Package leaflet: Information for the user

Viant powder for solution for infusion

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects even when they are not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Viant is and what it is used for

Viant is a powder for solution for infusion, which is administered using a drip. It contains 13 vitamins (see section 6).Viant is used to give your daily requirement of vitamins straight into your blood to maintain normal functions of the body in case you are not able to get the vitamins via normal food intake.
Viant can be given to adults and children aged 11 years and older.

2. What you need to know before you use Viant

Do not use Viant:
- if you are allergic to any of the ingredients of this medicine, to peanut or soybean or to any of the other ingredients of this medicine (listed in section 6)
- if you already have high levels of these vitamins
- if you have to much calcium in the blood (hypercalcaemia)
- if you have excessive urinary calcium excretion (hypercalciuria)
- if you receive vitamin A (retinol) from other sources or vitamin A derivatives (retinoids)
- in newborns, infants and children under 11 years of age

Warnings and precautions
Talk to your doctor before using Viant.

Your doctor will take special care if:
- you take vitamins from other sources
- you have digestive disorders
- you have liver or kidney problems
- you already have pre-existing diseases and/or disorders that can cause hypercalcaemia and/or hypercalciuria
- you are at risk for vitamin B12 (cyanocobalamin) deficiency, e.g. if you suffer from short bowel syndrome, inflammatory bowel disease (e.g. Crohn disease or ulcerous colitis), if you use metformin (medicine to help treat diabetes) more than four months, proton pump inhibitors or histamine H_2

blockers (medicines to treat gastroduodenal ulcers or decreasing acidity of stomach juices, e.g. omeprazole, pantoprazole etc., or ranitidine, famotidine etc.) more than 12 months, if you are vegan or strict vegetarian, if you are older than 75 years
- you are taking the vitamins for a long time
- you are taking this medicine straight after a long period of severe starvation or malnourishment
- you regularly consume alcohol (more than 3 drinks per day or more than 7 drinks per week)

Call the doctor or nurse immediately in case of signs of allergic reaction such as sweating, reddening of the skin, hives, difficulties with breathing so that the infusion is stopped immediately and appropriate treatment will be given.

Further monitoring and tests such as various examinations of blood samples and of liver function may be done to make sure that your body handles the administered vitamins properly.

The nursing staff may also take measures to ensure that your body's vitamin requirements are met. In addition to Viant you may receive further vitamins in order to fully cover your requirements.

Children
This solution must not be given to newborns, infants and children's under 11 years of age.

Other medicines and Viant
Tell your doctor, pharmacist or nurse if you are taking , or have recently taken or might take any other medicines.
Any medicines containing vitamin A or vitamin A derivatives (retinoids) must not be taken during treatment with Viant, due to the risk of hypervitaminosis A (see section 3).

Viant can interact with some other medicines. Please tell your doctor, pharmacist or nurse if you are using any of the following:
- Drugs for acne or psoriasis (retinoids) e.g. bexarotene or acitretin
- Drugs used to treat epilepsy e.g. phenobarbital, phenytoin, carbamazepine, fosphenytoin and primidone
- Drugs used to treat HIV (antiretrovirals, Tipranavir)
- Antibiotics
- Anti-inflammatories
- Antifungals e.g. ketokonazole
- Drugs used to treat seizures or bipolar disorder (anticonvulsants) e.g. cycloserine, hydralazine, isoniazid, pennicillamine, phenelzine, theophyllin, phenytoin, carbamazepine, phenobarbital
- Ethionamide (antibiotic used to treat tuberculosis)
- Drugs that block folic acid (antifolates) e.g. methotrexate, pyrimethamine
- Deferoxamine (drug to treat iron poisoning)
- Drugs that can cause pressure around the brain (some tetracyclines)
- Drugs to prevent blood clotting (acenocoumarol, warfarin, phenoprocoumon)
- Fluoropyrimidine (drugs used to treat cancer)

Viant and tests
Viant should not be given to you directly before having your blood glucose or urine tested, because it contains vitamin C which may produce inaccurate test results.

Viant contains 0.06 mg biotin per vial. If you are about to undergo laboratory testing you must tell your doctor or the laboratory personnel that you are taking or have recently taken Viant, because biotin may affect results of such tests. Depending on the test, the results may be falsely elevated or falsely low due to biotin. Your doctor may ask you to stop taking Viant before performing laboratory tests. You should also be aware that other products that you may take, such as multivitamins or supplements for hair, skin, and nails could

also contain biotin and affect the results of laboratory tests. Please inform your doctor or the laboratory personnel, if you are taking such products.

Pregnancy, breast-feeding and fertility

Pregnancy
You may receive Viant during pregnancy if required, providing the indication and dosages are observed to avoid vitamin overdose.
The recommended daily dose should not be exceeded as high doses of vitamin A during pregnancy can cause foetal malformations.

Breast-feeding
The use of Viant is not recommended if you are breast-feeding. If you breast-feed whilst taking Viant there is a danger that your baby could get an overdose of vitamin A.

Fertility
No data are available on the effect of Viant on male or female fertility.

Driving and using machines
Viant has no or negligible influence on the ability to drive and use machines.

Viant contains sodium
This medicine contains up to 46 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.3 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Viant

The Viant powder will be first dissolved in a liquid solution. After that it will be mixed with a larger volume of fluid (parenteral nutrition regime, glucose or electrolyte solution) before it is given to you. Viant will be administed into a vein as a drip.

The recommended dose is 1 vial per day for adults and children 11 years of age and above.

