

# DEVELOPMENT OF ENTERAL NUTRITION SUPPORT FORMULAS

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Technical, bibliographic, regulatory and sourcing study for adults with advanced illness and undernourished maternal and child populations

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**RESEARCH AND PREFORMULATION DOCUMENT. This is not a medical prescription or an authorized formula for human use.**

## Purpose

To establish a scientific and technological basis for two highly sensitive needs: a high calorie, high protein enteral formula for adults with advanced illness, and a differentiated nutrition strategy for children 6 to 59 months old and undernourished pregnant or lactating women. The study converts current literature and standards into realistic prototypes, raw material specifications, sourcing routes and a validation program.

## Executive conclusion

The industrial opportunity is viable only as a product family, not as a universal mixture. The adult candidate may advance as a food for special medical purposes under professional supervision. The maternal and child line must be divided into a maternal supplement and a pediatric recovery product; severe acute malnutrition must continue to be treated with WHO protocols and validated therapeutic products. The appropriate next step is stage gated development with a regulatory dossier, pilot batches, stability, safety, tolerance and clinical evaluation.

## Decision summary

| Decision             | Recommendation                                                                                   |
|----------------------|--------------------------------------------------------------------------------------------------|
| One formula for all  | No. Develop three profiles with separate labeling and dosing.                                    |
| Protein              | WPH as a major adult component; pediatric use only in a specific framework.                      |
| Free amino acids     | Start without a broad cocktail; correct only against the amino acid profile and clinical target. |
| Industrial format    | Powder for initial feasibility; UHT liquid as a second platform.                                 |
| Severe child wasting | Follow WHO F 75 F 100 or validated RUTF; the prototype does not replace them.                    |

## 1 Scope and central criterion

Enteral food includes products given orally or through a feeding tube when the gastrointestinal tract functions. Indication, route, rate and duration depend on diagnosis, gastrointestinal function, aspiration risk, renal and hepatic status, patient goals and consent. Near the end of life, feeding is not automatically beneficial; each decision should be individualized, proportionate and reviewable.

The proposed formulation is not intended to treat disease or replace an adequate regular diet. It is conceived as a food for special medical purposes used under medical supervision. Infants under six months, patients with inborn errors of metabolism, cow milk protein allergy, decompensated renal or hepatic failure, and conditions requiring disease specific formulas are excluded.

## 2 Clinical evidence for adults with advanced illness

In cancer and catabolic disease, ESPEN uses 25 to 30 kcal per kilogram per day and more than 1 g protein per kilogram per day, reaching 1.5 g/kg/day when possible, as starting points. These are clinical targets, not automatic instructions; they require adjustment for body composition, inflammation, activity, treatment and tolerance.

An energy density of 1.5 kcal/mL reduces required volume and can help with anorexia, early satiety or fluid restriction. Hydrolyzed protein can aid dispersion and digestion, but does not by itself guarantee better clinical outcomes. Bitterness, osmotic load and cost rise with the degree of hydrolysis. Peptides, free amino acids, carbohydrates, fats and fiber must be balanced.

Tube feeding requires controlled viscosity, low sedimentation, compatible particle size, strict hygiene and defined hang times after opening or reconstitution. In palliative care, comfort, thirst relief, preferences and shared goals take priority; artificial nutrition may be discontinued when burden exceeds expected benefit.

### 3 Evidence for child and maternal undernutrition

WHO distinguishes severe acute malnutrition, moderate wasting, nutritional risk and recovery. During stabilization of severe acute malnutrition, F 75 limits protein, sodium and metabolic load. F 100 or ready to use therapeutic food is used during transition and rehabilitation according to protocols. An experimental high protein formula must not be used during stabilization.

For children 6 to 59 months old without complications and in recovery, a complementary product may be developed within the applicable composition and with monitoring of growth, edema, appetite, infections and electrolytes. Breastfeeding must be protected. Infants under six months require a separate clinical program centered on breastfeeding and mother infant care.

In undernourished populations, WHO recommends balanced energy and protein supplementation during pregnancy, avoiding an excessive share of energy from protein. A supplement does not replace national iron, folic acid or other antenatal regimens and must account for nausea, gestational diabetes, anemia and access to a diverse diet.

### 4 Recommended product portfolio

Product A Adult 1.5: ready to drink liquid or reconstitutable powder, complete or supplemental, for adults under supervision. Product B Child Recovery: only for children 6 to 59 months in recovery and according to local protocol; not for stabilization of severe acute malnutrition. Product C Maternal BEP: balanced energy protein serving for undernourished pregnant or lactating women.

