

## INSTRUCTION FOR USE

### OPTIMAVEN 50g/240 ml Oral Suspension

It is taken orally.

- **Active ingredient:** Each 1 ml suspension contains 208 mg of activated charcoal.
- **Excipients:** Purified water, sorbitol, citric acid monohydrate, orange flavored

**Read this INSTRUCTION FOR USE carefully before you start using this medicine because it contains important information for you.**

- *Keep these instructions for use. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the recommended dose for the medicine.*

#### **In this Instructions for Use:**

- 1. What is OPTIMAVEN and what is it used for?*
- 2. Things to consider before using OPTIMAVEN.*
- 3. How to use OPTIMAVEN?*
- 4. What are the possible side effects?*
- 5. How to store OPTIMAVEN?*

**Topics are included.**

#### **1. What is OPTIMAVEN and what is it used for?**

OPTIMAVEN is an antidote. It is available as an oral suspension (solid-liquid mixture) containing 50 grams of activated charcoal in 240 milliliters.

OPTIMAVEN is used in drug intoxication or overdose drug intake. It prevents toxic substances from entering the blood by adsorbing (clinging).

#### **2. Things to consider before using OPTIMAVEN.**

**DO NOT USE OPTIMAVEN in the following situations;**

- In case of poisoning with caustic substances
- If you are allergic to any of the ingredients of OPTIMAVEN, do not use this medicine.

**USE OPTĪMAVEN CAREFULLY in the following situations;**

OPTĪMAVEN should not be used if the clinical condition of the patient is unfavorable (such as unconscious patients with unopened airway or patients with seizures). In this case, it should be applied under the supervision of a specialist with the help of stomach or nasal gastric tube.

OPTĪMAVEN is not effective in cyanide, mineral acids, caustic alkalis, organic solvents, iron salts, ethanol, methanol, lithium, malathion and DDT poisoning.

Drug (anticholinergics, opioids) poisoning that slows down or stops gastrointestinal movements may cause obstruction in the digestive tract when OPTĪMAVEN is used.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

**Using OPTĪMAVEN with food and drink;**

It should not be mixed with milk, ice cream, sherbet or marmalade as the effectiveness of activated charcoal may be reduced.

**Pregnancy**

Consult your doctor or pharmacist before using this medication.

OPTĪMAVEN is used in pregnant women only according to the doctor's advice. If you notice that you are pregnant during the treatment process, consult your doctor, your doctor will decide to the need for treatment or terminate.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

**Breast-feeding**

Consult your doctor or pharmacist before using this medication.

OPTĪMAVEN can be used during breastfeeding.

**Vehicle and machine use**

OPTĪMAVEN does not have any negative effects on the use of vehicles and machines.

**Important information about some of the excipients contained in OPTĪMAVEN**

This medicinal product contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**Use with other drugs**

Activated charcoal can reduce the effects of other medicines administered simultaneously (emetic drugs, special antidotes or other treatments).

If you are currently using any prescription or non-prescription medication or have used it recently, please inform your doctor or pharmacist about them.

**3. How to use OPTĪMAVEN?****Instructions for appropriate use and dose / frequency of administration:**

Your doctor will determine the dose to be given to you.

**Application way and method:**

It is administered orally.

It should be shaken vigorously before use.

If it will be given with the help of stomach or nose-stomach tube; The conical mouth of OPTIMAVEN tube is connected directly to the probe by using one of the adapters in the package and OPTIMAVEN tube is tightened.

**Different age groups:****Use in children:**

Your doctor will determine the dose to be given to your child.

**Use in the elderly:**

The effectiveness and safety of OPTIMAVEN in elderly patients has not been examined.

**Special use cases:****Kidney / Liver failure:**

The efficacy and safety of OPTIMAVEN in patients with kidney and liver failure have not been examined.

If you have the impression that the effect of OPTIMAVEN is too strong or too weak, talk to your doctor or pharmacist.

**If you have used more OPTIMAVEN than you should**

Since OPTIMAVEN will be applied to you under the supervision of a doctor, it is not possible that you have used more OPTIMAVEN than you should. However, if you think that you are using a high dose of OPTIMAVEN, inform your doctor.

If you have used more than you should use from OPTIMAVEN, talk to a doctor or pharmacist.

