an onset which often begins between the fourth and seventh week after the first missed menstrual period and resolves by the 20th week of gestation.^[4] It is a syndrome caused by the complex interaction of genetic and environmental factors beginning during a unique period: organogenesis.^[2] The risk factors of NVP include race, baby's sex, young maternal age, multi-fetal gestation, low income, low education level, history of premenstrual syndrome, and unwanted pregnancy.^[5] The severity of NVP has a broad spectrum therefore it is critical to have a graded scale to track the severity of symptoms as a guide to determine the appropriate treatment and response to treatment. In 2002 Ebrahimi et al. introduced the Pregnancy- Unique Quantification of Emesis (PUQE) scoring system. The updated PUQE score assesses the severity of NVP based on three physical symptoms: nausea, vomiting, and retching over the previous 24 hours.^[6]

II. Etiology of Nausea vomiting in Pregnancy

A. Evolutionary perspective

Normal levels of NVP protect pregnant women and their foetuses against harmful substances in food.^[8] This maternal and embryonic protection hypothesis takes into account primary symptoms of nausea and vomiting, as well as secondary symptoms such as heightened olfaction, that may be related to increased hormone levels.^[9]

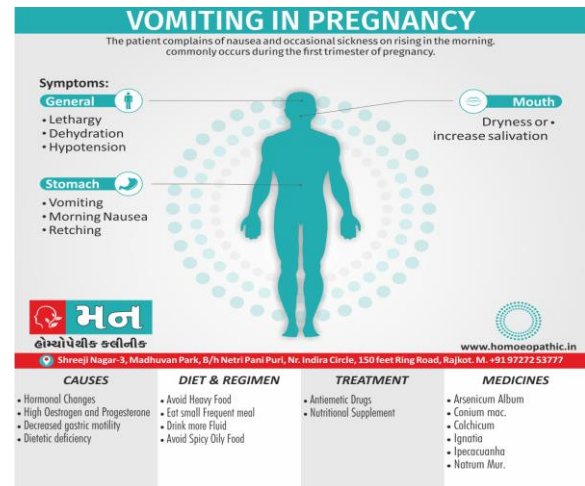


Fig. 2: Etiologies of Vomiting in Pregnancy.

B. Genetic

NVP and HG show patterns of familial aggregation. A higher risk of severe NVP/HG is found among women with mothers and/or sisters who have experienced severe NVP/HG. Monozygotic female twin pairs are found to be more concordant than dizygotic female twin pairs concerning experiencing NVP.^[8]

C. Endocrine

Hormonal changes occurring in pregnancy are thought to be part of the aetiology of NVP and HG, and the most commonly proposed hormones involved include the hCG, oestrogen, progesterone and thyroid hormones.^[1]

- **hCG:** The most implicated factor is hCG. When hCG concentration increases in body, nausea and vomiting also increase. Between 12-14 weeks of pregnancy hCG is its peak concentration, at the same time, there are more chances of NVP.^[10]
- **Oestrogen and progesterone:** Estradiol & progesterone increases early in pregnancy and slowly rises throughout the remainder of the pregnancy.^[11]
- **TSH:** Since hCG and TSH are structurally related, the observed association with hyperthyroidism may be explained by characteristics facilitating highly stimulating properties of the thyroid gland among women with HG. However, since hyperthyroidism itself is seldom a cause of nausea and vomiting, the focus is switched back to hCG.^[8]

D. Psychological factors

Pregnant women with stress and emotional tensions often have this condition.^[12]

E. Gastric dysrhythmias

Changes in gastric rhythmic activity may contribute to NVP. The intensity of nausea is significantly greater in pregnant women with gastric dysrhythmias than in those with normal electrogastric patterns.^[8]

NAUSEA & VOMITING IN PREGNANCY		
	HYPEREMESIS GRAVIDARUM less common than nausea/vomiting alone intractable vomiting weight loss volume depletion hypokalemia or ketonemia/ketonuria	NAUSEA + VOMITING OF PREGNANCY nausea and vomiting very common in pregnancy first 12 weeks usually worse
DIAGNOSIS	clinical ketones in blood or urine	clinical no ketosis or severe weight loss
WORKUP	urinalysis for ketones consider: electrolytes, renal function If patient has abdominal pain, consider/workup other etiologies: ectopic or molar pregnancy cholecystitis/cholelithiasis (more common in pregnancy) HELLP (hemolysis, elevated liver enzymes, low platelets) syndrome pancreatitis or hepatitis appendicitis pyelonephritis/cystitis	
TREATMENT	Fluids with dextrose (D5 0.9% NaCl or D5 LR) Anti-emetics Admission if: uncertain diagnosis intractable vomiting persistent ketone or electrolyte abnormalities after volume repletion weight loss of >10% of pre-pregnancy weight	Avoid trigger odors Anti-emetics Class A (First Line): Ginger (500-1000 mg daily) Pyridoxine (B6; 25 mg q8 hours) Doxylamine/pyridoxine (Diclegis 10mg/10mg; 2 tabs qHS) Class B: ondansetron metoclopramide diphenhydramine Class C: promethazine

