FRESENIUS KABI

PACKAGE INSERT

ADDAVEN CONCENTRATE FOR SOLUTION FOR INFUSION

1mL of Addaven contains:
5.33 microgram of Chromic chloride hexahydrate
0.10 mg of Copper chloride dihydrate
0.54 mg of Ferric chloride hexahydrate
19.8 microgram of Manganese chloride tetrahydrate
16.6 microgram of Potassium iodide
0.21 mg of Sodium fluoride
4.85 microgram of Sodium molybdate dehydrate
17.3 microgram of Sodium selenite anhydrous
1.05 mg of Zinc chloride

PHARMACEUTICAL FORM
Clear solution, almost colourless.

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: Electrolytes in combination with other drugs, ATC code: B05X A31

Addaven is a mixture of trace elements in amounts normally absorbed from the oral diet and should have no pharmacodynamic effect besides maintaining or repleting the nutritional status.

PHARMACOKINETIC PROPERTIES
When infused intravenously, the trace elements in Addaven are handled in a similar way to trace elements from an oral diet. Individual trace elements will be taken up by tissues to different extents, depending on the requirements within each tissue to maintain or restore the concentration of each element for the metabolic requirements of that tissue.

Copper and manganese are normally excreted via the bile, whereas selenium, zinc and chromium (especially in patients receiving intravenous nutrition) are mainly excreted via the urine.

The main route of molybdenum excretion is the urine, although small amounts are excreted in the bile.

Iron is eliminated in small amounts by superficial loss and desquamation of gut cells. Premenopausal women can lose 30-150 mg of iron in the monthly blood loss.

THERAPEUTIC INDICATIONS
To meet basal to moderately increased requirements of trace elements in intravenous nutrition.

POSOLOGY AND METHOD OF ADMINISTRATION
Posology

Adults: The recommended daily dose of Addaven in adult patients with basal to moderately increased requirements is 10 ml (one ampoule).

In patients with renal or hepatic impairments, or mild cholestasis the dose should be adapted.

Children ≥15 kg: 0.1 ml Addaven is given per kg body weight and day.

Method of administration

Addaven must not be given undiluted. Addaven shall be given as an intravenous infusion, diluted in a parenteral nutrition solution/emulsion.
For instructions on dilution of the medicinal product before administration, see section Warning and Precautions.

ROUTE OF ADMINISTRATION
Intravenous

CONTRAINDICATIONS
- Hypersensitivity to the active substances or to any of the excipients.
- Conditions with total biliary obstruction.
- Wilson's disease, hemochromatosis.
- Children less than 15 kg body weight.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Parenterally administered iron or iodine preparations can cause hypersensitivity reactions on rare occasions, including serious and potentially fatal anaphylactic reactions.

Patients should be clinically observed for signs and symptoms of hypersensitivity reactions. In case of hypersensitivity reactions, the infusion should be stopped immediately and appropriate measures performed.

If iron is taken orally in parallel with infusion of Addaven, the total intake of iron should be determined to ensure that there is no iron accumulation.

Addaven should be used with caution in patients with liver dysfunction. Liver dysfunction, including impaired biliary excretion, may interfere with excretion of trace elements from Addaven, leading to a risk of accumulation.

Addaven should be used with caution in patients with impaired renal function as excretion of some trace elements in urine may be significantly decreased.

If the treatment is continued for more than 4 weeks, checking trace element levels in plasma, especially manganese, is required.

If an individual patient has a markedly increased requirement for any of the trace elements, the regimen can be adjusted using separate supplements.

Incompatibilities
This medicinal product must only be mixed with other medicinal products for which compatibility has been documented.

Compatibility
Addaven may only be added to medicinal or nutrition solutions for which compatibility has been documented. Compatibility with different products and the storage time of the different admixtures will be available upon request.

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

Interaction with other medicinal products and other forms of interaction
No interactions with other drugs have been observed.

Pregnancy and Lactation
Pregnancy
Animal reproduction studies or clinical investigations during pregnancy have not been carried out with Addaven. However, the requirements of trace elements in a pregnant woman are slightly increased compared to non-pregnant women.
No adverse events are to be expected when Addaven is administered during pregnancy.

Breast-feeding
The active substances in Addaven are secreted in human milk and effects have been shown in breastfed newborns/infants of treated women. These effects are desirable and anticipated.

Undesirable effects
No adverse effects related to the trace elements in Addaven, following intravenous administration according to recommendations, have been reported.

Effects on ability to drive and use machines
Addaven has no or negligible influence on the ability to drive and use machines.

Overdose
In patients with impaired renal or biliary function, there is an increased risk for accumulation of trace elements. In case of a chronic overload of iron there is a risk of haemosiderosis, which in severe and rare cases can be treated by venesection.

Shelf life
Shelf life of the medicinal product as packed for sale
3 years

Shelf life after mixing
Chemical and physical in-use stability after dilution has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately. 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.

Storage Condition
Store below 30°C.

Dosage Forms and Packaging Available
Ampoule (polypropylene) 20 x 10 ml

MANUFACTURER:
HP Halden Pharma AS,
Svinesundsveien 80,
1788 Halden,
Norway
for Fresenius Kabi AB,
Uppsala, Sweden.

PRODUCT REGISTRATION HOLDER/IMPORTER:
Fresenius Kabi Malaysia Sdn Bhd
3-1 & 3-2, Axis Technology Centre,
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FRESENIUS KABI
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