

## Package leaflet: Information for the user

### Esberitox® tablets

For use in adults and children 4 years and older

Dry extract from a mixture of wild indigo rootstock, purple coneflower root, pale coneflower root and arbour vitae tips and leaves

#### **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 talk to a doctor if your symptoms worsen or do not improve after several days.
- If you are considerably affected by any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Esberitox® tablets are and what they are used for
2. What you need to know before you take Esberitox® tablets
3. How to take Esberitox® tablets
4. Possible side effects
5. How to store Esberitox® tablets
6. Further information

#### **1. What Esberitox® tablets are and what they are used for**

Esberitox® tablets are an herbal medicine for common colds.

Esberitox® tablets are used for supportive therapy of viral colds.

#### **2. What you need to know before you take Esberitox® tablets**

##### **2.1 Do not take Esberitox® tablets**

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

For general reasons, Esberitox® tablets should not be used in case of

- progressive systemic diseases such as tuberculosis and a rare inflammatory disease (sarcoidosis)
- diseases causing the body's immune system to turn against itself (autoimmune diseases) like inflammatory connective tissue diseases (collagenoses), multiple sclerosis
- acquired immunodeficiency disorders like AIDS, HIV-infections
- an immunosuppressive therapy e.g. after transplantations or chemotherapy for treatment of cancer (cytostatic therapy)

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

## **2.2 Take special care with Esberitox<sup>®</sup> tablets**

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

In these cases talk to a doctor.

## **2.3 Children**

There are no adequate studies on the use of this medicine in children under 4 years of age. In particular, studies regarding the long-term effects of Esberitox<sup>®</sup> tablets on the maturing immune system of children in this age group are lacking. Esberitox<sup>®</sup> tablets should, therefore, not be given to children under 4 years of age.

## **2.4 Other medicines and Esberitox<sup>®</sup> tablets**

Interactions with other medicines are not known.

Studies on possible interactions of Esberitox<sup>®</sup> tablets with other medicines are not available.

Tell your doctor or pharmacist, if you are taking/using or have recently taken/used other medicines, including medicines obtained without a prescription.

## **2.5 Pregnancy and breast-feeding**

### **a. Pregnancy**

The safety of the use of Esberitox<sup>®</sup> tablets during pregnancy has not been proven. You should only take Esberitox<sup>®</sup> tablets after talking to your doctor, and he/she has assessed the benefits and risks.

### **b. Breast-feeding**

It is not known whether certain ingredients of Esberitox<sup>®</sup> tablets are excreted in human milk and result in adverse effects for the breastfed baby. As a precaution, you should not take Esberitox<sup>®</sup> 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<sup>®</sup> tablets**

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

## **3. How to take Esberitox<sup>®</sup> tablets**

Always take Esberitox<sup>®</sup> tablets exactly as described in this leaflet. Check with your doctor or pharmacist if you are not sure.

### **3.1 Unless otherwise prescribed by your doctor, the recommended dose is**

Adults and adolescents 12 years and over take 4 – 6 tablets 3 times a day.

Children 7 to 11 years take 2 – 3 tablets 3 times a day.

Children 4 to 6 years take 1 – 2 tablets 3 times a day.

There is not enough data for specific dosage recommendations in impaired kidney / liver functions.

Please take Esberitox<sup>®</sup> tablets in the morning, in the middle of the day, and in the evening with sufficient liquid, preferably water. The tablets may also be chewed.

### **3.2 Duration of use**

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

Do not take Esberitox<sup>®</sup> tablets longer than 10 days without medical advice.

Please talk to your doctor or pharmacist if you feel like the effects of Esberitox<sup>®</sup> tablets are too strong or too weak.

### **3.3 If you take more Esberitox<sup>®</sup> tablets than you should**

To date no poisoning with Esberitox<sup>®</sup> tablets has been reported. If you have accidentally taken one or two tablets more than you should, there are normally no adverse effects. If you have taken a considerably larger quantity of Esberitox<sup>®</sup> tablets than you should, please talk to a doctor. He/she can decide on the appropriate measures to take, if necessary.

### **3.4 If you forget to take Esberitox<sup>®</sup> tablets**

Do not take a double dose. Continue to take as described in this leaflet or as prescribed by your doctor.

## **4. Possible side effects**

Like all medicines, Esberitox<sup>®</sup> tablets can cause side effects, although not everybody gets them.

Possible side effects:

Immune system disorders:

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

Gastrointestinal disorders:

Abdominal pain, nausea, diarrhoea

General disorders:

Dizziness

No data are available regarding frequency.

In these cases you should discontinue taking the medicine and talk to your doctor. As soon as the first symptoms of a hypersensitivity reaction appear, do not take any more Esberitox<sup>®</sup> tablets.

### **Reporting of side effects**

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 to Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: [www.bfarm.de](http://www.bfarm.de). By reporting side effects, you can help provide more information on the safety of this medicine.

## **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).

Extracting agent: ethanol 30% (V/V)

The other ingredients are:

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

Note for diabetics: 1 tablet contains 0.02 calculable carbohydrate units (CU).

### **What Esberitox® tablets look like and contents of the pack**

Round, beige-brown tablets

Esberitox® tablets are available in packs containing 60, 100 (N3) or 200 tablets. (Hospital pack size 1000 tablets [10 x 100 tablets].)

### **Marketing authorisation holder and manufacturer**

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