



sphere™

Backed  
by Science

Curriculum Vitae

Vitaflo sphere. PKU without compromise  
Taste | Nutrition | Convenience



Enhancing Lives Together

## PERSONAL PROFILE



PKU sphere™ is uniquely validated by the largest comprehensive 3-year clinical study in children and young people.<sup>1-4</sup>



PKU sphere has been designed to have a range of adherence optimising features to help support successful management.



All PKU sphere range of products contain the same carefully designed and clinically evaluated GMP:AA protein source.<sup>\*1-3</sup>



## KEY SKILLS



A distinctive 60:40 GMP:AA blend, specifically formulated to maximise taste whilst maintaining metabolic control.<sup>1,5</sup>



PKU sphere meets or exceeds the World Health Organisation (WHO) requirements for essential AA levels from 3 years of age.<sup>1,5,6</sup>



Increased versatility for the management of PKU:<sup>3</sup>

- ✦ PKU sphere empowered up to ~50% of children<sup>†</sup> to fully transition to a GMP-based protein substitute, without compromise.<sup>†1,3</sup>
- ✦ All individuals who required an AA protein substitute alongside PKU sphere (n=16/29), demonstrated good metabolic control<sup>§</sup> and adherence over a 3-year study period.<sup>3</sup>



PKU sphere supports growth, body composition, bone health and protein nourishment<sup>||</sup> in children.<sup>1,3,4</sup>



PKU sphere significantly improved some GI symptoms when compared with AA-based protein substitutes in children with PKU (n=12, ages 4-9 years).<sup>7</sup>

## PKU without compromise

PKU sphere is available in FIVE flavours:



Please refer to additional information on the back page for product flavour profiles.

AA, amino acid; DHA, Docosahexaenoic acid; GI, gastrointestinal; GMP, glycomacropeptide; Phe, phenylalanine

\*The protein source in PKU sphere powder has been extensively researched in children with PKU from 4 years of age<sup>1,3,7</sup> to demonstrate safety, efficacy and metabolic control.<sup>1</sup>

<sup>†</sup>n=13-14 of 29 children (~45-50%) from the 3-year clinical trial.<sup>3</sup>

<sup>‡</sup>Without any adjustment to dietary Phe or compromise to metabolic control.<sup>1,3</sup>

<sup>§</sup>Target blood Phe range for children aged 5-11 years was 120 to  $\leq$ 360  $\mu$ mol/L and for 12 years and older was 120 to  $<$ 600  $\mu$ mol/L.<sup>3</sup>

<sup>||</sup>PKU sphere meets or exceeds the WHO minimum requirements for essential amino acids.<sup>6</sup>

## EXPERIENCE



### Delivers clinically proven long-term benefits from 5-16 years of age<sup>1-4</sup>

- ✦ As a sole source of protein substitute, long-term use of PKU sphere in children may improve growth and body composition when compared to, or when used in combination with AA-based protein substitutes.<sup>3</sup>
- ✦ Comprehensive assessments into bone health have also demonstrated long-term use of PKU sphere helps to support normal bone development.<sup>4</sup>



### Clinically proven to maintain metabolic control<sup>1,3,5</sup>

The specifically formulated blend of AA with GMP significantly influences and maintains metabolic control, \*<sup>§1,5</sup> better stabilising blood Phe levels compared to AA protein substitutes.<sup>8</sup>



### PKU sphere was the preferred protein substitute amongst children and adolescents<sup>1,3</sup>

60% of children and adolescents (n=29/48) preferred PKU sphere over AA-based protein substitutes.<sup>1,3</sup>



### Children have reported that PKU sphere has a positive impact on breath malodour<sup>9</sup>



### PKU sphere supports adults:

In a survey of majority adults (n=31/36, aged >18 years):

- ✦ **91% (n=31)** stated physical properties of PKU sphere supported adherence, including being supplied with a sports shaker, easy to transport and low in volume.<sup>10</sup>
- ✦ **About 80%** of individuals selected taste as a reason to help them consume their protein substitute everyday.<sup>10</sup>

In a study of 9 participants (mean age 30 years):

- ✦ **Adherence to PKU sphere intake was good**, consuming the prescribed amount on 85% of total study days.<sup>11</sup>
- ✦ **Overall metabolic control remained stable on PKU sphere** with metabolic control in 2 participants significantly improving.<sup>11</sup>



## ACHIEVEMENTS

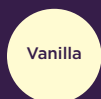
PKU sphere is the only GMP-based protein substitute backed by an extensive, long-term trial in children and adolescents.<sup>1-4</sup>

## ADDITIONAL INFORMATION

### PKU sphere™ 20 powder

Suitable from 4 years of age onwards

**36mg Phe 120 kcals**



PIP CODE: 404-0028



PIP CODE: 409-7473



PIP CODE: 404-0010



PIP CODE: 422-1958



PIP CODE: 422-1941

### PKU sphere™ 15 powder

Suitable from 4 years of age onwards

**28mg Phe 91 kcals**



PIP CODE: 404-8161



PIP CODE: 409-7465



PIP CODE: 404-8005

### PKU sphere™ 20 liquid

Suitable from 3 years of age onwards

**30mg Phe 120 kcals**



PIP CODE: 423-4118



PIP CODE: 425-6665

### PKU sphere™ NEXT15

Suitable from 1 year of age onwards

**23mg Phe 160 kcals**



Neutral

Clinical trials were conducted with PKU sphere powder.

The protein source in PKU sphere powder has been extensively researched in children with PKU from 4 years of age<sup>1,3,7</sup> to demonstrate **safety, efficacy and metabolic control**.<sup>1</sup>



VitaFlo in Association  
With You

VitaFlo in Association (VIA) is a website specifically designed for Health Care Professionals (HCP). It contains educational materials such as information sheets, case studies, practical resources as well as information on events. You can even access films of presentations and previous webinar recordings by various HCPs worldwide. For further information on PKU sphere™ and PKU, please visit: <https://www.vitaflo-via.com/pku-gmp>.

**PKU sphere is a Food for Special Medical Purposes to be used under medical supervision.  
For healthcare professional use only.**

#### References:

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9. Tiele A, Daly A, Hattersley J, et al. Investigation of paediatric PKU breath malodour, comparing glycomacropeptide with phenylalanine free L-amino acid supplements. *J Breath Res* 2019;**14**(1):016001.
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11. Van Calcar SC, Johnson EB, Coode RE. Evaluation of acceptability, tolerance, and metabolic control of patients with Phenylketonuria consuming PKU sphere. Poster. Genetic Metabolic Dietitians International; 2022; Las Vegas, USA.



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