

## PACKAGE LEAFLET: INFORMATION FOR THE USER

---

### CARBOMED

150 mg tablet

ACTIVATED MEDICAL CHARCOAL

---

*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

---

*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

---

#### What is in this leaflet?

1. What CARBOMED is and what it is used for
2. Before you take CARBOMED
3. How to take CARBOMED
4. Possible side effects
5. How to store CARBOMED
6. Further information

#### *1. WHAT CARBOMED IS AND WHAT IT IS USED FOR*

Activated medical charcoal is a nonspecific intestinal adsorbent.

It is used in conditions such as:

- Acute oral poisoning by medicine or toxin (analgesics, antipyretics, sedatives, hypnotics, anticonvulsants, tricyclic antidepressants, cardiotonic glycosides, sulfonamides, quinine, theophylline, nicotine);
- Food poisoning;
- Diarrhea;
- Flatulence.

In the treatment of acute poisoning, the use of rectally or orally administered laxative (sodium sulfate or magnesium sulfate) is recommended.

## 2. BEFORE YOU TAKE CARBOMED

### **Do not take CARBOMED**

- If you are allergic (hypersensitive) to activated medical charcoal
- If there is the possibility of oral administration of specific antidote

### **Take special care with CARBOMED**

Consult your doctor if you have a chronic disease, a metabolic disorder, if you are allergic or are taking some medicines.

The person to whom we give the suspension of active medical charcoal must be conscious. During the application, the inhalation of particles of activated charcoal should be avoided.

Long-term therapy with active medical charcoal can cause digestive disorders due to adsorption of enzymes and vitamins from food. Active medical charcoal can make it difficult to detect pathogenic parasites in the gut so in the case of suspected diarrhea caused by parasites the stool should be inspected before the treatment with active medical charcoal.

It is recommended that the women who use oral contraceptives at the time of taking the active medical charcoal should use other forms of contraception.

In the case of acute dysentery with bloody stools and fever it is more appropriate to use the appropriate antibiotic instead of active medical charcoal. The use of active medical charcoal is not recommended in cases of poisoning with mineral acids or alkalis, detergents, and salts of heavy metals, methanol, ethanol, ethylene glycol, because active medical charcoal has a low adsorptive capacity.

It should be noted that the presence of medical charcoal in the digestive system interferes with the possible need for an urgent examination (endoscopy).

In the case when the taken poison has diuretic properties or it is taken with alcohol, after administration of medical charcoal, it is recommended to take a greater amount of liquid (water).

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Active medical charcoal reduces the effect of the majority simultaneously orally administered medicines. The cause is their binding to the particles of the charcoal. Therefore, in the case of concomitant use the space between their intakes should be at least two hours.

Simultaneous treatment with active medical charcoal and a medicine that causes vomiting (emetic) or antidote reduces the effect of emetics or antidote.

Concomitant use of sorbitol and active medical charcoal can lead to dehydration.

Milk, ice cream and similar products reduce the effect of the active medical charcoal.

### **Taking carbomed with food and drinks**

To achieve an optimal effect, CARBOMED tablets should be taken 1-2 hours after a meal.

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

In pregnant and breastfeeding women have not been reported problems associated with the use of active medical charcoal. Charcoal is not absorbed from the gastrointestinal tract.

### **Driving and using machines**

CARBOMED should not affect your ability to drive and use machines.

### **Other warnings**

This medicine contains sucrose and lactose. In case of intolerance to some sugars, contact your doctor before using this medicine. Every Carbomed tablet contains 110 mg of lactose and 110 mg of sucrose.

This should be taken into account in patients with diabetes.

### 3. HOW TO TAKE CARBOMED

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

#### **Acute oral poisonings**

If possible, active medical charcoal should be taken within 30 minutes of entering the toxins in the body, in order to effectively prevent the absorption of toxins.

To stimulate the secretion of toxin the usual dose is 20 tablets, which need to be crushed in the glass (200 ml) of water or tea at the beginning of therapy, and then taken every 4 hours or more often.

The medicine should not be taken with milk. Also, you need to make sure that the patient does not inhale the medicine.

Diarrhea and flatulence

#### **Adults**

Unless otherwise stated, you should take 4-7 tablets of the active medical charcoal, 4 times a day after meals. Active medical charcoal in case of diarrhea should be taken until the stool is normalized, but no longer than four days. In case of flatulence active medical charcoal can be taken up to 7 days. If there is no improvement, you should contact your doctor.

#### **Children**

Children older than three years should take 2-4 tablets, 1-2 times a day.

It is not recommended to give active medical charcoal to children under three years.

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

Considering the mechanism of action of medical charcoal, there is no risk of overdosing.

Talk to your doctor or pharmacist if you have any additional questions.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, CARBOMED can cause side effects, although not everybody gets them. Active medical charcoal colors the stool in black.

#### **Uncommon side effects** (in 0.1% or more patients but less than 1%)

- Constipation.

#### **Rare side effects** (in 0.01% or more patients, but less than 0.1%)

- Vomiting, abdominal pain
- Hypokalemia, acidosis
- Dyspnea, respiratory disorder with renal, pulmonary infiltration, aspirations
- Slight skin and / or mucous membranes irritation, allergic reaction
- Fever, stupor.

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

### 5. HOW TO STORE CARBOMED

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use CARBOMED after the expiry date which is stated on the label.

Shelf life: 4 years.

## **6. FURTHER INFORMATION**

### ***What CARBOMED contains***

1 tablet contains 150 mg of activated medicinal charcoal.

The other ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, sucrose.

### ***What CARBOMED looks like and contents of the pack***

The tablets are black, homogeneous shape, size and color, sweet taste and no smell.

30 tablets in PVC / aluminum blisters (2 blisters of 15 tablets).

### ***Regime of dispensing***

The medicine is issued without doctor's prescription.

### ***Manufacturer***

JADRAN • GALENSKI LABORATORIJ d.d.

Pulac bb, Rijeka, Croatia