

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Addnutriv™
Trace Elements for Injection

Read this carefully before you start taking Addnutriv and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Addnutriv.

What is Addnutriv used for?

- Addnutriv is used along with other products that contain nutrients that are given to you through an infusion into your vein.
- It contains trace elements which are nutrients that your body needs in very small amounts.
- It is given to meet your body's trace element needs when you cannot eat normally.
- It is used in adults only.
- It prevents reduction of trace elements in your body and feeling unwell due to their lack.

How does Addnutriv work?

Addnutriv gives you the trace elements that your body needs. These are given directly into your blood. The trace elements are then used by your body for many different functions.

What are the ingredients in Addnutriv?

Medicinal ingredients

Chromium	(as Chromic chloride hexahydrate)
Copper	(as Cupric chloride dihydrate)
Iron	(as Ferric chloride hexahydrate)
Manganese	(as Manganese chloride tetrahydrate)
Iodine	(as Potassium iodide)
Fluoride	(as Sodium fluoride)
Molybdenum	(as Sodium molybdate dihydrate)
Selenium	(as Sodium selenite)
Zinc	(as Zinc chloride)

Non-medicinal ingredients: hydrochloric acid water for injection and xylitol.

Addnutriv comes in the following dosage forms:

As a solution that contains:

Chromium	10 micrograms / 10 mL
Copper	380 micrograms / 10 mL
Iron	1100 micrograms / 10 mL
Manganese	55 micrograms / 10 mL
Iodine	130 micrograms / 10 mL
Fluoride	950 micrograms / 10 mL
Molybdenum	19 micrograms / 10 mL
Selenium	79 micrograms / 10 mL
Zinc	5000 micrograms / 10 mL

Do not use Addnutriv if you:

- are allergic to Addnutriv.
- are allergic to any of the ingredients in Addnutriv or to a component of the container.
- have a biliary obstruction, a condition where your bile ducts are blocked.
- have Wilson's disease, a genetic disorder where your body stores too much copper.
- have hemochromatosis, a condition where your body stores too much iron.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you receive Addnutriv. Talk about any health conditions or problems you may have, including if you:

- have kidney problems.
- have liver problems.
- have a condition called cholestasis where bile does not flow properly from the liver to the intestine.
- are taking an iron supplement by mouth in addition to Addnutriv. Your doctor will make sure that too much iron does not collect in your body.
- are pregnant.
- are breast-feeding.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or other medicines.**The following may interact with Addnutriv:**

- Nutritional supplements that contain molybdenum.
- Vitamin C supplement that is given to you through an infusion into your vein

How to take Addnutriv:

- Addnutriv will be given to you by a healthcare professional.
- Your healthcare professional will make sure that Addnutriv is prepared correctly before it is given to you.
- It will first be mixed with another solution before it is given to you.
- It will then be infused slowly into your vein.
- It will usually be infused over a period of 8 hours.
- Follow all instructions given to you by your health care professional.

Usual dose:

- Your doctor will decide how much Addnutriv you will receive.
- The usual dose is 10 mL of Addnutriv a day.
- Your doctor may give you a lower dose of Addnutriv if you have:
 - kidney problems
 - liver problems
 - or if you have a condition called cholestasis where bile does not flow properly from the liver to the intestine

Overdose:

If you think you have taken too much Addnutriv, contact your healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using Addnutriv?

These are not all the possible side effects that you may feel when taking Addnutriv. If you experience any side effects not listed here, contact your healthcare professional.

Addnutriv is used along with other products that contain nutrients. **Serious side effects may include:**

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Very Rare			
Allergic Reaction: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, loss of consciousness, rash, swelling of your tongue, throat or face.			✓
Digestive system problems: diarrhea, nausea, vomiting.		✓	
General: chills, pain, chest discomfort and pain, tiredness	✓		
Heart problems: heart beating too hard or too fast, skipping a beat, or fluttering, irregular heartbeats.		✓	
Infections: body aches and pains, chills, burning or pain with urination, coughing, fatigue, fever, new onset of pain, not feeling well, any unusual discharge from your body		✓	
Injection site reactions: pain, redness or swelling at the injection site.		✓	
Kidney problems: back and abdominal pain, change in the colour of urine (pale or dark), decrease in amount of urine produced, pain or discomfort when urinating, swelling of the legs and ankles.	✓		
Liver problems: abdominal pain, dark urine, fatigue, loss of appetite, nausea, swollen abdomen, vomiting, weakness, yellowing of the skin or eyes (jaundice).		✓	
Muscle problems: back pain, muscle cramps, pain or twitching	✓		
Lung problems: blue tint to the face and lips, shortness of breath, too much fluid in lung.	✓		
Skin problems: cold sweat, redness, sweating.	✓		
Blood clot in a vein: pain, tenderness, redness, warmth or swelling of a body area, swelling or hardening of a vein near the surface of the skin.		✓	
Low blood pressure		✓	

Addnutriv can cause abnormal blood test results. Your doctor may perform blood tests and will interpret the results. If you receive Addnutriv for more than 4 weeks, your doctor will check the levels of

manganese in your blood

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15°C to 30°C). Do not freeze. No special precautions for storage of the unopened plastic container.

Keep out of reach and sight of children.

If you want more information about Addnutriv:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<https://www.fresenius-kabi.com/en-ca/>), or by calling 1-877-821-7724.

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