*Doxylamine/pyridoxine is a combination pill of 2 over the counter medications (an antihistamine "sleep aid" and vitamin B6) which is about \$400 USD without insurance. They do have a program for people without insurance (90 tabs = \$90) @FOAMedEast

Fig. 3: Causes of vomiting in Pregnancy.

III. Classification of Vomiting

The causes of vomiting in pregnancy can be classified as follows.

A. Early Pregnancy

➤ Related to pregnancy (vomiting of pregnancy)

- Simple vomiting (morning sickness, emesis gravidarum)
- Hyperemesis gravidarum (pernicious vomiting)

➤ Associated with pregnancy

Medical	Surgical	Gynecological
Intestinal infestation	Appendicitis	Twisted ovarian tumor
Urinary tract infection	Peptic ulcer	Red degeneration of fibroid
Hepatitis	Intestinal obstruction	
Ketoacidosis diabetes	Cholecystitis	
Pyelonephritis	Pancreatitis	

B. Late Pregnancy

➤ Related to pregnancy

- Continuation or reappearance of simple vomiting of pregnancy
- Acute fulminating preeclampsia

➤ Associated with pregnancy

- Medical, surgical, gynaecological causes as above.
- Hiatus hernia.^[2,4]

IV. Unani Concept of Nausea vomiting in Pregnancy

- According to Abu Bakr Muhammad Bin Zakaria Al-Razi (865-925 A.D) in his authentic book “Kitab Al-Hawi” that female fetus is more responsible for nausea and vomiting then male because of male fetus having hotness (harart) and female having coldness (barudat).
- Nausea and vomiting usually occur in first trimester, and disappear after 4th month. But in some female it

occur throughout the pregnancy.^[12]

In Unani classical literature, the term coined for nausea and vomiting in pregnancy is Qay'al Haml. According to Unani scholars, the cause of NVP is morbid material which accumulates in the cavity of the stomach or the muscles or layers of the stomach.^[13,14] This material can be bilious, phlegmatic (often balgham-i-milh)^[13,15] or black bile.^[13] More often nausea in pregnancy is due to bile, although bile is not a morbid material.¹⁶ Bilious material causes irritation in the stomach and hence vomiting. Thick and viscous material firmly accumulated on the surface of the stomach produces nausea and retching not vomiting.

V. Differential diagnosis of Qay'al-haml^[14]

- A. Non- obstetrical causes of vomiting are- Haida, Su'-i-hadm, Waja-al mi'da, Quruh al-Mari wa Litha, Inqil-ab al- mi'da, Waram al-jigar, Qulanj, Waram al-tihal, Humma, Waram al-gurda, Deedan If vomiting is not due to these diseases, then itself is a disease.
- B. Enquire about diet before vomiting, improper food habit, rotten food then cause is attributed to fasad-i-ghidha. (Food poisoning).
- C. If vomiting is not persistent and is associated with dis- orders of the liver, gall bladder, spleen and uterus or any other organ of the body then the cause of vomiting is due to these disorders.
- D. Su'-i-mizaj
 - Su'-i-mizaj sa'da: If no other cause of vomiting is diagnosed then it indicates that it is solely due to su'-i-mizaj sa'da. In this vomitus contains food particles but no other khilt. Urine is clear and diluted.
 - Su'-i-mizaj harr sa'da: Increase thirst, dry mouth, burning sensation in the stomach, hadam qawi, hot drinks are harmful.
 - Su'-i-mizaj barid sa'da: Decrease thirst, weak digestion, pale face, soft stool, increase appetite, belching.
 - Su'-i-mizaj ratb sa'da: Coldwater, wet and moist things are harmful. Dry food and a small quantity of food is beneficial, increase salivation, nausea.
 - Su'-i-mizaj yabis: Dry tongue, constipation, dislikes dry foods.
- E. Su'-i-mizaj Maddi: If manifestations of any khilt (humour) are present, then the type of vomiting depends upon khilt (humour) present in vomitus. If vomitus contain food particles along with khilt, then the cause of vomiting is su'-i-mizaj maddi and urine is viscous, turbid.
- F. Su'-i-mizaj safravi: Bitterness in mouth, nausea, yellow urine, belching. Su'-i-mizaj saudawi: All signs of su'-i-mizaj ya-bis including increase appetite, improper digestion, dark yellow pigmentation of the face, urine is a viscous and dark colour.
- G. Su'-i-mizaj balghami: decreased appetite, fatigue, nausea, increased salivation, pale face, urine is white,

vomitus contains phlegm

- H. With manifestations of cold temperament, there is tension in ribs and increased flatulence- then the cause isriyah.

