

INSTRUCTION MANUAL

OPTIMAVEN 50g/240ml Oral Suspension

It is taken orally.

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

Read this DIRECTIONS FOR USE carefully before you start using this medicine.

Please read it because it contains important information for you.

- Keep this user manual. Need to read again later
- you can hear.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally, do not give it to others.
- When you go to a doctor or hospital during the use of this medicine, tell your doctor about this.
- Tell them that you are using the drug.
- Follow exactly what is written in this instruction. Apart from the dose recommended to you about the drug

Do not use high or low doses

In this Instructions for Use:

1. What Optimaven is and what it is used for
2. Before you use OPTIMAVEN
3. How is OPTIMAVEN used?
4. What are the possible side effects?
5. Storage of OPTIMAVEN

Headings are included.

1. What Optimaven is and what it is used for

OPTIMAVEN is an antidote (antidote). By mouth, containing 50 grams of activated charcoal per 240 milliliters It is offered for use in the form of applied suspension (solid-liquid mixture). OPTIMAVEN is used in drug poisoning or drug overdose. toxic substances it adsorbs (adheres) and prevents it from passing into the blood.

2. Before you use OPTIMAVEN DO NOT USE in the following situations

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

USE OPTIMAVEN CAREFULLY in the following situations

If the patient's clinical condition is unsuitable (unconscious patients with an unopened airway or convulsions)

OPTIMAVEN should not be used. In this case, stomach or nose-stomach It should be applied under the supervision of an expert with the help of a probe. OPTIMAVEN, cyanide, mineral acids, caustic alkalis, organic solvents, iron salts, It is not effective in ethanol, methanol, lithium, malathion and DDT poisoning. Medicine that slows or stops gastrointestinal movements (anticholinergics, opioids) When OPTIMAVEN is used in poisoning, obstruction in the digestive

tract may occur. If these warnings apply to you, even at any time in the past, please consult your doctor. Please consult.

Using OPTIMAVEN with food and drink

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

Pregnancy

Consult your doctor or pharmacist before using this medication. OPTIMAVEN is used in pregnant women only on the advice of a doctor. If treatment If you realize that you are pregnant during the treatment, consult your doctor, the necessity of treatment or Your doctor will decide to terminate it.If you find out that you are pregnant during your treatment, contact your doctor or pharmacist immediately.Please consult.

Breast-feeding

Consult your doctor or pharmacist before using this medication.
OPTIMAVEN can be used during breastfeeding.

Vehicle and machine use

OPTIMAVEN has no adverse effects on the ability to drive and use machines.

Important information about some of the ingredients of OPTIMAVEN

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

Use with other drugs

Activated charcoal can be administered concomitantly by mouth (e.g. emetics, special antidotes or other treatments) may reduce the effects of other drugs. If you are currently using or have recently used any prescription or over-the-counter medication If you have used it, please inform your doctor or pharmacist about them.

3. How is OPTIMAVEN used?

Instructions for proper use and dose/frequency of administration:

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

Application route and method:

It is administered orally. It should be shaken vigorously before use. If it will be given with the help of a stomach or nasal-stomach tube; Conical mouth of the OPTIMAVEN tube It is connected directly to the probe using one of the adapters included 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 efficacy and safety of OPTIMAVEN in elderly patients have not been studied.

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

Efficacy and safety of OPTIMAVEN in patients with renal and hepatic impairment has 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 use more OPTIMAVEN than you should

Since OPTIMAVEN will be administered to you under the supervision of a doctor, you need to use more

It is not possible that you have used OPTIMAVEN. However, high doses of OPTIMAVEN

Inform your doctor if you think you are using

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

If you forget to use OPTIMAVEN

Since OPTIMAVEN will be administered to you under the supervision of a doctor, it is not possible to skip the dose.

If you still think that 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

Stool may appear black after treatment

4. What are the possible side effects?

Like all medicines, OPTIMAVEN has side effects in people who are sensitive to the substances in its content.

effects can occur.

Side effects are listed as shown in the following categories:

Very common : It can be seen in at least 1 in 10 patients.

Common : less than 1 in 10 patients, but more than 1 in 100 patients.

Uncommon: less than 1 in 100 patients, but more than 1 in 1000 patients.

Rare : less than 1 in 1,000 patients.

Very Rare : It can be seen in less than 1 in 10,000 patients.

Not known : Cannot be estimated from the available data.

Effects of unknown frequency

- Escaping of stomach contents or charcoal into the lungs (aspiration)
- Vomiting
- Diarrhea
- Abdominal swelling
- Bowel obstruction
- Appendicitis
- Black color of stool
- Concomitant with cathartics (laxative substances such as sorbitol, mannitol, magnesium sulfate) high sodium level in the blood (hypernatremia) in case of simultaneous administration low potassium level (hypokalaemia), high magnesium level in the blood have (hypermagnesemia)

If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects In case of any side effects that are included or not included in the instructions for use talk to your doctor, pharmacist or nurse. Also, any side effects www.titck.gov.tr. By clicking on the "Drug Side Effects Notification" icon on the website or 0 800 Turkish Pharmacovigilance Center by calling 314 00 08 side effect reporting line. (TÜFAM). By reporting the side effects that occur, the drug you are using You will contribute to learning more about its safety.

5. Storage of OPTİMAVEN

Keep OPTİMAVEN out of the sight and reach of children and in its package.

Do not throw away expired or unused medicines!Environment and Urbanism

Give it to the collection system determined by the Ministry.

Store at room temperature below 25°C.

Use in accordance with expiration dates.

Do not use OPTİMAVEN after the expiry date.

Do not use this product and/or its packaging if it contains any defects.

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Factories Mah.3026 St.N0:9 Kepez /ANTALYA

Production place: Bölükbaşı İlaç san.tic.ltd.şti.

Fabrikalar Mah.3026 St.N0:9 Kepez /ANTALYA

This instruction for use was approved on 08.08.2018.

THE FOLLOWING INFORMATION IS FOR THE HEALTHCARE PERSONAL TO APPLY THIS DRUG.

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

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

One-time application:

- 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 aged 1-12 : 25-50 grams of activated charcoal

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

Repeat application:

Although the optimal dose for activated charcoal is unknown, clinical experience suggests that for adults 50-100 grams of activated charcoal followed by 12.5 g/h hourly, every 2 hours or every 4 hours. It is recommended to repeat the application at the dose. In children aged

1-5 years, the starting dose is 10-25 grams of activated charcoal, and the application is clinical. It should be repeated hourly, every 2 hours or every 4 hours at a dose of 2.5-6 grams (0.25 g/kg) depending on the response. recommended.

Additional information about the application:

- Flavored substances such as chocolate, concentrated fruit juice or bentonite, Thickening agents such as carboxymethylcellulose can improve the taste of activated charcoal.
- If ipecac syrup is included in the treatment, vomiting before the administration of activated charcoal must be provided

Overdose and treatment:

OPTIMAVEN is well tolerated and, as it is not toxic, in case of overdose requiring treatment. is unlikely to develop. A laxative to increase the elimination of the product applicable