Separating products reduces dosing errors, permits age appropriate micronutrients and prevents children from receiving adult levels of protein, minerals or free amino acids. It also simplifies regulatory dossiers, labeling, trials and traceability.

| Product        | Population                            | Format                     | Critical control                        |
|----------------|---------------------------------------|----------------------------|-----------------------------------------|
| Adult 1.5      | Adults with a clinical indication     | 250 mL RTD or powder       | Tolerance, osmolality, renal function   |
| Child Recovery | 6 to 59 months, recovery              | Closed dose or safe powder | WHO protocol and clinical monitoring    |
| Maternal BEP   | Undernourished pregnancy or lactation | Sachet or beverage         | Coordination with antenatal supplements |

### 5 Ingredient selection and rationale

Protein: select a whey protein hydrolysate specified for degree of hydrolysis, molecular weight distribution, dry basis protein, lactose, fat, ash, moisture, solubility, allergens and microbiology. A

hydrolysate remains milk derived and must not be labeled hypoallergenic without supporting evidence and authorization.

Amino acids: whey already supplies all essential amino acids. Fortification should correct a demonstrated compositional target, not add a list by intuition. Methionine and cysteine require control of total sulfur amino acids; arginine may be problematic in specific conditions; tryptophan affects stability and taste. Limit free amino acids in the first prototype and adjust only after amino acid profile analysis.

Carbohydrates: low dextrose equivalent maltodextrin and glucose syrup solids provide energy with moderate sweetness. Simple sugars should be limited. Fats: combine high oleic oil, canola and MCT with controlled sources of linoleic and alpha linolenic acids. Long chain omega 3 oils require antioxidants, barrier packaging and oxidation studies.

Fiber: use a low viscosity soluble blend, such as resistant dextrin or partially hydrolyzed guar gum, and titrate clinically. In therapeutic pediatric foods, every fiber and additive must meet the specific standard. Micronutrients: prefer a professionally designed premix. Chelated salts may improve tolerance in some settings, but superiority should not be assumed without finished product stability and bioavailability data.

## 6 Technical and clinical risks

Key risks include refeeding syndrome, phosphorus, potassium and magnesium shifts, fluid overload, hyperglycemia, aspiration, diarrhea, constipation, contamination of reconstituted product, milk allergy, micronutrient excess and medication interactions. A formula cannot compensate for an incorrect administration rate.

The repeated L arginine in the initial brief is treated as a list error, not an instruction to double the dose. Vitamin B8 may mean inositol in some countries, whereas B7 is biotin; common number labels must be replaced by chemical names and quantities.

Mineral classification clarification: potassium K, phosphorus P and calcium Ca are macrominerals, as are magnesium Mg, sodium Na and chloride Cl, because the body requires them in relatively large amounts. Zinc Zn, copper Cu, selenium Se, chromium Cr, iron Fe, manganese Mn, iodine I and molybdenum Mo are trace minerals. In an enteral formula, K, P, Ca and Mg must be adjusted for age, renal function, refeeding stage and total daily intake. In addition to chemical form, elemental dose, the calcium to phosphorus relationship, solubility, interactions and osmotic load must be controlled. Chelates or glycinate salts do not replace these controls.

## 7 Proposed manufacturing process

Powder process: quarantined receipt, sampling, screening, microingredient premixing, staged blending, addition of powdered fat or agglomeration, homogeneity testing, metal detection and filling under low humidity and protective atmosphere. Validation must demonstrate micronutrient uniformity, wettability, dispersibility, bulk density and stability.

Liquid process: treated water, controlled dispersion, protein and stabilizer hydration, emulsification, homogenization, validated UHT processing and aseptic filling. Heat sensitive vitamins require suitable forms, technically justified overages and end of shelf life verification. Commercial sterility does not replace raw material control.

The quality system should integrate HACCP, good manufacturing practices, allergen management, food defense, supplier approval, lot traceability, recall planning, environmental monitoring and accredited laboratory testing. For pediatric populations, Cronobacter and Salmonella deserve special attention according to category and process.

## 8 Regulatory strategy

In Argentina, classification should be discussed with ANMAT and the competent food authority before labeling or claims are fixed. Establishment and product registrations, quantitative composition, manufacturing process, specifications, stability, labeling, evidence for intended use and safety substantiation are required. Applicable Argentine Food Code and Mercosur rules should be confirmed in a formal classification meeting.

