PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ADDAVEN® concentrate for solution for infusion

Chromic chloride hexahydrate

Cupric chloride dihydrate

Ferric chloride hexahydrate

Manganese chloride tetrahydrate

Potassium iodide

Sodium fluoride

Sodium molybdate dihydrate

Sodium selenite anhydrous

Zinc chloride

Contains sugar alcohol, xylitol (3 g/10 mL)

Read all of this leaflet carefully before you are given ADDAVEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

6. Contents of the pack and other information

1. What ADDAVEN is and what it is used for

ADDAVEN is a sterile concentrated solution that contains a mixture of trace elements normally absorbed from the oral diet. 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 used as part of a balanced intravenous diet, together with proteins, fat, carbohydrates, salts and vitamins.

2. What you need to know before you are given ADDAVEN

ADDAVEN should not be administered to you:

- 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**;
- if your bile excretion is blocked (some signs may be pain on your tummy, dark urine, feeling feverish and nauseous);
- if you have Wilson's disease (a genetic disorder in which copper builds up in the body) or haemochromatosis (accumulation of iron in the body).

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

Special care should be taken with ADDAVEN:

- if you have problems with the way your liver and/or kidney work.

ADDAVEN must not be given undiluted. See section 3.

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.

Your doctor may want to do regular blood tests to check your condition. If you are taking iron orally in parallel with the infusion your doctor will check that iron is not accumulating in your body.

ADDAVEN should not be given to children aged less than 12 years as adequate safety data are not available for children.

Other medicines and ADDAVEN

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interactions with other medicines are known.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving ADDAVEN.

Driving and using machines

ADDAVEN has no or negligible effect on driving and using machines.

It is not always possible to predict to what extent ADDAVEN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ADDAVEN affects them.

3. How ADDAVEN will be administered to you

You will not be expected to give yourself ADDAVEN. It will be given to you by a person who is qualified to do so.

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

The usual dose is 10 millilitres (mL) each day. If you have problems with your liver or kidneys you may receive a lower dose.

You will receive your medicine by infusion (drip) into a vein. ADDAVEN should be mixed with another nutritional solution before it is given to you. Your doctor or nurse will make sure it is prepared correctly.

Your doctor will tell you how long your treatment with ADDAVEN will last. If you have the impression that the effect of ADDAVEN is too strong or too weak, tell your doctor or nurse.

If you receive more ADDAVEN than you should

Since a healthcare provider will administer ADDAVEN, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive ADDAVEN

Since a healthcare provider will administer ADDAVEN, it is unlikely that the dose will be missed.

4. Possible side effects

ADDAVEN can have side effects.

Not all side effects reported for ADDAVEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ADDAVEN, please consult your healthcare provider for advice.

If any of the following happens, stop receiving ADDAVEN and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ADDAVEN. You may need urgent medical attention or further hospitalisation.

Tell your doctor if you notice any of the following side effects:

Frequency unknown

- Headache
- Nausea, vomiting
- Chills, fever

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of ADDAVEN.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How to store ADDAVEN

Store all medicines out of reach of children.

Store at or below 30 °C.

After dilution:

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

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

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ADDAVEN contains

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

Chromic chloride hexahydrate	53,3 µg (microgram)
Cupric chloride dihydrate	1,02 mg
Ferric chloride hexahydrate	5,40 mg
Manganese chloride tetrahydrate	198 µg (microgram)
Potassium iodide	166 µg (microgram)
Sodium fluoride	2,10 mg
Sodium molybdate dihydrate	48,5 µg (microgram)
Sodium selenite anhydrous	173 µg (microgram)
Zinc chloride	10,5 mg

- The other ingredients are xylitol, hydrochloric acid (for pH adjustment) and water for injections.

  ADDAVEN contains 52 µmoL of sodium (1,20 mg) per 10 mL dose.

