

Package leaflet: Information for the user

Esberitox[®]

mono drops

liquid

for use in adults and adolescents from the age of 12 years
expressed juice of purple coneflower herb

Read all of this package leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Esberitox[®] mono drops as directed in order to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after several days.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

In this leaflet:

1. What Esberitox[®] mono drops are and what they are used for
2. Before you take Esberitox[®] mono drops
3. How to take Esberitox[®] mono drops
4. Possible side effects
5. How to store Esberitox[®] mono drops
6. Further information

1. What Esberitox[®] mono drops are and what they are used for?

Esberitox[®] mono drops are a herbal medicinal product for the short-term prevention and treatment of common cold diseases.

2. Before you take Esberitox[®] mono drops

2.1 Do not take Esberitox[®] mono drops

- The use in children under one year of age is contraindicated, because the immune system is not yet fully developed.
- if you are hypersensitive (allergic) to purple coneflower herb, to plants of the Asteraceae (Compositae) family or to any of the other ingredients of Esberitox[®] mono drops.

For principle reasons Esberitox[®] mono drops should not be used in case of:

- progressive systemic diseases such as tuberculosis or a rare inflammatory disease (sarcoidosis),
- systemic diseases of the white blood cell system (e.g. leukaemia or leukaemia-like diseases),

- autoimmune diseases like e.g. inflammatory connective-tissue diseases (collagenoses) or multiple sclerosis,
- acquired immunodeficiencies (AIDS/HIV-infections),
- immunosuppression (e.g. after organ or bone marrow transplantation, chemotherapy in case of cancer diseases).

2.2 Take special care with Esberitox® mono drops

- if the complaints persist longer than 10 days or if breathlessness, fever, purulent or bloody secretion occurs. In these cases you should consult a doctor.
- if you are allergically predisposed. There is possibly an increased risk of a severe allergic reaction (anaphylactic shock). You should first consult your doctor before using Esberitox® mono drops.

2.3 Children

Children under 1 year of age must not take Esberitox® mono drops (see also 2.1 „Do not take Esberitox® mono drops“).

There are no sufficient data regarding the use in children under 12 years. The use in children under 12 years is, therefore, not recommended, although a specific risk for children over 1 year of age is not documented.

2.4 Taking other medicines:

Please inform your doctor or pharmacist, if you take/use or have recently taken/used other medicines, including medicines obtained without a prescription.

Interaction studies with Esberitox® mono drops have not been performed. Interactions during the intake of products of pressed juice of purple cone flower herb together with other medicinal products have not been reported. Due to the alcohol content, the effects of other medicinal products may be impaired or increased.

2.5 Pregnancy and breast-feeding:

Due to insufficient data the medicinal product should not be used during pregnancy and breast-feeding.

See also section 2.7 „Important information about some of the other ingredients of Esberitox® mono drops“.

2.6 Driving and using machines:

No special precautions are required.

2.7 Important information about some of the other ingredients of Esberitox® mono drops:

This medicinal product contains 22 vol.-% alcohol. Observing the dosage instruction there will be an alcohol intake of 0.7 g per dosage unit (4 ml). Among others, there is a health risk for patients with liver disease, alcoholics, epileptics, patients with organic diseases of the brain, pregnant or nursing women and for children.

3. How to take Esberitox® mono drops

Always take Esberitox® mono drops exactly as instructed in this package leaflet. You should check with your doctor or pharmacist, if you are not quite sure.

3.1 Unless otherwise prescribed by the doctor, the usual dose is:

Adults and adolescents from the age of 12 years take **3 times daily 4 ml** Esberitox[®] mono drops.

The use in children under 12 years of age is not intended (see section 2.3).

There are no sufficient data for specific dosage recommendations in case of impaired renal/liver function.

Mode of application:

For internal use. For accurate dosage the bottle closure has a measuring cap with a 4 ml mark.

Please take Esberitox[®] mono drops in the morning, in the middle of the day and in the evening, preferably undiluted.

Please consult your doctor or pharmacist, if you have the impression that the effects of Esberitox[®] mono drops are too strong or too weak.

3.2 Duration of use:

The duration of use depends on the underlying disease. The treatment should be started as early as possible after the first symptoms appear and continued until the symptoms disappear. Esberitox[®] mono drops should, however, not be taken longer than 10 days without interruption.

Please take note of the information under section 2.2.

3.3 If you take more Esberitox[®] mono drops than you should:

Toxications with preparations of purple coneflower herb have not been known until now. In case of overdose of Esberitox[®] mono drops the complaints listed under 4. "Side effects" may increasingly occur. The medicinal product should then be discontinued and a doctor should be consulted.

3.4 If you forget to take Esberitox[®] tablets:

Do not take a double dose at the next time, but continue the intake as described in this package leaflet or as prescribed by your doctor.

If you have further questions about the use of this medicinal product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Esberitox[®] mono drops can cause side effects, although not everybody gets them.

Possible side effects:

During intake of medicinal products with preparations of purple coneflower herb hypersensitivity reactions (skin rash, urticaria, shortness of breath, dizziness, drop in blood pressure, Stevens-Johnson Syndrome, facial swelling/swelling of the skin and/or mucosa, bronchospasm with obstruction, asthma, anaphylactic shock) have been observed. In allergically predisposed patients allergic reactions may be triggered.

Gastrointestinal complaints such as nausea, vomiting and diarrhoea may occur.

The intake of medicinal products with preparations of purple coneflower herb is seen in relation with the occurrence of immune diseases.

In case of long-term treatment (more than 8 weeks) blood count changes (leucopenia, i.e. a reduction of the number of white blood cells) may occur.

The frequency of the side effects is not known.

Should you experience swellings in the face, mouth and/or throat or allergic reactions of the respiratory tract, you should discontinue Esberitox[®] mono drops and immediately consult a doctor who can decide on the severity and required measures, if necessary.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via (...*the national reporting system*). By reporting side effects you can help to provide more information on the safety of this medicine.

5. How to store Esberitox[®] mono drops

Keep out of the reach and sight of children.

Do not use the medicinal product after the expiry date which is stated on the label and the carton after "use before". The expiry date refers to the last day of that month.

In liquids produced of natural products turbidity or slight precipitation may occur.

After opening of the bottle the medicinal product may be used for 1 month.

6. Further information

What Esberitox[®] mono drops contain:

Active substance:

100 g liquid contain 64 g pressed juice of fresh, flowering purple coneflower herb (1–2 : 1).

The other ingredients are:

ethanol (alcohol) 96 %, purified water (total alcohol content 22 vol.-%).

What Esberitox[®] mono drops look like and contents of the pack:

Brown liquid in a brown glass bottle.

Esberitox[®] mono drops are available in packs with 50 ml und 100 ml.

Marketing authorization holder and manufacturer

Schaper & Brümmer GmbH & Co. KG

Bahnhofstr. 35

38259 Salzgitter

Germany

Tel.: +49 - 53 41 3 07-0

Fax: +49 - 53 41 3 07-124

info@schaper-bruemmer.de

http://www.schaper-bruemmer.com

This product information leaflet was last revised in November 2014