Codex CXS 180 covers the concept and labeling of foods for special medical purposes; CXS 72 covers infant formulas and CXS 95 covers ready to use therapeutic foods. The European Union applies Delegated Regulation 2016/128. In the United States the path depends on positioning, ingredients and population; dedicated regulatory advice and review of GRAS or other permitted use status is required for each component.

Claims such as cure, anti aging, guaranteed recovery, hypoallergenic or superior absorption should not be used without admissible evidence. Labels should state medical supervision, intended population, preparation, storage, allergens, osmolality or osmolality when appropriate, and not for parenteral use.

## 9 Development and validation program

Stage 0: define indication, population, exclusions, market and target product profile. Stage 1: regulatory gap analysis and permitted ingredients. Stage 2: bench formulation and sensory evaluation. Stage 3: pilot batch and process validation. Stage 4: accelerated and real time stability. Stage 5: tolerance and performance study under an ethical protocol. Stage 6: industrial transfer, dossier and controlled launch.

Minimum criteria include identity and potency, amino acid profile, energy by validated calculation or calorimetry, fat and fatty acids, vitamins and minerals at release and end of shelf life, water activity, moisture, pH, viscosity, osmolality, peroxide value, anisidine value, microbiology, contaminants, allergens, reconstitution and flow through representative feeding tubes.

## 10 Quantitative working prototypes

The following quantities are development targets, not a manufacturing or administration recipe. Actual totals depend on raw material assays, density, losses and the regulatory framework.

### 10.1 Adult 1.5 per liter

| Parameter     | Target        | Equivalent             | Comment                                                                      |
|---------------|---------------|------------------------|------------------------------------------------------------------------------|
| Energy        | 1.50 kcal/mL  | 1,500 kcal/L           | High density at lower volume                                                 |
| Total protein | 7.5 g/100 mL  | 75 g/L; 20% of energy  | 70 to 85% WPH with the balance as intact milk protein according to tolerance |
| Carbohydrate  | 18.0 g/100 mL | 180 g/L; 48% of energy | Maltodextrin and glucose syrup solids; adjust sweetness and osmolality       |
| Fat           | 5.3 g/100 mL  | 53 g/L; 32% of energy  | High oleic, canola and MCT; validate essential fatty acid profile            |

| Parameter      | Target                               | Equivalent                                                      | Comment                                                        |
|----------------|--------------------------------------|-----------------------------------------------------------------|----------------------------------------------------------------|
| Fiber          | 1.5 g/100 mL                         | 15 g/L                                                          | Low viscosity soluble fiber; fiber free version when indicated |
| Water          | Balance                              | To 1 L                                                          | Validated process water quality                                |
| Micronutrients | Target per 1,000 to 1,500 kcal       | At least 100% of reference value only if nutritionally complete | Adjust for law, losses and upper limits                        |
| Osmolality     | Preliminary target below 450 mOsm/kg | Confirm by testing                                              | Reduce free amino acids and highly dissociated salts if needed |

## 10.2 Child Recovery

| Parameter      | Preliminary target                                                | Condition                                                                         |
|----------------|-------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| Intended use   | Recovery, 6 to 59 months                                          | Not for stabilization of severe acute malnutrition                                |
| Energy         | 100 kcal/100 mL reconstituted                                     | Align with F 100 only as a density reference, not therapeutic equivalence         |
| Protein        | 2.9 to 3.2 g/100 mL                                               | Hydrolyzed whey with dairy matrix; validate protein quality and renal solute load |
| Fat            | 5.0 to 5.5 g/100 mL                                               | Fatty acid profile must meet the applicable standard                              |
| Carbohydrate   | 11 to 13 g/100 mL                                                 | Adjust to achieve energy target and osmolality                                    |
| Micronutrients | According to CXS 95, WHO protocol and national rules              | Do not extrapolate adult levels                                                   |
| Electrolytes   | Clinically controlled potassium, phosphorus, magnesium and sodium | Overall balance matters more than using chelates alone                            |
| Presentation   | Prefer a closed dose or high safety powder                        | Reconstitution with unsafe water can eliminate benefit                            |

