

## NIGELLA SATIVA IN MODERN HEALTHCARE: PHARMACOLOGY, SAFETY, AND INTERACTION WITH CONVENTIONAL DRUGS

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### ABSTRACT

Nigella sativa, commonly known as black seed or Karunjeeragam, is a widely used medicinal plant consumed daily as a culinary spice, traditional remedy, and herbal supplement. It has been extensively used in Ayurveda, Unani, and traditional systems of medicine for the management of diabetes, hypertension, inflammatory disorders, and immune-related conditions. The increasing popularity of herbal medicines and their concurrent use with conventional allopathic drugs has raised concerns regarding herb–drug interactions and safety issues. Although Nigella sativa is generally considered safe, its bioactive constituents such as thymoquinone possess pharmacological properties that may influence drug metabolism and pharmacodynamics. This review aims to comprehensively compile and analyze existing literature on the botanical characteristics, phytochemical constituents, pharmacological

activities, safety profile, adverse effects, and potential herb–drug interactions of Nigella sativa. Special emphasis is given to its interaction with commonly prescribed drugs used in chronic diseases. Understanding these interactions is essential to ensure the safe use of Nigella sativa in daily life and to promote rational use of herbal medicines.

**KEYWORDS:** *Nigella sativa, Herb-drug interactions, Thymoquinone, Pharmacological activities, Safety and toxicity, Traditional medicine uses.*

## INTRODUCTION

Medicinal plants play a vital role in healthcare systems worldwide. According to the World Health Organization, a large proportion of the global population relies on traditional medicine for primary healthcare. In developing countries like India, herbal remedies are commonly used due to their easy availability, affordability, and cultural acceptance. *Nigella sativa* is one such medicinal plant that has gained immense popularity in recent years.<sup>[1]</sup> Traditionally, it is consumed as a spice in food and as a home remedy for various ailments. The seeds and oil of *Nigella sativa* are widely marketed as herbal supplements claiming multiple health benefits. In daily life, many individuals consume black seed oil capsules or sprinkle seeds over food as part of routine dietary practices. Despite its extensive use, there is a widespread misconception that herbal medicines are completely safe and free from adverse effects. This belief often leads to unsupervised use of herbal products along with prescribed drugs. Such practices increase the risk of herb–drug interactions, which may alter drug efficacy, enhance toxicity, or cause unexpected adverse reactions. Herb–drug interactions occur when the pharmacological effects of a drug are modified by the concurrent use of an herbal product. These interactions may be pharmacokinetic (affecting absorption, distribution, metabolism, or excretion) or pharmacodynamic (affecting drug action at the target site). Since *Nigella sativa* exhibits multiple pharmacological activities, it has the potential to interact with drugs used in chronic conditions such as diabetes, hypertension, and immune disorder. Therefore; this comprehensive review focuses on the safety concerns and herb–drug interaction risks associated with *Nigella sativa*, emphasizing its daily use and clinical relevance.<sup>[1]</sup>

## BOTANICAL DESCRIPTION AND TAXONOMY



Scientific name: *Nigella sativa*

Family: Ranunculaceae

Synonyms: Black cumin (not true cumin)

### Common names

English: Black seed

Tamil: Karunjeeragam

Hindi: Kalonji

*Nigella sativa* is an annual flowering plant native to South and Southwest Asia. The plant grows up to 20–30 cm in height and produces delicate pale blue or white flowers. The fruit is a large capsule containing numerous angular black seeds.<sup>[3]</sup>

### Parts Used

#### Seeds

#### Seed oil (cold-pressed oil)

The seeds have a characteristic pungent aroma and slightly bitter taste. They are widely used in cooking, bakery products, pickles, and traditional medicines.<sup>[2]</sup>

### TRADITIONAL AND ETHNOMEDICINAL USES



In traditional medicine systems, *Nigella sativa* is regarded as a “panacea”.

