

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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

1. WHAT ADDITRAC IS AND WHAT IT IS USED FOR

Additrac provides trace elements into your blood stream when you cannot eat normally. Trace elements are tiny amounts of chemicals that your body needs to work normally. Additrac 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 USE ADDITRAC

Do not use Additrac:

- if you are allergic to any of the ingredients of Additrac mentioned in section 6.

If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), please inform your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Additrac if you suffer from:

- impaired liver and/or kidney function

Your doctor may want to do regular blood tests to check your condition.

Additrac **must be diluted before use**. It will be added to another solution before it is given to you. Your doctor, pharmacist or nurse will make sure it is prepared correctly before you receive Additrac.

Additrac should not be used if the solution is cloudy or contains particles. The doctor, pharmacist or nurse will check that the solution is particle free before it is administered to you.

Other medicines and Additrac

Talk to your doctor, pharmacist or nurse 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 or pharmacist for advice before taking this medicine.

Driving and using machines

Additrac has no effect on the ability to drive and use machines.

3. HOW TO USE ADDITRACE

You will receive your medicine by infusion (IV drip).

Your doctor or pharmacist will decide on the correct dose for you to receive.

Dosage

The recommended dose of Additrac for adults is 10 millilitres each day when added to Vamin 9 Glucose, Vamin 14, Vamin 14 Electrolyte-Free, Vamin 18 Electrolyte-Free, and Glucose 5%-50%.

Use in children and adolescents

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

If you received more Additrac than you should

It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. However if you think that you have received too much Additrac, inform your doctor or nurse immediately. If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Although no known undesirable effects have been reported with the use of Additrac, like all medicines, this medicine can cause side effects.

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 via the national reporting schemes listed below. By reporting side effects you can help provide more information on the safety of this medicine.

For UK - you can report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard

For Ireland – you can also report side effects directly via:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

5. HOW TO STORE ADDITRACE

Keep this medicine out of the sight and reach of children.

Your doctor, pharmacist and nurse are responsible for the correct storage, use and disposal of Additrac.

Do not use this medicine after the expiry date stated on the carton and ampoule label after EXP.

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

Store below 25°C. Do not freeze.

Keep the ampoules in the outer carton in order to protect from light.

Do not use this medicine if it is cloudy or contains particles.

After dilution:

The addition of Additracce should be performed immediately before the start of 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.

Disposal:

Any unused solution should be discarded. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Additracce contains**

Each ampoule contains 10ml of concentrate.

Active ingredients:	1 millilitre of Additracce contains:	Each ampoule contains 10ml of concentrate.
Ferric chloride, 6H ₂ O	540 microgram	20 micromol
Zinc chloride	1.36 mg	100 micromol
Manganese chloride 4H ₂ O	99.0 microgram	5 micromol
Copper chloride 2H ₂ O	340 microgram	20 micromol
Chromic chloride 6H ₂ O	5.33 microgram	0.2 micromol
Sodium selenite anhydrous	6.9 microgram	0.4 micromol
Sodium molybdate, 2H ₂ O	4.85 microgram	0.2 micromol
Sodium fluoride	210 microgram	50 micromol
Potassium iodide	16.6 microgram	1 micromol

Note: Less than 1 mmol for potassium and sodium

Additracce also contains xylitol, hydrochloric acid, water for injections.

What Additracce looks like and contents of the pack

Additracce Concentrate for Solution for Infusion is a clear, almost colourless solution of trace elements.

Additracce is available in a clear glass ampoule or polypropylene ampoule containing 10 ml of concentrate, in the following pack sizes:

- glass ampoule, 10 x 10ml
- polypropylene ampoule, 20 x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing authorisation holder

MAH for UK

Fresenius Kabi Limited
Cestrian Court
Eastgate Way
Manor Park
Runcorn
Cheshire
WA7 1NT
UK

MAH for IE

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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