## 10.3 Maternal BEP per serving

| Parameter          | Preliminary target | Condition                                                              |
|--------------------|--------------------|------------------------------------------------------------------------|
| Energy per serving | 350 to 450 kcal    | Supplement, not total diet replacement                                 |
| Protein            | 18 to 22 g         | 16 to 22% of energy in this concept; maintain balanced supplementation |

| Parameter      | Preliminary target                                    | Condition                                                             |
|----------------|-------------------------------------------------------|-----------------------------------------------------------------------|
| Fat            | 12 to 16 g                                            | Include essential fatty acids; DHA according to policy and assessment |
| Carbohydrate   | 45 to 60 g                                            | Limit free sugars and adapt to tolerance                              |
| WPH            | Part of protein, not necessarily 100%                 | Balance cost, palatability and tolerance                              |
| Micronutrients | Antenatal profile coordinated with the health program | Avoid duplicating iron, vitamin A or other supplements                |

## 10.4 Preliminary ingredient mass balance

The balance approximates a laboratory batch and must be normalized to 100% after measuring protein, moisture, ash and fat in each input. The free amino acids in the initial brief are initially set at zero: lysine, cysteine, methionine, arginine, glycine and tryptophan will be added only if the amino acid profile demonstrates a gap against the selected reference pattern.

### Adult liquid per liter

| Ingredient                            | Starting quantity | Function and adjustment                                                    |
|---------------------------------------|-------------------|----------------------------------------------------------------------------|
| WPH at 80% protein                    | 85 g              | Provides about 68 g protein; correct against the actual certificate        |
| Complementary milk protein at 88%     | 8 g               | Provides about 7 g; may be omitted with WPH adjustment                     |
| Maltodextrin and glucose syrup solids | 180 g             | Split according to osmolality, sweetness and processing                    |
| Oil blend                             | 53 g              | Concept example: 50% high oleic, 30% canola, 20% MCT; validate fatty acids |
| Soluble fiber                         | 15 g              | Resistant dextrin or PHGG; fiber free option                               |
| Emulsifier and stabilizer             | 2 to 5 g          | Only permitted additives at the minimum technological level                |
| Vitamin mineral premix                | q.s.              | Designed against daily serving, law, losses and upper limits               |
| Flavor and sweetening                 | q.s.              | Mask bitterness without excessive sugar or osmolality                      |
| Treated water                         | to 1 L            | For liquid; define powder solids and reconstitution after testing          |

## Maternal supplement per serving

| Ingredient                                        | Starting quantity  | Function and adjustment                                     |
|---------------------------------------------------|--------------------|-------------------------------------------------------------|
| WPH at 80% protein                                | 18 g               | Provides about 14.4 g protein                               |
| Skim milk powder                                  | 12 g               | Provides about 4 g protein and milk solids                  |
| Maltodextrin                                      | 48 g               | Moderately sweet energy source                              |
| Instant oat flour or validated local carbohydrate | 20 g               | Improves nutrient density and acceptance; control allergens |
| Powdered oil or lipid emulsion                    | 15 g effective fat | Adjust essential fatty acids and oxidation                  |
| Maternal premix                                   | q.s.               | Coordinate with iron, folic acid and antenatal supplements  |
| Flavor and carrier                                | q.s.               | Complete a serving near 400 kcal after analysis             |

## 11 Purchasing specifications

| Block              | Minimum requirement                                                                      |
|--------------------|------------------------------------------------------------------------------------------|
| Identity and grade | Chemical name, origin, authorized food use and lot number.                               |
| Certificates       | Lot CoA, technical sheet, SDS, allergens, GMO, BSE TSE, Halal Kosher when required.      |
| Safety             | Microbiology, heavy metals, pesticides, mycotoxins and solvents according to risk.       |
| Performance        | Solubility, particle size, flavor, color, hygroscopicity, viscosity and stability.       |
| Supply chain       | Origin plant, qualified second site, MOQ, lead time, Incoterm, shelf life and transport. |

## 12 Supply centers and sourcing routes

Reference suppliers verified through public information as of September 15, 2026. Inclusion is not a commercial endorsement; availability, grade, representation, price and authorization require written confirmation, samples and audit.