- I. Stretched ribs along with nausea, burning sensation inthe stomach, stool with bad odor the cause is then attributed to spoiled food.

VI. Management of Nausea vomiting in Pregnancy Pharmacological treatment with dose and mode of action

Drug Name	Category	Dose	Mode Of Action	Any Other Remark
Doxylamine succinate	Antihistamine pyridoxine hydrochloride combination	20mg Orally	Interrupt the histamine pathway	In 2013 US FDA approved doxylamine succinate (20 mg) an antihistamine and pyridoxine hydrochloride (20 mg) combination for the treatment of NVP
Meclizine, hydroxyzine, dimenhydrinate,	Antihistamines	25 mg, 50 mg and 50 to 100 mg, every 4-6 hours orally	Block the Histaminic receptors in both vestibular-system (H1) and chemoreceptor trigger zone (H2) receptors	Both 1st and 2nd generation anti-histamines are safe in pregnancy.
Metoclopramide	Promotility agents	10mg orally, every 6 hours	increase LES pressure and gastric transit	-----
Phenothiazine	Antipsychotics	30mg	It interferes with dopamine to bind its own receptors.	-----
Ondansetron	serotonin receptor antagonist	4-8mg IV, every 8-10 hours	Block the signals generated by vomiting center in brain	-----

VII. Unani management of Nausea vomiting in Pregnancy

Usoole ilaj (Unani principles of treatment) may be divided into following sub headings.^[20]

- Ilaj bi'l ghidha (Dieto-therapy)
- Ilaj bi'l tadbeer (Regimental therapy)
- Ilaj bi'l Dawa (Pharmacotherapy)
- Ilaj bi'l yad (Surgery)

A. Ilaj bi'l ghidha (Dieto-therapy)^[14,19,21]

Advise women to avoid exposure to triggers such as specific odours and particular foods. Symptoms may be reduced by eating dry bland foods, little and often, and ensuring adequate hydration. Data suggest that women with a high intake of fatty foods have a higher risk of hyperemesis gravidarum and that low energy high protein diets are associated with a reduction of nausea and vomiting in pregnancy compared with a diet high in carbohydrates.^[17] After admission to hospital with hyperemesis gravidarum, some advocate withholding food to "rest" the gastrointestinal tract, but this has never been formally evaluated. All women at less than 12 weeks' gestation should be taking folic acid 0.4 mg daily. Pyridoxine (vitamin B-6) supplements reduce symptoms, and in many countries pyridoxine is used first line in combination with an antiemetic such as doxylamine. Individual responses vary greatly, however, probably because of large differences in the onset and action of pyridoxine.^[18] Ginger has also been used as an antiemetic in several small randomised controlled trials (RCTs), both alone and combined with pyridoxine, but

with no significant difference in nausea scores between the two groups. The conflicting data on the efficacy of ginger may result from different preparations and potencies of ginger used in various studies.^[19] The benefits of ginger are likely to be in early nausea and vomiting in pregnancy, with no convincing evidence of benefit in severe hyperemesis gravidarum.

- Light diet is advisable which provides strength to the stomach and stops vomiting example titar, chuza murg.
- Advise empty stomach- rube reebas, rube hasram.
- Eat a pomegranate in the early morning and lies on the bed for 1 hour.
- Avoid hot and warm food.
- Avoid sweet dishes.

B. Ilaj bi'l tadbeer (Regimental therapy)^[21,22]

- Moderate walk, light exercise.
- Dimad on the abdomen- badiyan alone or along with qinnab and sharab Rehani or grape flowers and gulnar or barge kiram, gulnar and karafs Roomi, tukhme razyana.

C. Ilaj bi'l Dawa (Pharmacotherapy)^[16,19,21,22]

- Gule surkh 9g, gule gaozaban 9g, sapistan 10g seeds, unnab 7g, khubani 7g, aloo bukhara 11g. All these drugs are soaked overnight in gulab jal and kewda. To this maghze khyare shambar 72 g, sheere khisht, gulqand each 48 g are added, grind the mixture and filter and give orally with 7 g roghane badam.