What ADDAVEN looks like and contents of the pack

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 10 mL.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The corresponding Professional Information (PI) can be accessed at

https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

ADDAVEN® konsentraat vir oplossing vir infusie

Chroomchloriedheksahidraat

Koperchlorieddihidraat

Ysterchloriedheksahidraat

Mangaanchloriedtetrahidraat

Kaliumjodied

Natriumfluoried

Natriummolibdaatdihidraat

Natriumseleniet anhidries

Sinkchloried

Bevat alkoholsuiker, xilitol (3 g/10 mL)

Lees hierdie hele inligtingsblad aandagtig deur voordat ADDAVEN aan jou gegee word

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat in hierdie inligtingsblad is

5. Hoe om ADDAVEN te bewaar
6. Inhoud van die pak en ander inligting

1. Wat ADDAVEN is en waarvoor dit gebruik word

ADDAVEN is ‘n steriele, gekonsentreerde oplossing wat ‘n mengsel van spoorelemente bevat, wat gewoonlik deur die mondelikse dieet geabsorbeer word. Spoorelemente is klein hoeveelhede chemikalieë wat jou liggaam benodig om normaal te funksioneer. ADDAVEN word intraveneus (as ‘n drup in ‘n aar) gegee wanneer jy nie normaal kan eet nie. Hierdie medisyne word gebruik as deel van ‘n gebalanseerde intraveneuse dieet, saam met proteïene, vet, koolhidrate, soute en vitamiene.

2. Wat jy moet weet voordat ADDAVEN aan jou gegee word

ADDAVEN moenie aan jou toegedien word nie:

- indien jy allergies (hipersensitief) is vir enige van die bestanddele van hierdie medisyne (gelys in afdeling 6). **Indien jy ‘n uitslag of ander allergiese reaksies (soos gejeuk, geswelde lippe of gesig, of kortasemheid) ontwikkel, lig jou dokter dadelik in**;
- indien jou galuitskeiding geblokkeer is (sommige tekens kan pyn op jou maag, donker urien, koorsige gevoel en naarheid wees);
- indien jy Wilson se siekte het (‘n genetiese afwyking waar koper in die liggaam opbou) of hemochromatose (ophoping van yster in die liggaam).

Waarskuwings en voorsorgmaatreëls

Lig jou dokter of gesondheidsorgverskaffer in voordat die inspuiting aan jou gegee word:

Spesiale sorg moet geneem word met ADDAVEN:

- indien jy probleme het met die manier waarop jou lewer en/of niere werk.

ADDAVEN moenie onverdun gegee word nie. Sien afdeling 3.

Yster en jodium kan allergiese reaksies veroorsaak in seldsame gevalle wanneer dit as ‘n drup gegee word. Lig jou dokter of verpleegster in indien jy enige allergiese reaksie kry wanneer jy ADDAVEN ontvang.

Jou dokter sal moontlik gereelde bloedtoetse wil laat doen om jou toestand na te gaan. Indien jy yster mondeliks in parallel met die infusie neem, sal jou dokter nagaan dat dit nie in jou liggaam ophoop nie.

ADDAVEN moenie aan kinders jonger as 12 jaar gegee word nie, aangesien voldoende veiligheidsdata nie vir kinders beskikbaar is nie.

Ander medisyne en ADDAVEN

Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Geen interaksies met ander medisyne is bekend nie.

Swangerskap, borsvoeding en vrugbaargheid

Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om ‘n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy ADDAVEN ontvang.

Bestuur en die gebruik van masjinerie

ADDAVEN het geen, of ‘n onbeduidende effek op bestuur en die gebruik van masjinerie.

Dit is nie altyd moontlik om te voorspel tot watter mate ADDAVEN die daaglikse aktiwiteite van ‘n pasiënt kan beïnvloed nie. Pasiënte moet seker

maak dat hulle nie aan die bogenoemde aktiwiteite deelneem totdat hulle nie bewus is tot watter mate ADDAVEN hulle affekteer nie.

3. Hoe ADDAVEN aan jou toegedien sal word

Daar sal nie van jou verwag word om ADDAVEN aan jouself te gee nie. Dit sal aan jou gegee word deur 'n persoon wat opgelei is om dit te doen.

Jou dokter sal op die korrekte dosis wat jy moet ontvang, besluit. Die gebruiklike dosis is 10 milliliter (mL) elke dag. Indien jy probleme met jou lewer of niere het, sal jy moontlik ‘n laer dosis ontvang.

