Package leaflet: Information for the user

Additrace N concentrate for solution for infusion

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.

What is in this leaflet

1. What Additrace N is and what it is used for

Additrace N is a medicine that contains trace elements. Trace elements are tiny amounts of chemicals that your body needs to work normally. Additrace N 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 Additrace N

You should not receive Additrace N:
- if you are allergic (hypersensitive) 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.**

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 Additrace N
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
Additrace N has no effect on driving or using machines.

3. How you are given Additrace N

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.
Additrace N 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 Additrace N.

Use in children

Additrace N is not recommended for use in children weighing less than 40 kilograms.

If you receive too much Additrace N

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 Additrace N, 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 Additrace N.

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 to;

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Additrace N

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 use if Additrace N is cloudy or contains sediment.

This medicine does not require any special storage conditions.

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

After dilution: The addition of Additrace N 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 Additrace N concentrate for solution for infusion contains

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

Chromic chloride hexahydrate	53.3 micrograms
Copper chloride dihydrate	1.02 milligrams
Ferric chloride hexahydrate	5.40 milligrams
Manganese chloride tetrahydrate	198 micrograms
Potassium iodide	166 micrograms
Sodium fluoride	2.10 milligrams
Sodium molybdate dihydrate	48.5 micrograms
Sodium selenite anhydrous	173 micrograms
Zinc chloride	10.5 milligrams

The active ingredients in 10 ml of Additrace N correspond to:

Cr	0.2 µmol	10 µg
Cu	6 µmol	380 µg
Fe	20 µmol	1.1 mg
Mn	1 µmol	55 µg
I	1 µmol	130 µg
F	50 µmol	950 µg
Mo	0.2 µmol	19 µg (as Mo6+)
Se	1 µmol	79 µg (as Se4+)
Zn	77 µmol	5 mg

The content of sodium and potassium in 10 ml corresponds to:

Sodium	1.0 mg	52 µmol
Potassium	39 µg	1 µmol

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

What Additrace N concentrate for solution for infusion looks like and contents of the pack

Additrace N is a clear, almost colourless solution of trace elements.
Additrace N 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
Else-Kröner-Straße 1,
61352 Bad Homburg v.d.Höhe
Germany

Manufacturer
Fresenius Kabi Norge AS
NO-1753 Halden
Norway

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