# Vitamin D: Is there a licensed product suitable for a patient with peanut or soya allergy?

Prepared by UK Medicines Information ([UKMi](http://www.ukmi.nhs.uk/ukmi/about/default.asp?pageRef=1)) pharmacists for NHS healthcare professionals

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## Background

Peanut protein and soya protein are known to cause severe and potentially life-threatening type 1 allergic reactions [1]. In the UK about 2 in 100 children and about 1 in 200 adults have an allergy to nuts. The number of people with peanut allergy is growing [2]. As peanut and soya belong to the same plant family (legumes), concern has been raised that patients allergic to peanuts might also be allergic to soya. There is however no consistent published advice on the risk of cross-sensitivity [3]. Further information regarding the issues which should be considered in patients with peanut allergy requiring a medicine containing soya is available [here](https://www.sps.nhs.uk/articles/what-issues-should-be-considered-in-patients-with-peanut-allergy-requiring-a-medicine-containing-soya-2/) [3].

## Answer

The tables below give information from the manufacturers regarding the suitability of their licensed colecalciferol and ergocalciferol products for patients with peanut or soya allergy. Manufacturers may change their products’ formulation or the suppliers of their excipients. **Current status of the product ingredients should therefore be obtained from the manufacturer.**

**Table 1: Vitamin D3 (colecalciferol/cholecalciferol) Liquid Products**

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| --- | --- | --- |
| **Preparation** | **Manufacturer** | **Manufacturer’s information** |
| **Colecalciferol**   * 3,000 IU/mL oral solution | Thame Laboratories | This product is manufactured in a facility where no soya or peanuts in any form are used. However, contact with soy and/or peanuts during or after manufacture cannot be excluded.  The product contains almond oil, therefore it is not suitable for patients with a nut allergy [4]. |
| **Fultium-D3 Drops**   * 2740 IU/mL (3 drops contain 200 IU) | Internis Pharmaceuticals Ltd | Suitable for patients with peanut and soya allergy [5]. |
| **InVita D3**   * 2,400 IU/mL oral drops, solution (one drop contains 67 IU) * 25,000 IU oral solution * 50,000 IU oral solution | Consilient Health Ltd | These products are considered free from peanuts, soya and their derivatives. This statement is based on the ingredients and the manufacturing process. Allergen testing has not been performed on the final product [6]. |
| **Thorens**   * 10,000 IU/mL oral drops, solution (one drop contains 200 IU) * 25,000 IU/2.5mL oral solution | Galen Ltd | Does not contain nut or soya derived ingredients. These products are deemed to be suitable for patients with nut or soya allergies [7]. |

**Table 2: Vitamin D3 (colecalciferol/cholecalciferol) Tablets and Capsules**

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| --- | --- | --- |
| **Preparation** | **Manufacturer** | **Manufacturer’s information** |
| **Colecalciferol**   * 1,000 IU capsules | Colonis Pharma Ltd | Capsules do not contain any peanut derived ingredients and does not contain components or use processes that involve soya protein [8]. |
| **Colecalciferol**   * 800 IU film-coated tablets | Consilient Health Ltd | These capsules are free from peanuts and soya, to the best of the manufacturer’s knowledge. This statement is based on the ingredients and the manufacturing process. The final product is not allergen tested [6]. |
| **Desunin**   * 800 IU tablets * 4,000 IU tablets | Mylan | It is not apparent that any of the product constituents include soya or peanut or are derived from nut or soya. Cross contamination of product with soya or peanut sources during manufacture is highly unlikely due to use of separated manufacturing areas. However, the manufacturers cannot guarantee the suitability of the product for soya bean and nut allergy sufferers as it may have come into contact with such allergens during transit [9]. |
| **Fultium-D3**   * 800 IU capsules * 3,200 IU capsules * 20,000 IU capsules | Internis Pharmaceuticals Ltd | These capsules are suitable for patients with peanut and soya allergy [5]. |
| **InVita D3**   * 400 IU soft capsules * 800 IU soft capsules * 5,600 IU soft capsules * 25,000 IU soft capsules * 50,000 IU soft capsules | Consilient Health Ltd | These products are considered free from peanuts, soya and their derivatives. This statement is based on the ingredients and the manufacturing process. Allergen testing has not been performed on the final product [6]. |
| **Plenachol D3**   * 20,000 IU capsules * 40,000 IU capsules | Accord-UK Ltd | Does not contain soya or peanut constituents, however it cannot be guaranteed that the products have not come into contact with these allergens during the manufacturing process [10]. |
| **Stexerol-D3**   * 1,000 IU tablets * 25,000 IU tablets | Kyowa Kirin Ltd | Does not contain ingredients sourced from nuts or soya derivatives; however, it cannot be guaranteed that they are manufactured in a nut or soya free environment [11]. |
| **Strivit-D3**   * 800 IU soft capsules * 3,200 IU Soft Capsules * 20,000 IU Soft Capsules | Strides Pharma UK Ltd | The full Strivit-D3 range is peanut and soya free.  The formulation for these capsules was changed from containing arachis oil to maize oil over 3 years ago; so all current stock are peanut and soya free. [12]. |

**Table 3: Vitamin D2 (ergocalciferol) Injection**

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| **Preparation** | **Manufacturer** | **Manufacturer’s information** |
| **Ergocalciferol injection**   * 300,000 IU/mL | RPH Pharmaceuticals AB | Does not contain any soya or nuts. It is not made in a nut or soya free facility but there should not be any nut or soya contamination within the injection. [13] |

Limitations

* The list of vitamin D products is not exhaustive.
* Vitamin D products which are marketed as nutritional supplements have not been included in this Q&A.
* Whilst a specific excipient may be listed as “not present” in a particular product, it cannot be guaranteed that the product has not been in contact with the listed excipients during the manufacturing process. Further information on the manufacturing process should therefore be obtained from the manufacturer if appropriate.
* Manufacturers may change the formulation of their products or the suppliers of the excipients. The current status of the peanut or soya content of the product should therefore be obtained from the manufacturer.

### References

1. EMEA. Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein. January 2006. Accessed via [www.ema.europa.eu/docs/en\_GB/document\_library/Scientific\_guideline/2010/04/WC500089954.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089954.pdf) on 18/8/2020
2. Harding M. Patient. Nut allergy. Updated 26/03/18. Accessed via <https://patient.info/health/food-allergy-and-intolerance/nut-allergy> on 18/8/2020
3. McKie J. Q&A 427.2 What issues should be considered in patients with peanut allergy requiring a medicine containing soya? 8th December 2016. Accessed via <https://www.sps.nhs.uk/articles/what-issues-should-be-considered-in-patients-with-peanut-allergy-requiring-a-medicine-containing-soya-2/> on 18/8/2020
4. Personal Communication with Medical Information Thame Laboratories (Syri Ltd) on 18/8/2020
5. Personal Communication with Medical Information Thornton & Ross Ltd on 12/8/2020
6. Personal Communication with Medical Information Consilient Health Ltd on11/8/2020
7. Personal Communication with Medical Information Almac Group on behalf of Galen Limited on 11/8/2020
8. Personal Communication with Medical Information Colonis Pharma Ltd on 11/8/2020
9. Personal Communication with Medical Information Mylan UK, Ireland & Malta on 12/09/2020
10. Personal Communication with Medical Information Accord-UK Ltd on 14/8/2020
11. Personal Communication with Medical Information Kyowa Kirin Ltd on 11/8/2020
12. Personal Communication with Strides Pharma UK Ltd on 12/8/2020.
13. Personal Communication with Medical Information ELC Group on behalf of RPH Pharmaceuticals AB on 12/8/2020

## Quality Assurance

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24th September 2020

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### Search strategy

* Electronic Medicines Compendium: ([www.medicines.org.uk/emc](http://www.medicines.org.uk/emc)): [cholecalciferol/ colecalciferol/ ergocalciferol]
* European Medicines Agency (<http://www.ema.europa.eu/ema/>): [peanut soya]
* Manufacturers contacted: Strides Pharma UK Ltd, , Accord-UK Ltd, Colonis Pharma Ltd, Consilient Health Ltd, Galen Ltd, Internis Pharmaceuticals Ltd, Kyowa Kirin Ltd, Mylan, Stirling Anglian Pharmaceuticals Ltd, Thame Laboratories, RPH Pharmaceuticals AB
* Embase: [PEANUT ALLERGY/CROSS REACTION/SOYBEAN]
* Medline: [PEANUT HYPERSENSITIVITY/SOYBEANS/CROSS REACTIONS]
* NHS Evidence: (<http://www.evidence.nhs.uk>): ["peanut allergy" soy]