Jy sal jou medisyne deur ‘n infusie (drup) in ‘n aar ontvang. ADDAVEN moet met ‘n ander voedingsoplossing gemeng word voordat dit aan jou gegee word. Jou dokter of verpleegster sal seker maak dat dit korrek voorberei word.

Jou dokter sal jou inlig hoe lank jou behandeling met ADDAVEN sal duur. Indien jy die indruk het dat die effek van ADDAVEN te sterk of te swak is, lig jou dokter of verpleegster in.

Indien jy meer ADDAVEN ontvang as wat jy moet

Aangesien ‘n gesondheidsorgverskaffer ADDAVEN sal toedien, sal hy/sy die dosis beheer. Nietemin, in die geval van oordosering, sal jou dokter die oordosering hanteer.

Indien jy vergeet om ADDAVEN te ontvang

Aangesien ‘n gesondheidsorgverskaffer ADDAVEN sal toedien, is dit onwaarskynlik dat die dosis oorgeslaan sal word.

4. Moontlike newe-effekte

ADDAVEN kan newe-effekte hê.

Nie alle newe-effekte wat vir ADDAVEN aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl jy ADDAVEN ontvang, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om ADDAVEN te ontvang en lig jou dokter dadelik in:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat sluk of asemhaling kan bemoeilik,
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit ervaar, het jy moontlik ’n ernstige allergiese reaksie teenoor ADDAVEN gehad. Jy het moontlik dringende mediese aandag of verdere hospitalisasie nodig.

Lig jou dokter in indien jy enige van die volgende newe-effekte waarneem:

<u>Gereeldheid onbekend</u>

- Hoofpyn
- Naarheid, braking
- Koue rillings, koors

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

<u>Aanmelding van newe-effekte</u>

Indien jy newe-effekte ervaar, raadpleeg jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en die eReporting-platform (who-

umc.org) op die SAHPRA webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van ADDAVEN te verskaf.

Pasiënte word versoek om enige vermoedelike ongunstige newe-effekte van geneesmiddels aan hulle gesondheidsorgverskaffer of die Houer van die Registrasiesertifikaat by die volgende e-posadres aan te meld: safety.fksa@fresenius-kabi.com en aan die betrokke medisyne se regulatoriese owerheid in die land waar die produk bemark word.

5. Hoe om ADDAVEN te bewaar

Bewaar alle medisyne buite bereik van kinders.

Bewaar by of onder 30 °C.

Na verdunning:

Die byvoeging van ADDAVEN moet onmiddellik voor die aanvang van die infusie gedoen word en moet binne 24 uur gebruik word.

Jou dokter en hospitaalapteker is verantwoordelik vir die korrekte bewaring, gebruik en wegdoening van ADDAVEN.

Moenie ná die vervaldatum wat op die etiket aangedui is, gebruik nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ADDAVEN bevat

- Die aktiewe bestanddele in een ampule (10 mL) is:

Chroomchloriedheksahidraat	53,3 µg (mikrogram)
Koperchlorieddihidraat	1,02 mg
Ysterchloriedheksahidraat	5,40 mg
Mangaanchloriedtetrahidraat	198 µg (mikrogram)

Kaliumjodied	166 µg (mikrogram)
Natriumfluoried	2,10 mg
Natriummolibdaatdihidraat	48,5 µg (mikrogram)
Natriumseleniet anhidries	173 µg (mikrogram)
Sinkchloried	10,5 mg

- Die ander bestanddele is xilitol, soutsuur (vir pH-aanpassing) en water vir inspuitings.

ADDAVEN bevat 52 µmoL natrium (1,20 mg) per 10 mL dosis.

Hoe ADDAVEN lyk en inhoud van die pak

ADDAVEN is ‘n deursigtige en kleurlose tot effens geel oplossing van spoorelemente.

ADDAVEN is beskikbaar in ‘n polipropileen ampule wat 10 mL gekonsentreerde oplossing bevat. Elke kartonhouer bevat 20 ampules van 10 mL.

Houer van Sertifikaat van Registrasie

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Hierdie inligtingsblad is laas hersien in

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Registrasienommer

49/24/0996

Toegang tot die ooreenstemmende Professionele Inligting

Die ooreenstemmende Professionele Inligting (PI) is beskikbaar by

https://www.fresenius-kabi.com/za/fresenius_kabi_south_africa_products