| Raw material             | Manufacturer or route  | Center                  | Qualification criterion                                                        | Website                                                                                   |
|--------------------------|------------------------|-------------------------|--------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| Whey protein hydrolysate | Arla Foods Ingredients | Denmark / international | Food, infant or medical nutrition grade; request degree of hydrolysis, peptide | <a href="https://www.arlafoodsingredients.com/">https://www.arlafoodsingredients.com/</a> |

| Raw material             | Manufacturer or route          | Center                        | Qualification criterion                                                                    | Website                                                                                     |
|--------------------------|--------------------------------|-------------------------------|--------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
|                          |                                |                               | profile, allergen and microbiology dossier                                                 |                                                                                             |
| Whey protein hydrolysate | Agropur Ingredients<br>BioZate | United States / Canada        | Hydrolyzed WPI; verify intended population and local approval                              | <a href="https://www.agropuringredients.com/">https://www.agropuringredients.com/</a>       |
| Whey protein hydrolysate | Hilmar Ingredients             | United States                 | Hydrolyzed whey options; obtain current technical data sheet and certificate of analysis   | <a href="https://www.hilmar.com/">https://www.hilmar.com/</a>                               |
| L amino acids            | Ajinomoto Health and Nutrition | Japan / Americas / Europe     | Food or compendial grade according to use; individual identity and purity testing          | <a href="https://www.ajihealthandnutrition.com/">https://www.ajihealthandnutrition.com/</a> |
| L amino acids            | Evonik Health Care             | Germany / international       | Pharmaceutical and nutrition amino acid portfolio; confirm food eligibility by market      | <a href="https://healthcare.evonik.com/">https://healthcare.evonik.com/</a>                 |
| Vitamin premix           | dsm firmenich                  | Switzerland / international   | Custom premix with overage and stability support                                           | <a href="https://www.dsm-firmenich.com/">https://www.dsm-firmenich.com/</a>                 |
| Vitamin premix           | SternVitamin                   | Germany / international       | Customized micronutrient premixes for beverages and medical nutrition                      | <a href="https://sternvitamin.com/">https://sternvitamin.com/</a>                           |
| Vitamins and carotenoids | BASF Human Nutrition           | Germany / international       | Food grade vitamins; technical and stability documentation                                 | <a href="https://nutrition.basf.com/">https://nutrition.basf.com/</a>                       |
| Chelated minerals        | Balchem Albion Minerals        | United States / international | Bisglycinates and chelates; confirm elemental mineral assay and sensory impact             | <a href="https://balchem.com/">https://balchem.com/</a>                                     |
| Mineral salts            | Jungbunzlauer                  | Switzerland / EU / Americas   | Citrates, gluconates and phosphates for food applications                                  | <a href="https://www.jungbunzlauer.com/">https://www.jungbunzlauer.com/</a>                 |
| Carbohydrates and fibers | Tate and Lyle                  | United Kingdom / Americas     | Maltodextrins, soluble fibers and texture systems; medical nutrition suitability to verify | <a href="https://www.tateandlyle.com/">https://www.tateandlyle.com/</a>                     |
| Carbohydrates and        | Cargill                        | United States /               | Maltodextrin, glucose                                                                      | <a href="https://">https://</a>                                                             |

| Raw material                       | Manufacturer or route     | Center                      | Qualification criterion                                                                                                  | Website                                                                          |
|------------------------------------|---------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| lipids                             |                           | international               | syrups, oils and emulsification support                                                                                  | <a href="http://www.cargill.com/food-beverage">www.cargill.com/food-beverage</a> |
| MCT lipids                         | IOI Oleo                  | Germany / international     | MCT oils and powders; request food grade oxidation specifications                                                        | <a href="https://www.ioioleo.de/">https://www.ioioleo.de/</a>                    |
| Omega 3 oils                       | KD Pharma                 | Germany / international     | EPA and DHA concentrates; oxidation and contaminant specifications                                                       | <a href="https://www.kdpharmagroup.com/">https://www.kdpharmagroup.com/</a>      |
| Aseptic processing and packaging   | Tetra Pak                 | International               | Pilot and industrial processing, UHT and aseptic packaging integration                                                   | <a href="https://www.tetrapak.com/">https://www.tetrapak.com/</a>                |
| Regional sourcing and distribution | IMCD / Brenntag / Barentz | Argentina and Latin America | Potential regional sourcing route; actual representation, stock and authorization must be confirmed by written quotation | <a href="https://www.imcdgroup.com/">https://www.imcdgroup.com/</a>              |

## 13 Sourcing strategy for Argentina

Request concurrent quotations from one primary manufacturer and two regional distributors. Clearly distinguish general food grade, medical nutrition grade and pediatric nutrition grade. Do not accept trade name substitutions without comparing composition and certificates.

