SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Addaven concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Chromic chloride hexahydrate	5.33 µg
Copper chloride dihydrate	0.10 mg
Ferric chloride hexahydrate	0.54 mg
Manganese chloride tetrahydrate	19.8 µg
Potassium iodide	16.6 µg
Sodium fluoride	0.21 mg
Sodium molybdate dihydrate	4.85 µg
Sodium selenite anhydrous	17.3 µg
Zinc chloride	1.05 mg

The active ingredients in 1 ml of Addaven correspond to:

Cr	0.020 µmol	1.0 µg
Cu	0.60 µmol	38 µg
Fe	2.0 µmol	110 µg
Mn	0.10 µmol	5.5 µg
I	0.10 µmol	13 µg
F	5.0 µmol	95 µg
Mo	0.020 µmol	1.9 µg (as Mo^{6+})
Se	0.10 µmol	7.9 µg (as Se^{4+})
Zn	7.7 µmol	500 µg

The content of sodium and potassium correspond to

Sodium	120 µg	5.2 µmol
Potassium	3.9 µg	0.1 µmol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion.
Clear solution, almost colourless.

- Osmolality: approx. 3100 mosm/kg water
- pH: 2.5

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

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

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

Method of administration

Addaven must not be given undiluted.
For instructions on dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.
- Conditions with total biliary obstruction.
- Wilson's disease.

4.4 Special warnings and precautions for use

Addaven should be used with caution in patients with impaired biliary and/or renal function in whom the excretion of trace elements may be significantly decreased.

Addaven should also be used with caution in patients with biochemical or clinical evidence of liver dysfunction (especially cholestasis).

If the treatment is continued for more than 4 weeks, checking of manganese levels in blood is required.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions with other drugs have been observed.

4.6 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.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

No adverse effects related to the trace elements in Addaven have been reported.

4.9 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 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.

5.2 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the safety evaluation beyond those already included in the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol
Hydrochloric acid, concentrated (for pH adjustment)

Water for injections

6.2 Incompatibilities

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

6.3 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.

6.4 Special precautions for storage

No special precautions for storage.

For storage conditions after mixing of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Ampoule (polypropylene) 20 x 10 ml

6.6 Special precautions for disposal and other handling

Handling
Additions of Addaven should be made aseptically within one hour prior to infusion start.

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.

7 MARKETING AUTHORISATION HOLDER

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT