

#### Frequently Asked Questions for VEG 1

#### General

#### 1. Why has VEG 1 been developed?

VEG 1 was developed to provide a convenient way of avoiding the most common weak points in a varied vegan diet: vitamin B12, iodine, vitamin D and selenium.

#### Vitamin B12

Vitamin B12 is almost entirely absent from modern plant foods which are not contaminated by bacteria and insects. Even unwashed, organically grown plants do not contain a significant amount of B12. Vegans often have intakes of vitamin B12 well below recommended intakes. Low vitamin B12 intake by vegans routinely leads to reduced activity of some important enzymes and increased levels of homocysteine and methylmalonic acid (MMA). Even moderately elevated homocysteine is associated with increased risk of death, depression, stroke, dementia and birth defects, though it remains unclear how many of these associations reflect true cause and effect.

Vegans who do not get vitamin B12 from fortified food or supplements are at increased risk of clinical deficiency symptoms such as anaemia and nervous system damage. The most common early symptoms of vitamin B12 deficiency are tiredness (from anaemia), numbness and tingling (from nervous system damage) and sore tongue.

VEG 1 is designed to provide sufficient absorbed vitamin B12 to match national and international recommended intakes. It is designed to be chewed as this increases the reliability of vitamin B12 absorption by dispersing and dissolving the tablet.

#### Vitamin D

In the winter – whenever our shadows at midday are more than twice as long as we are – our skin cannot produce vitamin D effectively and even small dietary intakes may become important to avoid deficiency. VEG 1 aims to eliminate the disadvantage to vegans from low dietary vitamin D intakes. UK recommendations for vitamin D intakes are 8.5-10µg/day for infants less than 1 year old and 10µg/day for everyone else (µg = microgram; sometimes also written mcg).

#### **Iodine and Selenium**

Most plants have no requirement for iodine or selenium for their growth, so the amounts of these nutrients in plants vary widely and iodine and selenium intakes from vegan diets can be lower than from omnivorous diets. In the UK and many other countries dairy products are a major source of iodine due to the use of iodine-fortified feed concentrates. Iodine and selenium are also provided to some farmed animals as supplements. A moderate, steady iodine intake is ideal for thyroid health and low iodine intake during pregnancy impairs intelligence in children. Selenium is an important protective anti-oxidant.

#### Other nutrients

We also included small amounts of folic acid, vitamin B2 and vitamin B6 in VEG 1 as they work along with vitamin B12 to reduce homocysteine levels. Folic acid is especially important for women planning to conceive.

We did not attempt to include all nutrients as most nutrients are not an issue for vegans eating a varied and sensible diet. VEG 1 is intended to complement a healthy vegan diet and does not seek to provide a substitute for such a diet.

We believe that VEG 1 continues to meet a need not addressed by the general supplement market for a supplement designed to meet the particular needs of vegans as a complement to a varied and healthful diet. Formulating such a supplement and ensuring that it is produced to high standards is no trivial task. We hope that our members and the many other VEG 1 users will agree that we have created a good and reasonably priced product that meets a real need.

#### 2. Under what circumstances is it recommended to take VEG 1?

It is recommended to take VEG 1, or another comparable supplement, if you are not reliably meeting your needs for vitamin B12, vitamin D, iodine and selenium by other means.

Fortified foods – many plant milks; some margarines/fat spreads, such as Pure; some nutritional yeast flakes, such as Engevita (blue pack only); fortified yeast extracts; fortified breakfast cereals – can provide a good alternative source of vitamin B12. If you are getting 3 µg or more of vitamin B12 per day from fortified foods then you are unlikely to need additional supplementary vitamin B12 though it is not harmful to get both.

Fortified foods also provide small amounts of vitamin D. More importantly, sun exposure when the sun is well above the horizon (at least above 30 degrees – shadow less than twice as long as your height – and preferably higher, especially if your skin is dark) can build up healthy vitamin D stores in the body. The safest way of getting vitamin D from sun is to expose as much skin as you can for about half the time that would cause your skin to appear slightly redder a day later: always avoid sunburn.

Seaweed can be a major source of iodine, but it is difficult to ensure a stable moderate intake as the iodine contents of seaweeds vary considerably even within a single type of seaweed such as kelp. This variability also applies to typical kelp supplements. Highly variable intakes may actually be worse for the thyroid than steady marginally low intakes.

lodised salt can provide an alternative source of iodine though there have been examples of poor quality control in this case as well, and it would not make sense to add more salt just to get iodine.

Brazil nuts are a good source of selenium as they grow in soil rich in selenium. About ten nuts a week provides a good intake. Don't overdo it: too much selenium can be harmful.

#### 3. How is VEG 1 tested?

We test a sample of tablets from each batch of VEG 1 before it is released for sale and we also sometimes test tablets from old batches. This testing has demonstrated that the production of VEG 1 is reliable and that the ingredients are sufficiently stable over time. Iodine content in VEG 1 has been found to be much more consistent than found in published surveys of iodine supplements.

#### 4. How should VEG 1 be used?

It is important to chew VEG 1 to promote reliable absorption of its contents. The ideal way to use VEG 1 is to chew it during or immediately after a meal. The fat content of the meal may assist vitamin D absorption and the digestive process may give more consistent absorption of vitamin B12. Taking VEG 1 with a meal also minimises the effect of its sugar content on teeth.

#### 5. What do I need to know before starting to use VEG 1?

If you suspect you are seriously deficient in terms of any nutrient or if you are taking prescription medicines you should consult a doctor or pharmacist.

### 6. Might I need more of the nutrients in VEG 1 than VEG 1 provides?

Higher doses of vitamin B12 and vitamin D than those in VEG 1 may be necessary if you have been diagnosed as seriously deficient. Check with your health adviser.

If you have had an inadequate supply of vitamin B12 for more than a year then taking a high dose supplement for a short time is recommended, e.g. 1,000  $\mu$ g (micrograms) a day for 2 months. This will boost blood levels rapidly even if there is a temporary malabsorption due to deficiency. After this VEG 1 would generally be sufficient.

A small minority of people have *persistent* severe vitamin B12 malabsorption. This is rare in young people but may affect about 2% of those over 65. In these cases much higher oral doses (at least 2,000 µg per week) are necessary to correct deficiency.

### 7. Can VEG 1 be used if I have any health problems or take medications?

You should not take VEG 1 if you have been told by your doctor or pharmacist to avoid supplements containing vitamin D.

Vitamin D supplements may have an altered effect if you are taking certain prescription medicines or if you have certain medical conditions. Due to the vitamin D content, talk to your doctor or pharmacist before taking VEG 1 if you have problems with your kidneys or if you have sarcoidosis or if you are taking prescription medicines.

Metformin can reduce B12 absorption.

#### 8. Is it OK to take VEG 1 during pregnancy?

None of the ingredients in VEG 1 are problematic during pregnancy. Indeed, its key nutrients (vitamin B12, iodine and vitamin D) are all particularly important during pregnancy. VEG 1 also contains folic acid which is recommended during pregnancy though the amount (200  $\mu$ g) is less than that recommended during early pregnancy and while trying to conceive (400  $\mu$ g).

# 9. Is VEG 1 suitable for people living in countries that may have a higher level of the other ingredients in the daily diet, e.g. Japan (higher iodine), or better availability of vitamin D from sunlight throughout the year?

The amounts of nutrients in VEG 1 would have little effect in themselves in countries with higher background exposures. For example, in Japan average iodine intakes exceed 1,000  $\mu$ g per day compared with 150  $\mu$ g in VEG 1. VEG 1 would have almost no impact relative to variations in seaweed consumption. The impact of VEG 1 on vitamin D levels would be much less than the impact of sun exposure when the sun is sufficiently high in the sky.

The nutrient contents of a VEG 1 tablet are all well below the tolerable upper limits for adults – less than 25% of the upper limits for the UK, EU and USA.

In certain contexts particular elements of VEG 1 can become *unnecessary* but they should not be harmful.

#### 10. How long does a tub of VEG 1 last?

The small VEG 1 tub contains 90 tablets which is a 3 months' supply for an adult. The large VEG 1 tub contains 180 tablets. For children under 12, the recommended use is half a tablet a day so VEG 1 lasts twice as long. There is a two-year shelf life on VEG 1 from the date of manufacture.

#### New Formulation (from August 2016)

#### 11. Why have you changed the formulation?

The changes are increases to the vitamin B12 and vitamin D content.

	Old formulation	New formulation	Tolerable Upper Limit for adults
Vitamin B12	10 µg	25 µg	None
lodine	150 µg	150 µg	600 to 1100 µg
Vitamin D	10 µg as D2	20 µg as D3	100 µg
Selenium	60 µg	60 µg	300 to 400 µg
Folic acid	200 µg	200 µg	1000 µg

Vitamin B2	1.6 mg	1.6 mg	40 mg
Vitamin B6	2 mg	2 mg	25 to 100 mg

In North America, the target for adequate blood levels of vitamin D has been raised from 25 nmol/l to 50 nmol/l and recommended intakes have increased to try to match this, with 20  $\mu$ g per day now recommended for older adults. European and UK safe/tolerable upper limits have doubled since VEG 1 was first produced in 2005: from 50 to 100  $\mu$ g per day for adults.

There have also been some reports from users of the original formulation that they have not achieved adequate blood levels of vitamin D. It should be noted that individual responses to sun exposure and supplementation are variable.

There is now a UK recommendation (RNI) of 10  $\mu$ g from diet or supplements for the whole population from 4 years upwards along with a 10  $\mu$ g "safe intake" for 1-3 year olds. Half a VEG 1 tablet (as recommended for younger children) would not be sufficient on the old formulation to meet this recommendation.

Based on this we decided to increase the amount of vitamin D in VEG 1. The new VEG 1 should be significantly more effective in raising blood vitamin D levels.

There is now a vegan D3 available, derived from lichen. While D2, which previously was the only vegan form of supplementary vitamin D, has similar effects at low doses it is not completely equivalent to D3 which is the form naturally produced by our skins given suitable sun exposure. We therefore decided to change from D2 to D3 at the same time as increasing the amount of vitamin D.

Once it was decided to make the change to vitamin D levels, there was a further suggestion to change the vitamin B12 content to match recent recommendations by some prominent vegan dietitians in the USA of at least 25  $\mu$ g a day from a daily supplement. This change from 10  $\mu$ g to 25  $\mu$ g will make a modest difference to the absorbed amount (about 5-20% extra) but the change is certainly not harmful and was made to remove inconsistency with these other recommendations.

### 12. Is there any problem if I continue taking the old formula VEG 1?

The old VEG 1 content of 10  $\mu$ g of D2 meets all UK recommendations for adult vitamin D intake and most international recommendations. 10  $\mu$ g of vitamin B12 as a daily supplement is also adequate to meet UK and international recommendations for vitamin B12.

Half an old formula VEG 1 would not be enough to meet the new (July 2016) vitamin D RNI for children of 10  $\mu$ g.

#### 13. Why won't the old formulation continue to be available?

Maintaining multiple formulas would increase costs and could be confusing. The new formulation has no disadvantages compared with the old one.

#### 14.Is the new formula okay for children and of which age?

As with the old formula, half a VEG 1 is suitable for children from 2 to 12 while older children can take the full tablet.

#### Ingredients

#### 15. What are the active ingredients?

Vitamin B12 (cyanocobalamin), iodine, vitamin D3 (cholecalciferol) [the original formula used D2, ergocalciferol], selenium, folic acid, vitamin B2 and vitamin B6.

### 16. Some quantities are above 100% of the EU Recommended Daily Amount (RDA)/Nutrient Reference Value (NRV), is this safe?

	Old formulation	New formulation	Tolerable Upper Limit for adults
Vitamin B12	10 µg	25 µg	None
lodine	150 µg	150 µg	600 to 1100 µg
Vitamin D	10 µg as D2	20 µg as D3	100 µg
Selenium	60 µg	60 µg	300 to 400 µg
Folic acid	200 µg	200 µg	1000 µg
Vitamin B2	1.6 mg	1.6 mg	40 mg
Vitamin B6	2 mg	2 mg	25 to 100 mg

Yes, all quantities are well within tolerable upper limits.

## 17. Why is there such a high amount of vitamin B12 compared with the UK Recommended Nutrient Intake (RNI) of 1.5 $\mu$ g and EU RDA/NRV of 2.5 $\mu$ g?

The percentage absorption of vitamin B12 depends very much on the amount taken. If you rely on a once a day supplement then you need more vitamin B12 in total than if you consume some vitamin B12 with each meal, as most omnivores do.

If vitamin B12 is taken as 3 separate 1  $\mu$ g doses each at least 4 hours apart then about 1.5  $\mu$ g will be absorbed by most people. This matches almost all recommended intakes across the world. To get the same amount from a single daily intake requires between 5 and 10  $\mu$ g. Further increases in dose give only small increases in the amount absorbed so even intakes much above the RDA/NRV do not translate to an excessive absorbed amount.

About 50% of amounts less than 1  $\mu$ g are absorbed by people with normal levels of intrinsic factor (more than 99% of the population). Moderate amounts – about 5 to 10  $\mu$ g – are sufficient to saturate the efficient absorption via intrinsic factor, giving a total absorbed amount of about 1.5  $\mu$ g. In addition, between 0.5% and 2%

of any dose is also absorbed independently of intrinsic factor so the total absorbed amount continues to increase as doses rise above 10 µg but the percentage absorbed is much less.

There is no tolerable upper limit for vitamin B12 as there is no known harmful effect but we still aim to avoid blood vitamin B12 levels rising above the normal range as there is no known benefit to be gained from moving into unknown territory.

