

Summary Public Assessment Report

**Viant powder for solution for infusion
(Vitamin A, Cholecalciferol (Vitamin D3), all-rac- α -tocopherol
(Vitamin E), Phytomenadione (Vitamin K1), Ascorbic acid
(Vitamin C), Thiamine (Vitamin B1), Riboflavin (Vitamin B2),
Pyridoxine (Vitamin B6), Cyanocobalamin (Vitamin B12), Folic
acid, Dexpanthenol, Biotin, and Nicotinamide)**

SE/H/1691/01/DC

Summary Public Assessment Report

Viant powder for solution for infusion, 932 mg,

Vitamin additive for intravenous solutions containing 13 water-and fat-soluble vitamins: Vitamin A, Cholecalciferol (Vitamin D3), all-rac- α -tocopherol (Vitamin E), Phytomenadione (Vitamin K1), Ascorbic acid (Vitamin C), Thiamine (Vitamin B1), Riboflavin (Vitamin B2), Pyridoxine (Vitamin B6), Cyanocobalamin (Vitamin B12), Folic acid, Dexpantenol, Biotin, and Nicotinamide.

This is a summary of the public assessment report (PAR) for Viant. It explains how Viant was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Viant.

For practical information about using Viant, patients should read the package leaflet or contact their doctor or pharmacist.

What is Viant and what is it used for?

Viant is a medicine with ‘well-established use’. This means that the medicinal use of the active substances of Viant is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Viant is a powder for solution for infusion, which is administered after reconstitution using a drip. It contains 13 vitamins. Viant is used to give the daily requirement of vitamins straight into the blood to maintain normal functions of the body in case food cannot or only insufficiently or must not be taken up orally.

Viant can be given to adults and children aged 11 years and older.

How does Viant work?

Vitamins are an indispensable component of nutrition. They serve to maintain the integrity of the organism and the body functions.

Viant is administered using drip to prevent vitamin deficiency in situations where food cannot or only insufficiently or must not be taken up orally.

How is Viant used?

The pharmaceutical form of Viant is a powder for solution for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Viant have been shown in studies?

As all 13 water-and fat-soluble vitamins are well-known substances, and its use as parenteral vitamin substitution, when oral or enteral nutrition is impossible, insufficient or contraindicated is well established, the applicant presented data from the scientific literature. To note is that in Viant, vitamin K is included whereas for other parenteral multivitamin products vitamin K is given separately. The literature provided confirmed the efficacy and safety of all 13 water-and fat-soluble vitamins for use as parenteral vitamin substitution, when oral or enteral nutrition is impossible, insufficient or contraindicated. Viant is indicated in adults and children aged 11 years and older.

What are the possible side effects of Viant?

For the full list of all side effects reported with Viant, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Viant approved?

The use of Viant as parenteral vitamin substitution, when oral or enteral nutrition is impossible, insufficient or contraindicated is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Viant's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Viant?

A risk management plan has been developed to ensure that Viant is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Viant, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Viant

The marketing authorisation for Viant was granted on 2018-10-10 in Sweden.

The full PAR for Viant can be found on the following website:
<http://mri.medagencies.org/Human/>. For more information about treatment with Viant, please read the [[package leaflet](#)] or contact your doctor or pharmacist.

This summary was last updated in 2018-10.