Package leaflet: Information for the user

ADDAVEN

Concentrate for solution for infusion
Trace elements

FRESENIUS KABI

Read all of this leaflet carefully before you start using 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

743

What is in this leaflet

1. What Addaven is and what it is used for

Addaven is a medicine that contains trace elements. Trace elements are tiny amounts of chemicals that your body needs to work normally. Addaven is given intravenously (into a vein) when you can not eat normally. This medicine is usually used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and vitamins.

2. What you need to know before you receive Addaven

You should not receive Addaven:
- if you are allergic to any of the ingredients of this medicine (listed in section 6). **If you develop a rash or other allergic reaction (like itching, swollen lips or face, or shortness of breath), inform your doctor immediately.**
- if your bile excretion is blocked;
- if you have Wilson's disease (a genetic disorder in which copper builds up in the body) or hemochromatosis (accumulation of iron in the body).

Addaven must not be given to children less than 15 kg body weight.

Warnings and precautions
Talk to your doctor if you have problems with the way your liver and/or kidney work. Your doctor may want to do regular blood tests to check your condition.

Other medicines and Addaven
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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

Driving and using machines
Addaven has no effect on driving or using machines.

3. How you are given Addaven

This medicine will be administered to you by a healthcare professional.
You will receive your medicine by infusion (IV drip), directly into a vein.
Your doctor will decide on the correct dose for you to receive.
The recommended dose for adults is 10 millilitres (ml) each day.
Addaven should be added to another solution before it is given to you.Your doctor or nurse will make sure it is prepared correctly before you receive Addaven.

Use in children
The recommended dose for children weighing more than 15 kg is 0.1 ml per kg body weight each day.

If you receive too much Addaven
It is very unlikely that you will receive more medicine than you should as your doctor or nurse will monitor you during the treatment. However if you think that you have received too much Addaven, inform your doctor or nurse immediately.

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

4. Possible side effects

No known undesirable effects have been reported with the use of Addaven. However, if you get any side effects, talk to your doctor or nurse.

Reporting of side effects
If you get any side effects, talk to your doctor,pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

TO REPORT ANY SIDE EFFECT(S):

- ***Saudi Arabia:***

• The National Pharmacovigilance Centre (NPC):
• SFDA Call Center: 19999
• E-mail: npc-drug@sfda.gov.sa Website: https://ade.sfda.gov.sa/

- ***UAE:***

- Pharmacovigilance & Medical Device section:
• P.O.Box: 1853
• Tel: 80011111
• E-mail: pv@mohap.gov.ae
Drug Department
Ministry of Health & Prevention - Dubai-UAE

- ***Other GCC states:***

Please contact the relevant competent authority

5. How to store Addaven

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 and vial label. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Your doctor and hospital pharmacist are responsible for the correct storage, use and disposal of Addaven infusion.

After dilution: The addition of Addaven should be performed immediately before the start of the infusion and should be used within 24 hours. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless mixing has taken place in controlled and validated aseptic conditions.

Any solution remaining after treatment should be thrown away via approved hospital procedures.

6. Contents of the pack and other information

What Addaven infusion contains

- The active substances in one ampoule (10 ml) are:

Chromic chloride hexahydrate	53.3 µg
Copper chloride dihydrate	1.02 mg
Ferric chloride hexahydrate	5.40 mg
Manganese chloride tetrahydrate	198 j.tg
Potassium iodide	166 j.tg
Sodium fluoride	2.10 mg
Sodium molybdate dihydrate	48.5 j.tg
Sodium selenite anhydrous	173 j.tg
Zinc chloride	10.5 mg

- The other ingredients are: xylitol, hydrochloric acid, water for injections.

What Addaven looks like and contents of the pack

Addaven is a clear, almost colourless solution of trace elements.
Addaven is available in a polypropylene ampoule containing 10 ml of concentrate, in the following pack
size:
20 x 10 ml

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Fresenius Kabi Deutschland GmbH
D-61346 Bad Homburg v.d.H. Germany

Manufacturer
HP Halden Pharma AS
Svinesundsveien 80
1788 Halden
Norway

This leaflet was last revised in April 2024.

FRESENIUS KABI