

Package leaflet: Information for the user

Addaven concentrate for solution for infusion

Trace elements

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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 function normally. Addaven is given intravenously (as a drip 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 reactions (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. If you are taking iron orally in parallel with the infusion your doctor will check that iron is not accumulating in your body.

Iron and iodine may cause allergic reactions on rare occasions when given as a drip. Tell your doctor or nurse if you get any allergic reaction when receiving Addaven.

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

Addaven can be used by pregnant and breast-feeding women.

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 using this medicine.

Driving and using machines

Addaven has no effect on driving or using machines.

3. How to use Addaven

This medicine will be administered to you by a healthcare professional.

You will receive your medicine by infusion (drip) 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. If you have problems with your liver or kidneys you may receive a lower dose.

Addaven should be mixed with another solution before it is given to you. Your doctor or nurse will make sure it is prepared correctly.

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 according to recommendation. 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 or nurse. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

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.

This medicine does not require any special storage conditions.

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 unused medicinal product or waste material should be disposed of in accordance with local requirements.

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 microgram
Copper chloride dihydrate	1.02 mg
Ferric chloride hexahydrate	5.40 mg
Manganese chloride tetrahydrate	198 microgram
Potassium iodide	166 microgram
Sodium fluoride	2.10 mg
Sodium molybdate dihydrate	48.5 microgram
Sodium selenite anhydrous	173 microgram
Zinc chloride	10.5 mg

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

This product contains 0.052 mmol of sodium (1.2 mg) per dose (10 ml).

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 SA (Pty) Limited
Stand 7, Growthpoint Business Park,
2 Tonetti Street, Halfway House
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Manufacturer
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