If you received more Viant than you should
This risk of vitamin overdose is higher if you are receiving other vitamin supplements or if the overall supplementation does not match your requirements or if you are already prone to high levels of vitamins (hypervitaminosis).
The most frequent symptoms of overdose are feeling sick, vomiting and diarrhoea. Other symptoms of long-term or acute overdose of vitamins include:

- dry, peeling skin
- headache, vomiting and weakness
- jaundice
- rise in pressure around your brain with symptoms like headache, vomiting, confusion about time and double vision
- coagulation disorders
- stomach pain
- signs of kidney disease like pain or difficulty when urinating
- high levels of calcium in the blood
- numbness, prickling or tingling in your feet or hands
- lack of coordination/falling
- yellow sweat

- darker urine

Tell your doctor if you are experiencing any of these symptoms after taking Viant .
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may be serious. If any of the following side effects occur tell your doctor immediately, he will stop giving you this medicine:

Not known (frequency cannot be estimated from the available data)
Severe allergic (anaphylactoid) reactions, feeling sick, vomiting, diarrhoea and burning sensation or rash at the site of injection. Blood liver tests may be increased.

To be completed nationally

Reporting of side effects
If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V.*
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Viant

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

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

Storage conditions
Store in a refrigerator (2°C – 8°C). If stored at room temperature (not above 25°C), this medicine can be used only for three months.

Viant should not be used if the reconstituted solution is not clear and yellow-orange in colour, or if the vial is damaged in any way. The reconstituted solution should be used immediately.

6. Contents of the pack and other information

What Viant contains

One vial with 932 mg dry substance (powder) contains:

1.	Retinol (Vitamin A) (as retinol palmitate)	0.99 1.82	mg mg	equivalent to Retinol (Vitamin A)	3300 IU
2.	Cholecalciferol	0.005	mg	equivalent to Vitamin D_3	200 IU
3.	all-rac-α-tocopherol (Vitamin E)	9.11	mg		
4.	all-rac-Phytomenadione (Vitamin K_1)	0.15	mg		

5.	Ascorbic acid (Vitamin C)	200	mg
6.	Thiamine (Vitamin B_1)	6.00	mg
	(as Thiamine hydrochloride)	7.63	mg
7.	Riboflavin (Vitamin B_2)	3.60	mg
	(as Riboflavin sodium phosphate hydrate)	4.58	mg
8.	Pyridoxine (Vitamin B_6)	6.00	mg
	(as Pyridoxine hydrochloride)	7.30	mg
9.	Cyanocobalamin (Vitamin B_{12})	0.005	mg
10.	Folic acid (Vitamin B_9)	0.60	mg
	(as Folic acid hydrate)		
11.	Pantothenic acid (Vitamin B_5)	15.0	mg
	(as Dexpanthenol)	14.0	mg
12.	Biotin (Vitamin B_7)	0.06	mg
13.	Nicotinamide (Vitamin B_3)	40.0	mg

The other ingredients are glycine, hydrochloric acid (for pH adjustment), sodium glycocholate, soyphosphatidylcholine, and sodium hydroxide (for pH adjustment).

What Viant looks like and contents of the pack

Viant is a powder for solution for infusion. It is a yellow-orange cake or powder supplied in brown glass vials.
It is packaged in cartons containing 5 or 10 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany

Manufacturer:
B. Braun Melsungen AG
Am Schwerzelshof 1
34212 Melsungen, Germany

Postal address
34209 Melsungen, Germany

Tel.: +49-5661-71-0
Fax: +49-5661-71-4567

<[To be completed nationally]>
This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Germany, Luxembourg:	Viant Pulver zur Herstellung einer Infusionslösung
Bulgaria:	Viant powder for solution for infusion
Croatia:	Viant prašak za otopinu za infuziju
Czech Republic, Denmark, Estonia, Finland, Norway, Portugal,	

Slovak Republic, Sweden:	Viant
Italy:	Envitavit
Poland:	Viantan
Slovenia:	Viant prašek za raztopino za infundiranje
Spain:	Viant polvo para solución para perfusión
United Kingdom (Northern Ireland):	Nutratain

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The following information is intended for healthcare professionals only:

Instructions for handling
Strict aseptic precautions must be followed during reconstitution and dilution of the product in a suitable solution/emulsion for infusion.
Viant should be administered slowly.
The content of a vial should be dissolved by adding 5 ml of a suitable solvent (water for injection or glucose solution 50 mg/ml or sodium chloride 9 mg/ml) and gentle shaking to dissolve the lyophilised powder. Do not use unless the reconstituted solution is clear and yellow-orange in colour. The reconstituted solution should be used immediately.

The powder must be completely dissolved before transferring to

- glucose solution 50 mg/ml
- sodium chloride 9 mg/ml
- lipid emulsion
- binary mixture for parenteral nutrition combining glucose, electrolytes and amino acids
- or ternary mixture for parenteral nutrition combining glucose, electrolytes, amino acid solutions and lipids

Mix the final solution thoroughly .
After addition of Viant to a parenteral nutrition solution, check for any abnormal colour change and/or the appearance of precipitates, insoluble complexes or crystals.

This medicinal product should not be mixed with other medicinal products except those mentioned above unless compatibility and stability have been demonstrated.
Use only when the original seal is intact and the container is undamaged.
For single use only. Container and unused residues must be discarded after use. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
If co-administration of drugs that are incompatible with Viant is necessary, administer via separate IV lines.

Additives may be incompatible with parenteral nutrition containing Viant.

Vitamin A and thiamine contained in Viant may react with bisulfites in parenteral nutrition solutions (e.g. as a result of admixtures) leading to degradation of vitamin A and thiamine.

An increase in pH of a solution may increase the degradation of some vitamins. This should be considered when adding alkaline solutions to the admixture containing Viant.
Folic acid stability can be impaired with increased calcium concentrations in an admixture.