

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Addaven?

Addaven contains the active ingredients chromic chloride hexahydrate, cupric chloride dihydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite and zinc chloride. Addaven is used to meet basal to moderately increased requirements of trace elements in parenteral nutrition in adults, when either oral or enteral nutrition is inappropriate.

For more information, see Section [1. Why am I using Addaven?](#) in the full CMI.

2. What should I know before I use Addaven?

Do not use if you have ever had an allergic reaction to Addaven or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Addaven?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Addaven and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Addaven?

- Your doctor will decide on the correct dose for you to receive.
- The recommended dose for adults is 10 mL each day. If you have problems with your liver or kidneys you may receive a lower dose.

More instructions can be found in Section [4. How do I use Addaven?](#) in the full CMI.

5. What should I know while using Addaven?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using Addaven.• If you are taking any other medicines, whether they require a prescription or not, talk to your doctor or pharmacist before taking Addaven.• Tell your doctor or pharmacist if, for any reason, you have not taken Addaven as prescribed.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly.
Driving or using machines	<ul style="list-style-type: none">• The effects of Addaven on a person's ability to drive and use machines were not studied.
Drinking alcohol	<ul style="list-style-type: none">• The effects of alcohol with Addaven use were not studied. Your doctor will decide what you need to do.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C in a cool dry place away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using Addaven?](#) in the full CMI.

6. Are there any side effects?

No known undesirable effects have been reported with the use of Addaven according to recommendation. If you get any adverse effects, talk to your doctor or nurse. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Addaven®

Active ingredients: *chromic chloride hexahydrate, cupric chloride dihydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite and zinc chloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Addaven. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Addaven.**

Where to find information in this leaflet:

- [1. Why am I using Addaven?](#)
- [2. What should I know before I use Addaven?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Addaven?](#)
- [5. What should I know while using Addaven?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Addaven?

Addaven contains the active ingredients chromic chloride hexahydrate, cupric chloride dihydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite and zinc chloride. 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 cannot eat normally. This medicine is usually used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and vitamins

Addaven is used to meet basal to moderately increased requirements of trace elements in parenteral nutrition in adults, when either oral or enteral nutrition is inappropriate.

2. What should I know before I use Addaven?

Warnings

Do not use Addaven if:

- you are allergic to the active ingredients chromic chloride hexahydrate, cupric chloride dihydrate, ferric chloride hexahydrate, manganese chloride tetrahydrate, potassium iodide, sodium fluoride, sodium molybdate dihydrate, sodium selenite or zinc chloride or any of the ingredients listed at the end of this leaflet. If you develop a rash or other allergic reactions (like itching, swollen lips or face, or

shortness of breath), inform your doctor immediately. Always check the ingredients to make sure you can use this medicine.

- 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 under 12 years of age.

Check with 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.
- 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.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in liver impairment

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.

Use in renal impairment

Addaven should be used with caution in patients with impaired renal function as excretion of some trace elements in urine may be significantly decreased. Monitoring of trace element levels, especially manganese, is recommended.

Use in elderly

Because of the increased likelihood of impaired renal or hepatic function or concomitant disorders and their treatment, Addaven should be used with cautious monitoring in the elderly.

Use in Paediatrics

Addaven is not recommended for use in children under 12 years of age.

Effects on laboratory tests

No effects on laboratory tests have been identified. Addaven is administered as part of parenteral nutrition.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Addaven and affect how it works.

Molybdenum interacts with copper to form complexes that increase urinary elimination of copper.

Amino acids, which are present in all total PN mixtures, could complex with zinc and copper and the complex could be excreted in urine. However, amino acid loss in urine is usually small.

Interactions of copper with ascorbic acid from vitamin supplementation of the parenteral nutrition mixture may occur, resulting in oxidative loss of ascorbic acid, which can be limited by use of oxygen impermeable bags.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Addaven.

4. How do I use Addaven?

How much to take

- Your doctor will decide on the correct dose for you to receive.
- The recommended dose for adults is 10 mL (one ampoule) each day. If you have problems with your liver or kidneys you may receive a lower dose.
- Follow the instructions provided and use Addaven until your doctor tells you to stop.

When to take Addaven

- Addaven should be used as recommended by your doctor. The recommended daily dosage is 10 mL.

How to take Addaven

- This medicine will be administered to you by a healthcare professional. You will receive your medicine by infusion (drip) into a vein.

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

If you forget to use Addaven

Addaven should be used regularly at the same time each day. If you miss your dose at the usual time, talk to your doctor or nurse and they will tell you what to do.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Addaven

If you think that you have used too much Addaven, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Addaven?

Things you should do

If you are taking any other medicines, whether they require a prescription or not, talk to your doctor or pharmacist before taking Addaven.

Tell your doctor or pharmacist if, for any reason, you have not taken Addaven as prescribed.

Call your doctor straight away if you:

- have signs and symptoms of allergic reactions. In case of an allergic reaction, the infusion should be stopped immediately, and appropriate measures need to be taken.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Addaven.

Things you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Addaven affects you.

The effects of Addaven on a person's ability to drive and use machines were not studied.

Drinking alcohol

Tell your doctor if you drink alcohol.

The effects of alcohol with Addaven use were not studied. Your doctor will decide what you need to do.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store below 30°C in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

After dilution:

The addition of Addaven should be performed immediately before the start of the infusion and should be used within 24 hours.

Do not use this medicine after the expiry date which is stated on the carton label and embossed on the ampoule. The expiry date refers to the last day of that month.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

No known undesirable effects have been reported with the use of Addaven according to recommendation. If you get any adverse effects, talk to your doctor or nurse.

The below less serious side effects were reported during post-market monitoring.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• Nausea, vomiting• Chills, pyrexia• Headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Addaven contains

Active ingredient (main ingredient)	chromic chloride hexahydrate 53.3 µg cupric chloride dihydrate 1.02 mg ferric chloride hexahydrate 5.40 mg manganese chloride tetrahydrate 198 µg potassium iodide 166 µg sodium fluoride 2.10 mg sodium molybdate dihydrate 48.5 µg sodium selenite 173 µg zinc chloride 10.5 mg
Other ingredients (inactive ingredients)	xylitol hydrochloric acid water for injections
Potential allergens	none

Do not take this medicine if you are allergic to any of these ingredients. This product contains 0.052 mmol of sodium (1.2 mg) per 10 mL dose.

What Addaven looks like

Addaven is a clear and colourless to slightly yellow solution of trace elements.

Addaven is available in a polypropylene ampoule containing 10 mL of concentrated solution. Each carton contains 20 ampoules of 10mL. (Aust R 244493).

Who distributes Addaven

Addaven is supplied in Australia by:
Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: 1300 361 004

This leaflet was prepared in July 2021.