

1. Generic Name

- Haridra
- Jesthamadh
- Pippali
- Bibhitak
- Dhanyak
- Rasanjan
- Bhuiamla
- Shirish
- Tulsi
- Palash
- Nirgundi
- Satapatri
- Madhu

2. Qualitative and Quantitative composition

Each ml contains standardized aqueous extracts derived from:

| No. | Ingredient | Latin | Configuration |
|-----|------------|--------------------|---------------|
| 1. | Haridra | Curcuma longa | 12.00% |
| 2. | Jesthamadh | Glycyrrhiza glabra | 10.00% |
| 3. | Pippali | Piper longum | 5.00% |
| 4. | Bibhitak | Terminalia chebula | 5.00% |
| 5. | Dhanyak | Coriander sativum | 10.00% |
| 6. | Rasanjan | Berberis aristata | 5.00% |
| 7. | Bhuiamla | Phyllanthus niruri | 5.00% |
| 8. | Shirish | Albizzia lebeck | 5.00% |
| 9. | Tulsi | Ocimum sanctum | 5.00% |
| 10. | Palash | Butea frondosa | 5.00% |
| 11. | Nirgundi | Vitex negundo | 3.00% |

| | | | |
|-----|-----------|----------------|--------|
| 12 | Satapatri | Rosa damascena | 15.00% |
| 13. | Madhu | Honey | 15.00% |

3. Dosage form and strength

Topical ophthalmic solution containing above ingredients.

4. Clinical particulars

4.1 Therapeutic indication

Britesite eye drops is indicated for:

Eye strain due to o Excessive computer usage,

- Pollution
- Dust,
- Smoke
- Foreign bodies etc.

Inflammatory conditions of the eye due to o Infection

- Allergy
- Injury
- Use of eye cosmetics

Maintenance of clear vision in healthy eyes

Supportive therapy for the treatment of

- Dry eyes
- Age-related Macular Degeneration
- Cataract
- Conjunctivitis allergic, bacterial and viral
- Post-operative care

4.2 Posology and method of administration

As directed by physician.

4.3 Contraindication

Britesite is contraindicated in case of hypersensitivity.

4.4 Special warnings and precautions for use

None.

4.5 Drug interactions

No data available.

4.6 Use in special population

- Pediatric: No data available.
- Geriatric: No data available.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: No data available.

4.7 Effects on ability to drive and use machine

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to Britesite is known.

4.8 Undesirable effects

No data available.

4.9 Overdose

There is limited experience of overdose with Britesite. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

BriteSite eyedrops is an absolutely sterile solution having 13 purified plant extracts having antioxidant and nutritional properties. It has an immediate cooling & soothing effect on the eye, which persists even after 30 minutes of the instillation. BriteSite eye drops do not cause any stinging and burning even in irritated eyes. BriteSite eye drops protects eyes from pollutants such as dust, smoke, fumes as well as occupation related disorders like Computer Vision Syndrome etc. BriteSite eye drops is boosted with natural anti-inflammatory herbs like Palash, Haridra; hence, is useful in the inflammatory conditions of the eye. Rosa damascena in BriteSite has a unique anti-solar effect, which protects the eyeball from harmful effects of the sunlight. The use of honey as an ophthalmic antioxidant is very well accepted even in western countries. Honey is a great source of trace nutrients like Folate, Vit. C, Vit. B, sodium, potassium, phosphorus, selenium, zinc, magnesium, manganese and copper etc. Daily instillation of BriteSite eye drops provides nutrition to the components of the eyeball and is beneficial to maintain eye health.

5.2 Pharmacodynamic properties

No data available.

5.3 Pharmacokinetic properties

No data available.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Not required.

7. Description

The ingredients of BriteSite could be categorized into four classes according to their mode of action:

1. Anti-inflammatory – Curcuma longa, Glycyrrhiza glabra, Piper longum, Berberis aristata, Phyllanthus niruri, Albizzia lebbeck, Ocimum sanctum, Vitex negundo, Butea frondosa, Rosa damascena, Honey
2. Antimicrobial – Curcuma longa, Glycyrrhiza glabra, Piper longum, Terminalia chebula, Coriandrum sativum, Berberis aristata, Albizzia lebbeck, Ocimum sanctum, Vitex negundo, Butea frondosa, Rosa damascena, Honey
3. Antioxidant – Curcuma longa, Glycyrrhiza glabra, Piper longum, Terminalia chebula, Coriandrum sativum, Phyllanthus niruri, Ocimum sanctum, Vitex negundo, Rosa damascena, Honey
4. Immunomodulatory – Curcuma longa, Glycyrrhiza glabra, Piper longum, Coriandrum sativum, Berberis aristata, Phyllanthus niruri, Albizzia lebbeck, Ocimum sanctum, Honey

Some of the key findings about BriteSite ingredients are as follows:

Berberis aristata - conjunctival scrapings of patients receiving the berberine chloride eye drops were negative for *C. trachomatis* and there were no relapses, even one year after treatment.

Curcuma longa - The results indicate that turmeric and curcumin are effective against the development of diabetic cataract. Further, turmeric may be explored for anticataractogenic agents that prevent or delay the development of cataract.

Glycyrrhiza glabra: Glycyrrhizin [Yashtimadhu] in a 5% solution showed a comparable anti-inflammatory effect to that of dexamethasone (0.1%).

Phyllanthus niruri: *P. niruri* is able to modulate the immune system, via proliferation and activation of T- and B-lymphocytes, activation of the complement system, activation of

phagocytic cells such as macrophages and monocytes, as well as increase of cytotoxic cells such as the Natural Killer cells.

Ocimum sanctum(OS): The extracts from the leaves of Ocimum sanctum showed better activity against the three MRSA strains. OS possesses a significant anticataract activity in vitro and its anticataract potential could be related with its AR inhibitory effect.

Rosa damascena: Rose water obtained from petals of Rosa damascena is known for its soothing effect and also found to be beneficial in ophthalmopathy

Honey: In eye research, flavonoids have been reported as anticataract agents in vivo and vitro because of their osmotic protection as inhibitors of aldose reductase.

Coriander sativum: The daily use of coriander fruits in various forms is very common in India and the present study revealed strong antioxidant activity of coriander extracts that was superior to known antioxidant ascorbic acid and indicate its intake may be beneficial.

Butea frondosa: The findings reveal statistically significant differences ($P < 0.05$) between the arkas of the Butea frondosa and the commercial eye drop of Flurbiprofen.

Thus, BriteSite eye drops are specifically designed to counter all 4 aforesaid pathological events and hence are useful in the treatment as well as prevention of eye diseases.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

36 months.

8.3 Packaging Information

BriteSite eye drops are available in 10 ml container sterilized by Gamma Irradiation.

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.8

9.3 Dosage

Refer part 4.5

9.4 Storage

Refer part 8.4

9.5 Risk factors

Refer part 4.4

9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by Sreedhareeyam Farmherbs India Pvt. Ltd.

11. Details of permission or license number with date

Licence No. 2/25 D/2008 dated 21/02/2008

12. Date of revision: January 2022