Qualify at least two sources for WPH, the vitamin mineral premix and the lipid system. Import enough material for pilot and stability lots and retain samples. Confirm tariffs, sanitary intervention, package labeling and transport humidity or temperature requirements with a specialized customs broker.

Delay final premix design until the daily serving and shelf life are frozen. Overages must be supported by degradation data; excessive overage may exceed safety limits at the beginning of shelf life.

## 14 Testing plan

| Stage            | Essential tests                                                                                       |
|------------------|-------------------------------------------------------------------------------------------------------|
| Raw material     | Identity, potency, moisture, microbiology, contaminants and allergens.                                |
| In process       | Homogeneity, pH, viscosity, temperature, water activity and UHT controls.                             |
| Finished product | Composition, osmolality, sterility or microbiology, sensory properties, reconstitution and packaging. |
| Stability        | Vitamin potency, fat oxidation, color, flavor, moisture, seal                                         |

| Stage        | Essential tests                                                                      |
|--------------|--------------------------------------------------------------------------------------|
|              | integrity and migration.                                                             |
| Clinical use | Gastrointestinal tolerance, achieved intake, adverse events and predefined outcomes. |

## 15 Working questions

- Which regulatory market comes first: Argentina, Mercosur, the United States or the European Union?
- Will the adult product be nutritionally complete or a modular supplement?
- What exact pediatric population will be included and which groups will be excluded?
- Will the company manufacture powder, aseptic liquid, or both?
- What daily volume, energy density and target cost per serving are required?
- Which clinical institution will lead tolerance, safety and nutritional performance studies?
- Which suppliers can guarantee traceability, continuity, certificates and compatible minimum order quantities?
- What will be the nutrition safety surveillance and product recall plan?

## 16 Nutritional dictionary of components

This dictionary describes general physiological functions. A nutrient contributes to normal processes, but does not act alone or guarantee prevention, cure or reversal of disease. In clinical nutrition, benefit depends on indication, dose, the complete formula, absorption, coexisting disease and professional monitoring.

### 16 1 Proteins and peptides

| Element                     | What it is                                                                    | General contribution                                                                                               | Main caution                                                                                                        |
|-----------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| Whey protein                | A complete dairy protein rich in indispensable amino acids.                   | Provides nitrogen and amino acids for tissue maintenance and repair and for enzymes, hormones and immune proteins. | Milk allergen; intake must fit age, renal function and nutrition goals.                                             |
| Hydrolyzed whey protein WPH | Whey treated with enzymes to split part of the protein into smaller peptides. | May aid digestion and dispersion and supplies rapidly available protein.                                           | Not automatically hypoallergenic or clinically superior; greater hydrolysis may increase bitterness and osmolality. |
| Peptides                    | Short amino acid chains produced by hydrolysis.                               | Absorbed through intestinal transport systems and contribute to total protein supply.                              | Profile depends on processing; molecular weight, taste, stability and ingredient evidence require control.          |

### 16 2 Amino acids

| Element  | What it is                | General contribution       | Main caution                 |
|----------|---------------------------|----------------------------|------------------------------|
| L lysine | Indispensable amino acid. | Supports protein synthesis | Whey is usually lysine rich; |

| Element            | What it is                                                       | General contribution                                                                | Main caution                                                                 |
|--------------------|------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
|                    |                                                                  | and tissue formation and can complement lysine limited proteins.                    | fortify only after amino acid profiling.                                     |
| L cysteine         | Sulfur amino acid that can become conditionally indispensable.   | Part of proteins and glutathione synthesis.                                         | Evaluate together with methionine and oxidation stability.                   |
| L methionine       | Indispensable sulfur amino acid and methyl donor.                | Supports protein synthesis and pathways producing cysteine and other compounds.     | Excess can disturb amino acid balance; control total sulfur amino acids.     |
| L arginine         | Conditionally indispensable amino acid.                          | Participates in the urea cycle, protein synthesis and nitric oxide production.      | Do not double dose; targeted use requires clinical review.                   |
| Glycine            | Nonindispensable amino acid and protein component.               | Participates in collagen, glutathione, creatine and metabolic conjugation.          | Can change taste and osmotic load and does not replace complete protein.     |
| L tryptophan       | Indispensable amino acid.                                        | Needed for protein synthesis and is a precursor of niacin, serotonin and melatonin. | Sensitive to degradation; do not make mood or sleep claims without evidence. |
| Amino acid profile | Quantitative measurement of amino acids in a protein or formula. | Shows whether the product meets the reference pattern for the target population.    | Must be interpreted with digestibility, not total protein alone.             |