#### Traditional uses include

Digestive disorders

Respiratory ailments (asthma, cough)

Diabetes mellitus

Hypertension

Skin disorders

Immune system enhancement

In Ayurveda and Unani medicine, *Nigella sativa* is used to balance bodily humors and improve overall vitality. Prophet Muhammad famously referred to black seed as a remedy for “every disease except death,” which has contributed to its widespread use in Islamic medicine.<sup>[3]</sup>

### **PHYTOCHEMICAL CONSTITUENTS**

The therapeutic and interaction potential of *Nigella sativa* is attributed to its rich phytochemical profile.

Major bioactive compounds

Thymohydroquinone

Nigellone

Alkaloids (nigellidine, nigellicine)

Flavonoids

Saponins

Fixed oils (linoleic acid, oleic acid, palmitic acid)

Volatile oils

Thymoquinone exhibits antioxidant, anti-inflammatory, antidiabetic, and immunomodulatory activities.<sup>[4]</sup> These actions can influence drug-metabolizing enzymes such as cytochrome P450, thereby contributing to potential herb–drug interactions.

### **PHARMACOLOGICAL ACTIVITY OF NIGELLA SATIVA**

**Antidiabetic Activity** - *Nigella sativa* reduces blood glucose levels by enhancing insulin secretion and improving insulin sensitivity.

**Antihypertensive Activity** - It produces vasodilatory effects and mild diuresis, contributing to blood pressure reduction.

**Anti-inflammatory and Analgesic Activity** - Inhibits cyclooxygenase and inflammatory cytokines.

**Immunomodulatory Activity** - Stimulates macrophage and lymphocyte activity.<sup>[3]</sup>

**Antioxidant Activity** - Neutralizes free radicals and reduces oxidative stress.

## **HERB-DRUG INTERACTION POTENTIAL OF NIGELLA SATIVA**

Herb–drug interactions occur when an herbal product alters the pharmacokinetics or pharmacodynamics of a concurrently administered drug. *Nigella sativa* contains several bioactive constituents, especially thymoquinone, which are capable of influencing enzyme systems, physiological pathways, and receptor responses. As a result, its concurrent use with conventional medicines may modify therapeutic outcomes. Herb–drug interactions associated with *Nigella sativa* can be broadly classified into pharmacodynamic interactions and pharmacokinetic interactions.<sup>[2]</sup>

### **Interaction with Antidiabetic Drugs**

*Nigella sativa* has well-documented antidiabetic activity. It reduces blood glucose levels by enhancing insulin secretion, improving insulin sensitivity, and reducing hepatic gluconeogenesis.<sup>[5]</sup> These effects can become problematic when *Nigella sativa* is used alongside antidiabetic drugs such as insulin, metformin, sulfonylureas, and thiazolidinediones.<sup>[6]</sup>

### **Mechanism of Interaction**

Additive or synergistic glucose-lowering effect

Enhancement of insulin action

Reduction of postprandial glucose levels

### **Clinical Significance**

When consumed together with antidiabetic drugs, *Nigella sativa* may cause excessive reduction in blood glucose, leading to hypoglycemia. Symptoms may include dizziness, sweating, confusion, weakness, and in severe cases, loss of consciousness.<sup>[5]</sup>

### **Risk Population**

Diabetic patients using herbal supplements.

Elderly patients

Patients with irregular food intake

### **Recommendation**

Regular monitoring of blood glucose levels

Dose adjustment of antidiabetic drugs if necessary

Avoid unsupervised use of *Nigella sativa* supplements.<sup>[6]</sup>

**Interaction with Antihypertensive Drugs**

*Nigella sativa* exhibits antihypertensive effects through vasodilation, calcium channel modulation, and mild diuretic action. These properties may interact with antihypertensive medications such as ACE inhibitors, beta-blockers, calcium channel blockers, and diuretics.

**Mechanism of Interaction**

Additive blood pressure lowering

Peripheral vasodilation

Increased diuresis

**Clinical Significance**

Concurrent use may result in excessive hypotension, leading to light-headedness, fatigue, fainting, and increased risk of falls, particularly in elderly patients.<sup>[5]</sup>

**Risk Population**

Patients on multiple antihypertensive drugs

Elderly individuals

Patients with dehydration.<sup>[2]</sup>

**Recommendation**

Blood pressure monitoring

Avoid high-dose *Nigella sativa* supplements

Medical supervision advised.