### 18. Why do the amounts of vitamin B12 recommended by vegan health professionals vary so much?

The evidence that all vegans should consume enough vitamin B12 to meet typical national and international recommended intakes is very strong. Most national and international recommended intakes correspond to absorbing 1.5  $\mu$ g of vitamin B12 per day on average.

This target for average absorbed vitamin B12 (1.5 µg/day) was the basis of the 2001 consensus statement (https://www.vegansociety.com/resources/nutritionand-health/vitamins-minerals-and-nutrients/vitamin-b12-your-key-facts/whatevery-vegan-should-know-about-vitamin-b12) and sets a solid lower limit for recommendations.

Eat fortified foods two or three times a day to get at least three micrograms (mcg or  $\mu$ g) of vitamin B12 a day

OR Take one vitamin B12 supplement daily providing at least 10 micrograms OR Take a weekly vitamin B12 supplement providing at least 2000 micrograms.

There is also a general acceptance that while there are no known adverse effects from higher intakes of vitamin B12 there is no evidence of a benefit from blood levels above the current normal range in omnivores. Very elevated blood vitamin B12 levels might lead to unnecessary medical investigations, if doctors are not aware of the supplement use.

Most evidence points to blood vitamin B12 levels around 300 pmol/l (close to the middle of the Western omnivore range) being sufficient for all possible benefits: there is little further reduction in either MMA or homocysteine beyond this point.

Some reports have indicated that active vitamin B12 (holoTC), MMA and homocysteine blood levels in omnivores plateau at dietary vitamin B12 intakes somewhere between 4 and 7  $\mu$ g and do not change significantly at higher intakes. This led some people to extrapolate this observation to a new target absorbed amount of vitamin B12 – assuming 50% absorption of these intakes – and then to adjust their vitamin B12 recommendations to match this new target. This corresponds to aiming for the upper end of effective absorbed vitamin B12 levels in omnivores.

4  $\mu$ g intake with 50% absorbed gives a target absorbed amount of 2  $\mu$ g. Given 1.5  $\mu$ g absorbed through intrinsic factor plus a further 1% of the overall dose then this would point to a daily supplement of 50  $\mu$ g to absorb 2  $\mu$ g (1.5 + 0.01 x 50)  $\mu$ g.

The expected average absorbed amount from 50  $\mu$ g would be 25% higher than that expected from a 10  $\mu$ g dose (1.6  $\mu$ g, 1.5 + 0.01 x 10).

Based on slightly more optimistic assumptions on absorption (1.7  $\mu$ g from 5  $\mu$ g plus 1.5% of 20  $\mu$ g), Jack Norris (http://www.veganhealth.org/b12/formula ) chose 25  $\mu$ g as the minimum daily supplement to absorb 2  $\mu$ g on average. Brenda Davis and Vesanto Melina in their book Becoming Vegan also recommend at least 25  $\mu$ g.

Michael Greger aims for an absorbed amount of 4  $\mu$ g (http://nutritionfacts.org/video/ vitamin-b12-recommendation-change, safest-source-of-b12, cheapest-source-of-vitamin-b12, daily-source-of-vitamin-b12) which requires 250  $\mu$ g per day (4 = 1.5 + 0.01 x 250).

All involved would accept that these recommendations are based on limited evidence. In the absence of better evidence, they are all credible recommendations. None are likely to result in excessive blood vitamin B12 measurements *on average* though Michael Greger's recommendations may well give abnormally high blood vitamin B12 readings for some people.

There are also a minority of people, especially among those over 65, who have very inefficient absorption of vitamin B12 due to a lack of intrinsic factor. To have a single dose that covers this group as well requires moving to very high doses indeed: 1,000 to 2,800  $\mu$ g per week (double that if taken with food as the absorption of very high doses decreases when taken with food). Some studies have shown that very high supplementary doses of vitamin B12 are required to minimise MMA levels in people over 65 who initially showed elevated MMA.

Based on this some health professionals recommend higher daily supplement intakes for people over 65: about 500 µg per day. This would be expected to be sufficient even for people who lack intrinsic factor (which is observed in up to 2% of people over 65) and it should therefore certainly be adequate. However, it goes well beyond current national and international recommendations for the omnivorous population and has the potential to give very high blood vitamin B12 levels in some people.

### The most important thing is that all vegans should at least meet the guidance from the 2001 consensus statement:

Eat fortified foods two or three times a day to get *at least* three micrograms (mcg or  $\mu$ g) of vitamin B12 a day

OR Take one vitamin B12 supplement daily providing *at least* 10 micrograms OR Take a weekly vitamin B12 supplement providing *at least* 2000 micrograms.

