

## **Package leaflet: Information for the user**

### **Benfogamma 50 mg coated tablets**

benfotiamine

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

#### **What is in this leaflet**

1. What Benfogamma is and what it is used for
2. What you need to know before you use Benfogamma
3. How to use Benfogamma
4. Possible side effects
5. How to store Benfogamma
6. Contents of the pack and other information

#### **1. What Benfogamma is and what it is used for**

Benfogamma contains benfotiamine. This is a fat-soluble form of vitamin B1 that is characterised by much better absorption than the traditional water-soluble form. After absorption into the organism, benfotiamine is converted into vitamin B1.

Vitamin B1 is a vital substance participating in a number of functions of the organism. The vitamin plays an important role in metabolism and participates in a number of biochemical processes where nutrients (incl. glucose) are transformed into energy.

Benfogamma coated tablets are used in the treatment of vitamin B1 deficiency in adults.

#### **2. What you need to know before you use Benfogamma**

##### **Do not use Benfogamma:**

- if you are allergic to benfotiamine, thiamine, or any of the other ingredients of this medicine (listed in section 6).

##### **Other medicines and Benfogamma**

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

5-fluorouracil inactivates thiamine.

##### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The recommended daily dose of vitamin B1 during pregnancy and breast-feeding is 1.4 to 1.6 mg. The dose can only be increased during pregnancy if you have a confirmed vitamin B1 deficiency, as the safety of ingesting doses larger than the recommended daily dose has not been proven.

Vitamin B1 is absorbed into breast milk.

##### **Driving and using machines**

No precautions are necessary.

##### **Benfogamma contains sucrose, glucose, sodium, and macrogolglycerol hydroxystearate**

If you have been told by your doctor that you have intolerance to some sugars, talk to your doctor

before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Macrogolglycerol hydroxystearate can cause stomach irritation and diarrhoea.

### 3. How to use Benfogamma

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Treatment involves administering 1 coated tablet 1–3 times per day; more can be taken in individual cases. The coated tablets are swallowed whole with fluids.

If you feel that the effect of Benfogamma is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more Benfogamma than you should**

Medical assistance is usually not necessary.

If you experience any unpleasant side effects, talk to your doctor about the continuation of the treatment.

#### **If you forget to use Benfogamma**

Do not take a double dose to make up for a forgotten dose.

Continue taking Benfogamma at the usual time and try not to forget taking the medicine in the future.

#### **If you stop using Benfogamma**

If you prematurely stop using Benfogamma, the treatment may not be successful.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are classified based on frequency as follows:

Very common:	occurs in more than 1 user in 10
Common:	occurs in 1–10 users in 100
Uncommon:	occurs in 1–10 users in 1,000
Rare:	occurs in 1–10 users in 10,000
Very rare:	occurs in less than 1 user in 10,000
Unknown	incidence cannot be estimated from available data

#### *Immune system disorders:*

Very rare: allergic reactions (urticaria, rash) can occur in isolated cases.

#### *Gastrointestinal disorders:*

Very rare: isolated cases of gastrointestinal disorders (i.e. nausea and other complaints) have been recorded in clinical trials. Relation between the use of benfotiamine and dose dependence is unknown.

#### **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 via [www.ravimiamet.ee](http://www.ravimiamet.ee). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Benfogamma

Do not store at a temperature higher than 25 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information What Benfogamma contains

- The active substance is benfotiamine. One coated tablet contains 50 mg of benfotiamine (fat-soluble vitamin B1).
- The excipients contained in the tablet core are corn starch, sucrose, gelatine, talc, stearic acid, magnesium stearate.

The excipients contained in the tablet coating are sucrose, talc, sodium carbonate, titanium dioxide (E171), heavy kaoline, spray-dried acacia gum, anhydrous colloidal silica, corn starch, macrogol 6000, montan glycol wax, polyvidone K25, sodium carmellose, liquid glucose, macrogolglycerol hydroxystearate, sodium lauryl sulfate.

Gluten-free. Does not contain lactose.

### What Benfogamma looks like and contents of the pack

White, coated, smooth-surfaced tablets, 3.7 to 4.6 mm high and 7.6 to 8.0 mm in diameter, packed in Al/PVC/PVDC blisters and cartons.

The pack contains 30, 50, 60, 100 or 500 coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder:

Wörwag Pharma GmbH & Co. KG Calwer  
Str. 7  
D-71034 Böblingen,  
Germany

#### Manufacturer:

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