

## Package leaflet: Information for the user

### Esberitox® COMPACT

tablets

for application in adults and adolescents from the age of 12 years

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® COMPACT as directed in order to get the best results from it.

- 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 7 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® COMPACT is and what it is used for
2. Before you take Esberitox® COMPACT
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4. Possible side effects
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#### **1. What Esberitox® COMPACT is and what it is used for**

Esberitox® COMPACT is a herbal medicine for common cold diseases.

Esberitox® COMPACT is used for supportive therapy of viral cold diseases.

#### **2. Before you take Esberitox® COMPACT**

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

- 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® COMPACT or to composites.

For principle reasons, Esberitox® COMPACT 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 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<sup>®</sup> COMPACT,

- if the complaints intensify or do not improve after one week,
- if breathlessness, fever or purulent or bloody secretion occurs.

In these cases consult a doctor.

## 2.3 Children:

This medicine is not suitable for children under the age of 12 years. For children adequate tablets with a lower potency are available.

## 2.4 Taking other medicines:

Interactions are not known.

Please nevertheless 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<sup>®</sup> COMPACT in pregnancy is not proven, you should take Esberitox<sup>®</sup> COMPACT 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<sup>®</sup> COMPACT are excreted in the breast milk and result in adverse effects for the nursed baby, you should as a precaution not take Esberitox<sup>®</sup> COMPACT during breast-feeding.

## 2.6 Driving and using machines:

No special precautions are required.

## 3. How to take Esberitox COMPACT

Always take Esberitox<sup>®</sup> COMPACT 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 1 tablet**.

Esberitox<sup>®</sup> COMPACT is not intended for use in children under the age of 12 years.

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

Please take Esberitox<sup>®</sup> COMPACT in the morning, in the middle of the day and in the evening with sufficient liquid, preferably 1 glass of 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> COMPACT 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<sup>®</sup> COMPACT longer than 10 days without medical advice.

Please consult your doctor or pharmacist, if you have the impression that the effects of Esberitox<sup>®</sup> COMPACT are too strong or too weak.

**3.3 If you take more Esberitox<sup>®</sup> COMPACT than you should:**

Toxications with Esberitox<sup>®</sup> COMPACT 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<sup>®</sup> COMPACT 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<sup>®</sup> COMPACT:**

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<sup>®</sup> COMPACT can cause side effects, although not everybody gets them.

Possible side effects:

Immune system:

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

Gastrointestinal tract:

Abdominal pain, nausea, diarrhoea

General disorders:

Dizziness

Regarding frequency no data are available.

As soon as first symptoms of a hypersensitivity reaction appear, do not take Esberitox<sup>®</sup> COMPACT again.

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<sup>®</sup> COMPACT**

Keep out of the reach and sight of children.

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

No special storage conditions are necessary for this medicine.

## 6. Further information

### **What Esberitox® COMPACT contains:**

The active substance is:

1 tablet contains

16 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:

Mannitol (Ph. Eur.), betadex, lemon flavouring, glycerol dibehenate (Ph. Eur.), magnesium stearate (Ph. Eur.), citric acid monohydrate, saccharin sodium.

### **What Esberitox® COMPACT looks like and contents of the pack:**

Round, beige-coloured tablets

Esberitox® COMPACT is available in packs with 20, 40 and 60 tablets.

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

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