- Qurs- qaranphal, quste sheerin, jooz, sak, mastagi, agar, ilaichi, kababa each of equal weight mix with aabe-tursh or aabe-bihi and make qurs (tablet). This tablet is a very useful formulation for vomiting and craving for food.
- Gulqand and sikanjabeen sada 24 g is beneficial or
- sikanjabeen lemooni or murabba leemu kaghzi.
- Oral intake of sharab rehani asfar is beneficial.
- Rewand chini before and after meal.
- Gile armani, mix with sharbate meeba.
- Joshanda of assiur ra'as (lal sa'ag) before and after meal.
- Joshanda shibt alone and along with shahed musaffa is beneficial in NVP.
- Mixture of oode kham and mastagi is also beneficial.
- For pregnant women with harr mizaj sharbate turanj, sharbate leemu, sharbate ghura and sharbate anar is beneficial.
- Safoof barai mitli-loung, qust sheerin, mastagi, jaipal, choti ilaichi, agar, kabab chini, sak each of equal weight are finely powdered.
- Dose- four and half gram with aabe-saib sheerin.
- If vomiting is due to fasad-i-ghidha or safra then oral intake of sikanjabeen 50 ml and salt 25 mg in water is effective as it helps in stomach wash, then drink arqe-gulab 120 g, and sharbate anar sheerin 25 ml.
- If vomiting is due to gastric ulcers then dimad of radia'at and sandal safaid, kishneez khushk is effective Mamoolate matab.
- Tukhme khurfa, tukhme khyarain, zarishk, munaqqa each 3 g, aloo bukhara 5, make sheera of all these in arqe-gulab 60 ml, drink after adding sharbate tamar hindi 12 ml.
- Tabasheer, zareward, kishneez khushk, post samaq, anar dana biryan each 1 g, after grinding and straining add sharbate ghura 25 ml, sikanjabeen lemooni 25 ml and take orally.
- Jawarish anarain 7 g with zarishk 3 g, sheera pudina 3 g, sheera dana ilaichi 3 g in arqe- gawzaban 150 ml with sharbate anar 25 ml orally in the morning and evening.
- Zarishk, samaq, anardana, dana heel finely grinded and given with sikanjabeen lemooni 25 ml half an hour after food.

COMPOSITION OF SIKANJABEEN LEMOONI^[19]

No	Name of Drugs	Scientific Name	Dose
1.	Sirka neshker	Acetum vinegar	150ml
2.	Arq gulab	Rosa domiscus	150ml
3.	Aab-e-lemoon kaghzi	Citrus limon	150ml
4.	Qand safaid	sugar	1kg

Actions of sikanjabeen lemooni

- Liver tonic
- Gastric and intestine tonic

Various unani drugs are mentioned for the treatment of qay'al-haml including gulqand, sikanjabeen sada, sharbat anar sheerin, sikanjabeen lemooni, jawarish anarain, mastagi, ilaichi etc^[8-11] although studies proving their effectiveness are scarce. Addressing these issues in the primary care management of the pregnant women with nausea and vomiting is the focus of this paper. Sikanjabeen lemooni, a poly herbal unani formulation consisting of sirka (acetum vinegar), aab-e-limu (citrus limon), sat limu (citric acid), qand safaid (sugar)^[12] possessing properties viz antiemetic, antianemic, appetizer, digestive, exhilarant, antioxidant properties is selected for the study.^[13,14] The aim is to validate scientifically the efficacy of sikanjabeen lemooni in qay'al-haml.



Fig. 5: Shakanjabeen-To control nausea and vomiting in Pregnancy.

VIII. Intervention of Sikanjabeen Lemooni

Sikanjabeen lemooni containing Aab-e-leemu (citrus. limon), Sirka desi (acetum vinegar), Shakar safaid (sugar), Sat leemu (citric acid).

This syrup was prepared according to the standard methods of preparation. Dose: Sikanjabeen Lemooni 25 ml twice daily for two weeks. The drug was dispense in bottles for 1 week only and the patient was asked to come with bottle in the follow up during treatment to check the compliance. As compliance is an important consideration as most NVP treatment is done on an outpatient basis.

USES Sikanjabeen Lemooni

- Nausea and vomiting
- Indigestion
- Appetizer
- Cholera

DOSE: Sikanjabeen Lemooni.
25-50ml twice a day in empty stomach.^[19]

IX. Indication of Sikanjabeen Lemooni to control Nausea and Vomiting during Pregnancy

A. The Citrusy Appeal of Sikanjabeen Lemooni in Pregnancy

Sikanjabeen Lemooni, a delightful mix of fresh lemon juice and water, is more than just a refreshing drink. Its popularity among pregnant women stems from both age-old wisdom and modern health insights. With its zesty flavor and a host of potential benefits, it's often seen as a natural remedy for some of the common discomforts of pregnancy. But like anything you consume during this critical time, it's essential to understand it from all angles.