**Interaction with Anticoagulant and Antiplatelet Drugs**

Certain studies suggest that *Nigella sativa* may possess mild antiplatelet and anticoagulant properties.<sup>[7]</sup> When used with anticoagulants such as warfarin, heparin, or antiplatelet drugs like aspirin and clopidogrel, interaction risk may increase.<sup>[9]</sup>

**Mechanism of Interaction**

Inhibition of platelet aggregation

Prolongation of bleeding time (theoretical and reported)

**Clinical Significance**

This interaction may increase the risk of bleeding, manifesting as easy bruising, nosebleeds, gastrointestinal bleeding, or prolonged bleeding time.<sup>[7]</sup>

**Recommendation**

Monitor INR in patients on warfarin

Avoid excessive intake before surgery

Discontinue *Nigella sativa* prior to surgical procedures.

**Interaction with Immunosuppressant Drugs**

*Nigella sativa* is known for its immunostimulatory activity, enhancing macrophage function, lymphocyte proliferation, and cytokine production.<sup>[7]</sup> This property may interfere with immunosuppressant drugs such as cyclosporine, tacrolimus, and corticosteroid.

**Mechanism of Interaction**

Stimulation of immune response

Antagonistic effect on immunosuppressive therapy

**Clinical Significance**

In patients with organ transplants or autoimmune diseases, this interaction may reduce the efficacy of immunosuppressive drugs, increasing the risk of graft rejection or disease flare-ups.<sup>[8]</sup>

**Recommendation**

Avoid use in transplant patients

Use only under strict medical supervision.

**Interaction with Hepatotoxic Drugs**

*Nigella sativa* may alter liver enzyme activity and hepatic metabolism. This is particularly relevant when taken with hepatotoxic drugs such as paracetamol (high doses), antitubercular drugs, or chemotherapeutic agents.<sup>[9]</sup>

**Mechanism of Interaction**

Modulation of liver enzymes

Altered drug metabolism.

**Clinical Significance**

This interaction may increase drug toxicity or reduce drug clearance, potentially leading to liver injury.<sup>[6]</sup>

**Recommendation**

Liver function monitoring

Avoid long-term high-dose use.<sup>[10]</sup>

**Pharmacokinetic Interaction****Considerations**

Although clinical evidence is limited, *Nigella sativa* may influence:

Cytochrome P450 enzyme system

Drug absorption due to altered gastric motility

**Drug bioavailability**

These interactions are mostly potential or theoretical, but they become clinically relevant with chronic or high-dose use.<sup>[11]</sup>

**Safety and Toxicity Studies of *Nigella sativa*****General Safety Profile**

*Nigella sativa* is generally considered safe when used in dietary amounts. Traditional use over centuries supports its safety. However, increased consumption in the form of concentrated oils and capsules raises safety concerns.<sup>[11]</sup>

**Acute Toxicity Studies**

Animal studies have shown that *Nigella sativa* has a high margin of safety. Acute toxicity studies indicate that very high doses are required to produce toxic effects. At recommended doses, no mortality or severe toxic symptoms were observed.<sup>[13]</sup>

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**Subacute and Chronic Toxicity Studies**

Long-term administration studies suggest that:

Normal doses are well tolerated

Excessive or prolonged use may affect liver and kidney function

Mild changes in liver enzymes have been reported in some experimental studies, indicating the need for cautious long-term use.<sup>[13]</sup>

**Reported Adverse Effects**

Although rare, the following adverse effects have been reported

Gastrointestinal irritation

Nausea and vomiting

Allergic skin reactions

Headache and dizziness

These effects are generally mild and reversible upon discontinuation

**Hepatotoxicity Concerns**

Some case reports suggest that prolonged or excessive consumption of herbal supplements containing *Nigella sativa* may be associated with liver enzyme elevation.<sup>[8]</sup> The exact mechanism is not clearly established but may be related to:

**High concentration of thymoquinone**

Poor-quality or adulterated products

Use in Pregnancy and Lactation

Scientific evidence regarding safety in pregnancy and lactation is limited. Due to possible uterine stimulant effects, excessive use is not recommended during pregnancy.<sup>[13]</sup>

**Safety in Elderly and Polypharmacy Patients**

Elderly individuals often consume multiple medications. The addition of *Nigella sativa* supplements may increase the risk of herb–drug interactions and adverse effects.<sup>[12]</sup>

**Toxicity Due to Overuse and Poor Quality Products**

Non-standardized herbal supplements

Overdosing due to self-medication

Lack of labeling and dosage instructions

These factors significantly contribute to safety issues.

**Risk–Benefit Assessment**

While *Nigella sativa* offers significant health benefits, its risk increases when:

Used in high doses

Taken as supplements instead of dietary

Combined with conventional medicines

**Use in Special Populations**

Pregnancy: Limited safety data; use with caution

Elderly: Increased risk due to polypharmacy

Chronic disease patients: Require close monitoring

**Contraindications and Precautions**

Patients on multiple medications

Organ transplant recipients

Individuals with bleeding disorders

Long-term supplement users

**Regulatory Status and Quality Issues**

Lack of global standardization

Variation in active constituents

Poor labeling and dosage inconsistency

**Future Perspectives**

Need for controlled clinical studies

Development of standardized formulations

Education of healthcare professiona

**CONCLUSION**

*Nigella sativa* (black seed or Karunjeeragam) is one of the most widely consumed medicinal plants in daily life, used both as a culinary spice and as a traditional remedy for various chronic ailments. Its long history of use in Ayurveda, Unani, and traditional household practices supports its therapeutic value and general safety when consumed in dietary amounts. The presence of bioactive constituents such as thymoquinone contributes significantly to its antidiabetic, antihypertensive, anti-inflammatory, immunomodulatory, and antioxidant activities, which explains its increasing popularity as an herbal supplement. However, the findings compiled in this review clearly indicate that the same pharmacological properties responsible for the beneficial effects of *Nigella sativa* may also contribute to potential herb–drug interaction risks when used concomitantly with conventional medicines. Evidence from preclinical studies, clinical observations, and theoretical pharmacological considerations suggests that *Nigella sativa* can interact with commonly prescribed drugs such as antidiabetic agents, antihypertensive drugs, anticoagulants, immunosuppressants, and

hepatotoxic medications. These interactions may result in additive or synergistic effects, leading to adverse outcomes such as hypoglycemia, hypotension, increased bleeding risk, reduced efficacy of immunosuppressive therapy, or altered liver function. Safety and toxicity data indicate that *Nigella sativa* is generally well tolerated at normal dietary doses, with minimal adverse effects reported. Nevertheless, the risk of toxicity increases with excessive or prolonged use, particularly when consumed in concentrated forms such as oils or capsules. Reports of gastrointestinal discomfort, allergic reactions, and mild elevations in liver enzymes highlight the importance of cautious use. Special populations, including pregnant women, elderly individuals, and patients with chronic diseases who are receiving multiple medications, are at a higher risk of experiencing adverse effects or interactions. This review emphasizes that the widespread perception of herbal medicines being completely safe is misleading. Rational use of *Nigella sativa* requires awareness of its interaction potential, appropriate dosing, and careful monitoring when used alongside allopathic drugs. Healthcare professionals, especially pharmacists, have a crucial role in educating patients about possible herb–drug interactions and encouraging disclosure of herbal product use during medical consultations. In conclusion, *Nigella sativa* remains a valuable and effective medicinal plant when used responsibly in daily life. Its benefits outweigh the risks when consumed in recommended amounts and under proper guidance. Future research should focus on well-designed clinical studies to establish definitive interaction profiles, standardized dosage guidelines, and quality control measures for herbal supplements. Such efforts will contribute to the safe integration of *Nigella sativa* into modern healthcare systems and promote its rational and evidence-based use.

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