

Safety Alert

Apr 2024

Ashwagandha – Risk of liver injury and GIT irritation

EDA performs label update to include the following:

8. Contraindications

- Existing or previous liver disorders.

9. Special warnings and precautions for use -

- If the symptoms worsen during the use of the medicinal product, a doctor or a pharmacist should be consulted.
- Use with caution in peptic ulcer; Ashwagandha may cause gastrointestinal irritation .
- The use is not recommended in patients below 18 years of age due to insufficient data on safety
- In case of yellowing of the skin or eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain or loss of appetite, the medicinal product should be stopped and a medical advice should be sought

13. Undesirable effects

In very rare cases, it may cause severe liver injury

Background:

Relevant biological activities

- Treatment of sleep disorders
- Anxiolytic and anti-stress effects
- Adaptogenic Effect

References:

Egyptian Herbal Monograph v1 ([Click here](#))