Those preferring to match the higher end of Western omnivorous B12 levels rather than just matching the national and international recommendations need about twice the absorbed amount that these recommendations are based on. If you fall into this category, consider taking half a tablet of VEG 1 with one meal and half a tablet with another meal at least four hours later: this will double absorption of vitamin B12 while leaving absorption of other nutrients unchanged.

### 19. Why is D3 (cholecalciferol) referred to as 'lichen' cholecalciferol?

The D3 in VEG 1 is derived from naturally occurring D3 in lichen. Usually D3 in supplements comes from animals via the action of ultraviolet radiation on their skin or is derived from cholesterol obtained from lanolin (also from animals). We include the word lichen to make it more obvious that the D3 in the new VEG 1 formula is suitable for vegans and does not come from animals.

#### 20. How do you know the D3 is really from lichen?

We have visited the company producing the D3 from lichen and they have shown us confidential test results that confirm that the D3 in their final product has come from lichen. Their D3 carries the Vegan Society's Trademark as the producer has provided clear and satisfactory assurances on its source.

#### 21. Why does VEG 1 contain sugar?

VEG 1 contains 0.625 grams (a sixth of a teaspoon) of sugar. Sugar is used because it provides a stable, palatable and chewable base for the tablets. These properties are important as chewing improves the reliability of vitamin B12 absorption and the supplement is intended for children as well as adults.

The only potential adverse effect of such a small amount of sugar would be to slightly increase risk of tooth decay and this can be minimised if VEG 1 is taken with or immediately after a meal.

We have looked at alternatives – including fruit extracts, stevia and xylitol –but have not found an equally satisfactory alternative. Fruit extracts were impractical due to instability. Stevia has a distinctive taste and there is a legal limit to the amount that can be used per kilo. To match the current sweetness level of VEG 1, we would need to exceed this. If xylitol is used at levels of over 10% of the total product weight the product has to carry the warning "Excessive consumption may cause laxative effects".

### 22. I have just found out that sugar contains "bone char" in the process of production. Is this true?

Bone char is sometimes used in cane sugar production but is not used in producing the sugar in VEG 1 and is not used for beet sugar.

#### 23. Why do you include folic acid in VEG 1?

Scientific trials have directly shown clear benefits from folic acid in reducing the incidence of birth defects. An intake of 400µg/day is recommended while trying to conceive and during the first 12 weeks of pregnancy.

Folic acid, vitamin B2 and vitamin B6 were included as they act along with vitamin B12 to reduce homocysteine. The amounts included were 100% of the recommended intake at the time and were intended to make sure there was no weak link in reducing homocysteine levels though insufficient vitamin B12 is the reason elevated homocysteine levels are seen in vegans.

#### 24. Does folic acid promote cancer?

There is a hypothesis that large doses of folic acid might promote cancer but the best evidence (combined analysis of many randomised trials) does not support this. The small amount in VEG 1 is similar to amounts obtained in some countries from fortified foods and is not expected to cause any problem.

### 25. Why do you use cyanocobalamin rather than methylcobalamin?

Cyanocobalamin is used because it is stable and it is readily converted in the body to methylcobalamin and adenosylcobalamin which are the two active forms of vitamin B12. For an independent commentary on the different forms of cobalamin (vitamin B12) see <u>http://veqanhealth.org/b12/noncyanob12</u>

#### 26. I have heard that PVP is not safe – why is this used?

Polyvinylpyrrolidone (PVP) is used to mask the strong flavour of selenomethionine and improve palatability. We use selenomethionine as it is the form of selenium found naturally in plants. Non-vegan supplements often use shellac (a resin from insects) rather than PVP. PVP is safe in amounts much larger than that used in VEG 1.

#### 27. Why don't you include calcium?

Calcium intake can easily be low in vegan diets but this can be readily addressed by dietary choices, e.g. using fortified soy milks, calcium-set tofu and green leafy vegetables. Including calcium in VEG 1 would also conflict with palatability and chewability.

#### 28. Why don't you include zinc?

We consider that a varied mostly whole-food vegan diet provides sufficient zinc.

#### 29. Why don't you include omega-3 fatty acids?

Dietary changes can easily improve the balance of omega-3 and omega-6 fats in the diet. For example, sunflower/corn oil can be replaced with rapeseed oil. Fatty acid supplements are normally provided as oil-filled capsules so could not easily be combined with the other ingredients of VEG 1.

#### 30. Are any of the ingredients from nuclear countries?

Ingredients are sourced globally, including from nuclear countries such as the UK, France, China and the USA.