**If you forget to use OPTIMAVEN**

Since OPTIMAVEN will be administered to you under the supervision of a doctor, it is not possible to miss a dose. If you still think the dose has been missed, inform your doctor.

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

**Effects that may occur when treatment with OPTIMAVEN is terminated**

After treatment, stool may turn black.

**4. What are the possible side effects?**

Like all medicines, there may be side effects in people who are sensitive to the substances contained in OPTIMAVEN.

Side effects are listed as shown in the following categories:

Very common: It can be seen in at least one of 10 patients.

Common: less than one in 10 patients, but more than one in 100 patients.

Uncommon: less than one in 100 patients, but more than one in 1000 patients.

Rare: less than one in 1,000 patients can be seen.  
Very Rare: Less than one in 10,000 patients can be seen.  
Unknown: It cannot be estimated from the available data.

### **Effects of unknown frequency**

- Stomach contents or coal entering the lungs (aspiration)
- Vomiting
- Diarrhea
- Abdominal swelling
- Intestinal obstruction
- Appendicitis
- Stool turning black
- In the case of simultaneous administration with cathetics (substances with laxative properties such as sorbitol, mannitol, magnesium sulfate), high sodium level in the blood (hypernatremia), low potassium level in the blood (hypokalemia), high magnesium level in the blood (hypermagnesemia)

If you encounter any side effects not mentioned in these instructions for use, inform your doctor or pharmacist.

### Reporting of side effects

If you experience any side effects that are included or nonincluded in the instructions for use, talk to your doctor, pharmacist or nurse. In addition, report the side effects you encounter by clicking the "Drug Side Effects Notification" icon on the website [www.titck.gov.tr](http://www.titck.gov.tr). or by calling 0800314 00 08 number one side effect reporting line Turkey Pharmacovigilance Center (TÜFAM). By reporting side effects, you will contribute to obtaining more information about the safety of the drug you are using.

## **5. Hiding OPTİMAVEN**

Keep OPTİMAVEN in places where children cannot see or reach and in its packaging.

Do not throw away expired or unused medicines! Give them to the collection system determined by the Ministry of Environment and Urbanization.

Store at room temperature below 25 ° C.

### **Use in accordance with expiration dates.**

Do not use OPTİMAVEN after the expiry date.

If this product and / or its packaging contains any defects, do not use it.

**License holder:** Bölükbaşı İlaç san.tic.ltd.şti.  
Fabrikalar Mah.3026 Sok.N0: 9 Kepez / ANTALYA

**Place of production:** Bölükbaşı İlaç san.tic.ltd.şti.  
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These instructions for use were approved on 08.08.2018.

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THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO WILL APPLY THIS MEDICINE.

OPTİMAVEN should be used alone or before and / or after gastric emptying, as soon as possible after ingestion of the substance considered to be toxic. It is recommended to consider the stomach capacity of the patient.

The treatment regimen should be determined by the physician individually for each patient.

**Application in one go:**

➤ For adolescents (over 12 years old) and adults:  
25-100 grams of activated charcoal

➤ For kids:

The pediatric dose should be adjusted according to the age and body weight of the child.

Children 1-12 years old : 25-50 grams of activated charcoal

Children under 1 year : 0.5 g - 1.0 g / kg of activated charcoal

**Repeated application:**

Although the most appropriate dose for activated charcoal is not known, it is recommended to apply 50-100 grams of activated charcoal for adults, followed by a dose of 12.5 g / hr every hour, every 2 hours or every 4 hours, according to clinical experience.

In children aged 1-5 years, the starting dose is 10-25 grams of activated charcoal, and the administration is recommended to be repeated at a dose of 2.5-6 grams (0.25 g / kg) every hour, every 2 hours or every 4 hours, depending on the clinical response.

**Additional information on the application:**

➤ Flavored substances such as chocolate, concentrated fruit juice or thickeners such as bentonite and carboxymethylcellulose can improve the taste of activated charcoal.

➤ If ipecac syrup is included in the treatment, vomiting should be provided before the application of activated charcoal.

**Overdose and treatment:**

Since OPTIMAVEN is well tolerated and has no toxicity, an overdose requiring treatment is unlikely to occur. A laxative can be applied to increase the elimination of the product.