

Dear Valued Customer,

We know that 2022 has been an incredibly tough year for the rare disease community with product recalls, shortages, and supply chain challenges. These challenges have driven us to find as many avenues as possible to provide alternative formula options safely and quickly for this community. That includes, for the first time, offering PKU start™ in the US.

PKU start became available earlier this year when the FDA allowed the importation of this specialized formula from Europe, based on meeting nutrition and safety criteria, for the nutrition management of infants with Phenylketonuria (PKU). **PKU start** has been available and safely used in 20 countries for several years.



Phenylalanine-free infant formula for the nutrition management of PKU. Suitable from birth.

Today, we have exciting news to share! Vitaflo[™] has now imported enough product to support the nutritional needs of around 100 infants with PKU through early 2024 (there are ~300 infants with PKU born annually in the U.S.). We are proud we could now support 1/3 of the PKU infants in the US and we are striving for more. Additionally, we continue to work with the FDA to provide an uninterrupted supply of **PKU start** on a permanent basis.

What does this mean for you?

It means PKU families have more formula options for their infants, and there is ample supply of **PKU start**. Fulfilling the essential nutrition needs of infants with PKU and providing consistent supply of formula in the US is important to **Vitaflo** now and in the future.

To learn more about **PKU start**, please <u>click here</u> or talk to your healthcare provider.

The Vitaflo USA Team

FOR USE UNDER MEDICAL SUPERVISION.

Not suitable for use as a sole source of nutrition. **PKU start** must only be consumed by infants with proven PKU in conjunction with human milk or standard infant formula to provide phenylalanine, fluid, and general nutrition requirements of infants in quantities as advised by a doctor or dietitian. Not for intravenous use. For enteral use only (tube and oral feeding).

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