

Package leaflet: Information for the user

Esberitox[®] tablets

Tablets each with 3.2 mg dry extract from a mixture of wild indigo rootstock, purple coneflower root, pale coneflower root and arbour vitae tips and leaves for application in children and adults.

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[®] tablets 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.

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1. What Esberitox[®] tablets are and what they are used for

Esberitox[®] tablets are a herbal medicine for common cold diseases.

Esberitox[®] tablets are used for supportive therapy of viral cold diseases.

2. Before you take Esberitox[®] tablets

2.1 Do not take Esberitox[®] tablets

- if you are hypersensitive (allergic) to the pharmacologically active ingredients (wild indigo rootstock, purple coneflower root, coneflower root, arbour vitae tips and leaves) or any of the other ingredients of Esberitox[®] tablets or to composites.

For principle reasons, Esberitox[®] tablets should not be used in case of

- progressive systemic diseases such as tuberculosis and a rare inflammatory disease (sarcoidosis);
- diseases directing the immune system against the own body (auto-immune diseases) like inflammatory connective-tissue diseases (collagenoses), multiple sclerosis;
- acquired immunodeficiency like Aids-diseases, HIV-infections;
- an immunosuppressive therapy e.g. after transplantations or by chemotherapy for treatment of cancer (cytostatic therapy);

- systemic blood diseases of the white blood cell system like leukaemia and a reduction of particular white blood cells (agranulocytosis).

2.2 Take special care with Esberitox[®] tablets,

- if the complaints intensify or persist longer than 10 days,
- if breathlessness, fever or purulent or bloody secretion occurs.

In these cases consult a doctor.

2.3 Children:

There are no adequate investigations with regard to the use of this medicine in children under 4 years. In particular, investigations regarding long-term effects of the application of Esberitox[®] tablets on the maturing immune system of children of this age group are lacking. Esberitox[®] tablets should, therefore, not be used in children under 4 years.

2.4 Taking other medicines:

It was found that preparations of purple coneflower root influence the activity of medicines which are catabolised via a particular enzyme system in the liver. Its scientific name is "cytochrom-P450" and especially refers to the isoenzymes CYP3A or CYP1A2.

This medicine is not sufficiently investigated regarding the above matter.

Therefore, Esberitox[®] tablets should not be used together with medicines being catabolised via the same enzyme system. Therefore, if you take other medicines, please ask your doctor whether such an influence would be possible.

For the further ingredients in Esberitox[®] tablets no investigations are available.

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

2.5 Pregnancy and breast-feeding:

a. Pregnancy

As the safety of the use of Esberitox[®] tablets in pregnancy is not proven, you should take Esberitox[®] tablets only after consultation with your doctor, after he/she has made a benefit/risk-assessment.

b. Breast-feeding

As it is not known whether or not certain ingredients of Esberitox[®] tablets are excreted in the breast milk and result in adverse effects for the nursed baby, you should as a precaution not take Esberitox[®] tablets during breast-feeding.

2.6 Driving and using machines:

No special precautions are required.

2.7 Important information about some of the other ingredients of Esberitox[®] tablets:

This medicine contains lactose and sucrose (sugar). Therefore, please take Esberitox[®] tablets only after consultation with your doctor, if you know, that you suffer from intolerance against certain sugars.

3. How to take Esberitox tablets

Always take Esberitox[®] tablets 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 – 6 tablets.
Children from 7 to 11 years take 3 times daily 2 – 3 tablets.
Children from 4 to 6 years take 3 times daily 1 – 2 tablets.

Please take Esberitox[®] tablets in the morning, in the middle of the day and in the evening with sufficient liquid, preferably water. The tablets may also be sucked.

3.2 Duration of use:

Start the treatment as early as possible after the first symptoms appear and continue taking Esberitox[®] tablets until the symptoms disappear. However, take note of the details on precautionary measures of section 2.2 and the details on side effects of section 4 in this package leaflet.

Do not take Esberitox[®] tablets longer than 10 days without medical advice.

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

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

Toxications with Esberitox[®] tablets have not been known until now. If you inadvertently have taken one or two tablets more than you should, this has normally no adverse effects. If you have taken a considerably larger quantity of Esberitox[®] tablets than you should, please consult a doctor. He/she can decide on required measures to be taken, if necessary.

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

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

4. Possible side effects

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

Immune system disorders:

Hypersensitivity reactions, e. g. skin rash, itching, facial swelling, shortness of breath, blood pressure decrease

Gastrointestinal disorders:

Abdominal pain, vomiting, diarrhoea

General disorders:

Dizziness

Regarding frequency no data are available.

In these cases you should discontinue taking the medicine and consult your doctor. As soon as first symptoms of a hypersensitivity reaction appear, do not take Esberitox[®] tablets again.

Please inform your doctor or pharmacist if any of the listed side effects considerably impairs you, or if you notice any side effects not listed in this leaflet.

5. How to store Esberitox[®] tablets

Keep out of the reach and sight of children.

Do not use the medicine after the expiry date which is stated on the carton.

Do not store above 30°C.

6. Further information

What Esberitox[®] tablets contain:

The active substance is:

1 tablet contains

3.2 mg dry extract (4-9:1) from a mixture of wild indigo rootstock : purple coneflower root : pale coneflower root : arbour vitae tips and leaves (4.92:1.85:1.85:1).

Extractant: ethanol 30% (V/V)

The other ingredients are:

Lactose monohydrate, magnesium stearate, macrogol (M:6000), sucrose (saccharose).

Esberitox[®] tablets do not contain alcohol.

Note for diabetics: 1 tablet is equivalent to 0.02 carbohydrate units.

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

Round, beige-brown tablets

Esberitox[®] tablets are available in packs with 60, 100 and 200 tablets.

Marketing authorisation holder and manufacturer

Schaper & Brümmer GmbH & Co. KG

Bahnhofstr. 35

38259 Salzgitter

Tel. (0 53 41) 3 07-0

Fax (0 53 41) 3 07-124

info@schaper-bruemmer.de

<http://www.schaper-bruemmer.com>

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