Fig. 6: Shikanjabeen- A Unani formulation.

B. Morning Sickness Relief in the First Trimester

For many women, the initial months of pregnancy are marked by the notorious morning sickness. Nausea and vomiting can take a toll on your daily life, and here's where lemon water might come to your rescue. The mild tanginess and soothing aroma of lemon are known to alleviate feelings of nausea, making it a go-to choice for many during the first trimester. But why does lemon water work? The answer lies in its citrusy scent and flavor, which have a natural calming effect on the stomach. Plus, staying hydrated is key to combating morning sickness, and the added flavor of lemon can make the regular intake of fluids more appealing.

C. Sikanjabeen Lemooni in the Later Stages of Pregnancy

As you glide into the second and third trimesters, your body undergoes more significant changes. This is where Sikanjabeen Lemooni continues to play a helpful role. Hydration becomes even more crucial as your pregnancy progresses. The refreshing taste of lemon water can

encourage you to drink more, ensuring you and your baby stay hydrated. But there's more to it than just quenching your thirst. The added hydration can help in managing bloating and constipation common issues as your pregnancy advances. Plus, the extra fluid intake can also aid in reducing swelling often seen in the later stages of pregnancy, making you feel more comfortable.

A Bounty of Benefits: Why Sikanjabeen Lemooni is a Pregnancy Favorite.

- 1. Digestive Comfort:** Digestive upsets are a common plight during pregnancy. Sikanjabeen Lemooni stimulates digestive processes, providing some relief from indigestion and bloating.
- 2. Immune Boosting Properties:** Pregnant or not, a strong immune system is your best defense against illnesses. Sikanjabeen Lemooni, rich in vitamin C and antioxidants, helps strengthen your immune system. This is particularly beneficial in safeguarding not just your health but also that of your growing baby.
- 3. Enhancing Iron Absorption:** Iron is a critical nutrient during pregnancy, essential for both maternal and fetal health. The vitamin C in lemon water can increase your body's ability to absorb iron from dietary sources. This is crucial in preventing anemia, a common concern during pregnancy.

XII. Navigating the Risks: When Sikanjabeen Lemooni Calls for Caution

While the benefits of Sikanjabeen Lemooni are plentiful, it's important to be mindful of its potential drawbacks during pregnancy.

- 1. Acidity and Heartburn:** The natural acidity of lemons can sometimes exacerbate heartburn and acid reflux, common discomforts in pregnancy. If you find Sikanjabeen Lemooni triggering these symptoms, it's wise to reduce the amount or frequency of consumption.
- 2. Dental Health:** The citric acid in lemon can be tough on tooth enamel. To minimize the risk of dental erosion, consider drinking lemon water through a straw and rinsing your mouth with plain water afterward.
- 3. Citrus Allergies and Sensitivities:** If you have a known allergy or sensitivity to citrus fruits, it's best to steer clear of lemon water.
- 4. Balance and Moderation:** As with many aspects of a pregnancy diet, moderation is key. Excessive consumption of lemon water might lead to overhydration or nutritional imbalances.

XIII. Safely Incorporate Sikanjabeen Lemooni into Your Pregnancy Diet



Fig. 6: Shakanjabeen-To control nausea and vomiting in Pregnancy.

Enjoying the benefits of lemon water during pregnancy can be simple and safe with these tips.

- **Quality Over Quantity:** Opt for fresh, organic lemons over processed Sikanjabeen Lemooni to avoid additives and preservatives.
- **Moderation is Key:** Stick to one or two glasses of Sikanjabeen Lemooni per day to avoid any adverse effects.
- **Temperature Matters:** While hot lemon water is comforting, lukewarm or room temperature water is gentler on your digestive system.
- **Mix It Up:** Combine lemon with other ingredients like mint or ginger for added flavor and health benefits.
- **Listen to Your Body:** Pay attention to how your body reacts to lemon water and adjust accordingly. If you experience any discomfort, it's best to cut back.

CONCLUSION

Three of every 10 pregnant women have nausea that is bad enough to interfere with their daily lives. Nausea and vomiting can have adverse effects on the mother health and also on fetus. Sikanjabeen lemooni is a poly herbal Unani formulation used in Unani system of medicine since the time Arab physicians. It possessing properties viz. antiemetic, antianemic, appetizer, digestive, exhilarant, ant oxidant property. Long term follow- up of the patients until delivery showed no adverse effect on the newborns.

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