## 16 3 Macrominerals

| Element                   | What it is                                             | General contribution                                                          | Main caution                                                                               |
|---------------------------|--------------------------------------------------------|-------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
| Potassium K               | Main intracellular cation.                             | Supports fluid balance, nerve transmission and muscle contraction.            | Low or high levels can affect cardiac rhythm; adjust in refeeding and renal disease.       |
| Phosphorus P              | Structural and metabolic mineral present as phosphate. | Builds bone and teeth and is part of ATP, membranes and acid base regulation. | Can fall dangerously during refeeding; control renal function and calcium relationship.    |
| Calcium Ca                | Macromineral stored mainly in bone.                    | Supports bone, muscle contraction, nerve signaling and coagulation.           | Control vitamin D context, calcium phosphorus relationship, solubility and interactions.   |
| Magnesium Mg              | Intracellular cation and enzyme cofactor.              | Supports energy production, protein synthesis and neuromuscular function.     | Deficiency and excess are clinically important; adjust in refeeding and renal dysfunction. |
| Sodium Na and chloride Cl | Major extracellular electrolytes.                      | Maintain volume, osmotic and acid base balance; chloride contributes to       | Excess can promote fluid retention in susceptible patients.                                |

| Element | What it is | General contribution | Main caution |
|---------|------------|----------------------|--------------|
|         |            | gastric acid.        |              |

## 16 4 Trace minerals

| Element       | What it is                                                               | General contribution                                                                   | Main caution                                                                          |
|---------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Zinc Zn       | Cofactor for many enzymes.                                               | Supports DNA and protein synthesis, immunity, growth and normal wound healing.         | High doses interfere with copper; elemental amount matters.                           |
| Copper Cu     | Trace element incorporated into enzymes.                                 | Supports iron metabolism, connective tissue, nervous function and antioxidant defense. | Excess can be toxic; control zinc copper balance and hepatobiliary disease.           |
| Selenium Se   | Component of selenoproteins.                                             | Supports antioxidant defense, thyroid metabolism and immune function.                  | Relatively narrow margin between need and excess.                                     |
| Chromium Cr   | Trace element whose essentiality and supplement response remain debated. | May participate in macronutrient metabolism, but added benefits are not established.   | Do not promise glucose control; exclude toxic hexavalent chromium.                    |
| Iron Fe       | Part of hemoglobin, myoglobin and enzymes.                               | Enables oxygen transport and energy metabolism.                                        | Do not add indiscriminately; assess inflammation, infection and prenatal duplication. |
| Manganese Mn  | Enzyme cofactor.                                                         | Supports metabolism, bone formation and antioxidant systems.                           | Can accumulate with liver disease or excessive exposure.                              |
| Iodine I      | Component of thyroid hormones.                                           | Supports thyroid function, growth and neurologic development.                          | Both deficiency and excess affect thyroid function.                                   |
| Molybdenum Mo | Cofactor for several enzymes.                                            | Participates in sulfur compound and purine metabolism.                                 | Needed only in very small amounts; avoid overformulation.                             |

## 16 5 Vitamins

| Element               | What it is                          | General contribution                                                         | Main caution                                                                       |
|-----------------------|-------------------------------------|------------------------------------------------------------------------------|------------------------------------------------------------------------------------|
| Vitamin B1 thiamin    | Water soluble coenzyme vitamin.     | Essential for carbohydrate metabolism and nerve function.                    | Critical before and during refeeding in at risk patients; sensitive to processing. |
| Vitamin B2 riboflavin | Precursor of FAD and FMN coenzymes. | Supports energy production and metabolism of fats, drugs and other vitamins. | Light sensitive; use protective packaging.                                         |

