

## Summary Public Assessment Report

### **Pedismof Preterm, Pedismof Infant, Pedismof**

(isoleucine, serine, histidine, threonine, lysine acetate, sodium glycerophosphate, anhydrous, magnesium sulfate heptahydrate, zinc sulfate heptahydrate, valine, proline, potassium chloride, fish oil, rich in omega-3-acids, alanine, zinc sulfate anhydrous, lysine, leucine, tyrosine, calcium chloride dihydrate, tryptophan, calcium chloride anhydrous, sodium acetate anhydrous, olive oil, refined, soya-bean oil, refined, methionine, phenylalanine, sodium acetate trihydrate, magnesium sulfate, anhydrous, arginine, glucose (anhydrous), triglycerides, medium-chain, glucose monohydrate, glycine, taurine)

**SE/H/2430/01-03/DC**

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aspartic acid, sodium glycerophosphate, anhydrous, tryptophan, lysine, phenylalanine, alanine, histidine, magnesium sulfate, anhydrous, calcium gluconate (monohydrate), methionine, soya-bean oil, refined, leucine, serine, isoleucine, magnesium sulfate heptahydrate, fish oil, rich in omega-3-acids, sodium glycerophosphate, hydrated, taurine, potassium chloride, olive oil, refined, valine, calcium gluconate, anhydrous, glutamic acid, arginine, proline, threonine, cysteine, glucose (anhydrous), glucose monohydrate, glycine, triglycerides, medium-chain, tyrosine, lysine monohydrate, sodium acetate trihydrate, sodium acetate anhydrous

Emulsion for infusion

This is a summary of the public assessment report (PAR) for Pedismof Preterm, Pedismof Infant, Pedismof. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

### **What is Pedismof Preterm, Pedismof Infant, Pedismof and what is it used for?**

The product is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

The product is indicated for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated:

- Pedismof Preterm is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (preterm and term).
- Pedismof Infant is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (preterm and term) and children up to two years of age.
- Pedismof is an emulsion for infusion which is specifically formulated to provide the right nutrition for new-born babies (term), infants, children and adolescents.

### **How does Pedismof Preterm, Pedismof Infant, Pedismof work?**

The product contains amino acids (components used to build proteins), electrolytes (salts), glucose (carbohydrates) and lipids (fat). It is given into your child’s blood by a drip (intravenous infusion) when your child is not able to eat all his or her food by mouth.

### **How is Pedismof Preterm, Pedismof Infant, Pedismof used?**

The pharmaceutical form is emulsion for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration.

The medicine can only be obtained with a prescription in Sweden.

### **What benefits of Pedismof Preterm, Pedismof Infant, Pedismof have been shown in studies?**

As aspartic acid, sodium glycerophosphate, anhydrous, tryptophan, lysine, phenylalanine, alanine, histidine, magnesium sulfate, anhydrous, calcium gluconate (monohydrate), methionine, soya-bean oil, refined, leucine, serine, isoleucine, magnesium sulfate heptahydrate, fish oil, rich in omega-3-

acids, sodium glycerophosphate, hydrated, taurine, potassium chloride, olive oil, refined, valine, calcium gluconate, anhydrous, glutamic acid, arginine, proline, threonine, cysteine, glucose (anhydrous), glucose monohydrate, glycine, triglycerides, medium-chain, tyrosine, lysine monohydrate, sodium acetate trihydrate, sodium acetate anhydrous are well-known substances, and its use for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of aspartic acid, sodium glycerophosphate, anhydrous, tryptophan, lysine, phenylalanine, alanine, histidine, magnesium sulfate, anhydrous, calcium gluconate (monohydrate), methionine, soya-bean oil, refined, leucine, serine, isoleucine, magnesium sulfate heptahydrate, fish oil, rich in omega-3-acids, sodium glycerophosphate, hydrated, taurine, potassium chloride, olive oil, refined, valine, calcium gluconate, anhydrous, glutamic acid, arginine, proline, threonine, cysteine, glucose (anhydrous), glucose monohydrate, glycine, triglycerides, medium-chain, tyrosine, lysine monohydrate, sodium acetate trihydrate, sodium acetate anhydrous in the treatment of the above-mentioned indication.

### **What are the possible side effects from Pedismof Preterm, Pedismof Infant, Pedismof?**

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

### **Why is Pedismof Preterm, Pedismof Infant, Pedismof approved?**

The Swedish Medical Products Agency decided that the benefits are greater than its risks and recommended that it can be approved for use.

### **What measures are being taken to ensure the safe and effective use of Pedismof Preterm, Pedismof Infant, Pedismof?**

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

### **Other information about Pedismof Preterm, Pedismof Infant, Pedismof**

The full PAR for Pedismof Preterm, Pedismof Infant, Pedismof can be found on the following website: [MRI - Home](#). For more information about treatment with Pedismof Preterm, Pedismof Infant, Pedismof, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-08.