| Element                            | What it is                                                                | General contribution                                                                                | Main caution                                                                          |
|------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Vitamin B3 niacin                  | Includes nicotinic acid and nicotinamide.                                 | Forms NAD and NADP for energy reactions and cellular repair.                                        | Pharmacologic doses cause adverse effects; use authorized nutrition levels.           |
| Vitamin B5 pantothenic acid        | Part of coenzyme A.                                                       | Supports fatty acid synthesis and breakdown and many metabolic pathways.                            | Deficiency is rare; account for processing loss.                                      |
| Vitamin B7 biotin                  | Cofactor vitamin for carboxylases.                                        | Supports fat, glucose and amino acid metabolism.                                                    | High doses can interfere with laboratory tests.                                       |
| Inositol called B8 in some markets | Vitamin like compound not universally recognized as an essential vitamin. | Part of phospholipids and cell signaling.                                                           | Do not confuse with biotin; permitted use and claims vary by jurisdiction.            |
| Vitamin B9 folate                  | Family of food folates and folic acid used in fortification.              | Needed for DNA synthesis, cell division and blood formation; especially important around pregnancy. | Coordinate with prenatal programs; high folic acid can mask B12 deficiency.           |
| Vitamin B12 cobalamin              | Water soluble cobalt containing vitamin.                                  | Supports red blood cells, neurologic function and DNA synthesis.                                    | Absorption can be reduced by disease or medication; verify stability and potency.     |
| Vitamin C ascorbic acid            | Water soluble antioxidant vitamin.                                        | Supports collagen synthesis, nonheme iron absorption and antioxidant protection.                    | Degraded by oxygen, heat, light and metals; requires justified overage and packaging. |

## 16 6 Lipids

| Element                        | What it is                                                | General contribution                                                                       | Main caution                                                                            |
|--------------------------------|-----------------------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| Total lipids                   | Energy nutrients including triglycerides and fatty acids. | Provide concentrated energy, essential fatty acids and absorption of fat soluble vitamins. | Amount, quality, tolerance and oxidation all matter.                                    |
| Medium chain triglycerides MCT | Fats containing medium length fatty acids.                | Relatively easy to digest and absorb and provide concentrated energy.                      | Do not supply all essential fatty acids; excess can cause gastrointestinal intolerance. |
| High oleic and canola oils     | Predominantly unsaturated oil sources.                    | Provide energy and help reduce the saturated share of the fat profile.                     | Control origin, refining, stability, allergens and omega balance.                       |
| Linoleic acid omega 6          | Essential fatty acid.                                     | Supports membranes, growth and lipid mediator production.                                  | Maintain proportional balance with other fats.                                          |
| Alpha linolenic acid omega 3   | Essential plant fatty acid.                               | Supports membranes and is a limited precursor of EPA and DHA.                              | Conversion is low and the oil oxidizes readily.                                         |

| Element                        | What it is                                   | General contribution                                           | Main caution                                                                             |
|--------------------------------|----------------------------------------------|----------------------------------------------------------------|------------------------------------------------------------------------------------------|
| EPA and DHA long chain omega 3 | Marine or algal polyunsaturated fatty acids. | Components of membranes; DHA is important in retina and brain. | Require oxidation and contaminant specifications; claims and doses need specific review. |

## 16 7 Carbohydrates and fiber

| Element                            | What it is                                               | General contribution                                                                       | Main caution                                                                   |
|------------------------------------|----------------------------------------------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Carbohydrates                      | A principal energy substrate group.                      | Supply glucose and energy and spare protein from use as fuel.                              | Source and delivery rate affect glycemia, tolerance and osmolality.            |
| Maltodextrin                       | Glucose polymers made from starch.                       | Provides energy with less sweetness and often less osmotic contribution than free glucose. | Raises blood glucose and is not fiber; specify source and dextrose equivalent. |
| Glucose syrup solids               | Starch derived carbohydrates of different chain lengths. | Supply energy and processing functionality.                                                | Control dextrose equivalent, sugars, osmolality and glycemic effect.           |
| Simple sugars                      | Rapidly available mono and disaccharides.                | Provide energy and palatability.                                                           | Excess increases sweetness, osmotic load and glycemic exposure.                |
| Resistant dextrin                  | Low viscosity fermentable soluble fiber.                 | May support bowel regularity and microbial metabolite production.                          | Introduce gradually; may cause gas and is not suitable for every condition.    |
| Partially hydrolyzed guar gum PHGG | Reduced viscosity soluble fiber.                         | May help normalize stool consistency and frequency in some people.                         | Response varies; validate tube flow, tolerance and stability.                  |

### How to interpret the dictionary

- Deficiency, adequacy and excess are different states; more does not mean greater benefit.
- Chemical form is only one determinant. Elemental dose, matrix, stability, interactions and tolerance also matter.
- In undernourished patients, refeeding alters phosphorus, potassium, magnesium, glucose and thiamin and requires clinical monitoring.
- Final values must be stated per 100 mL, per serving and per intended daily intake and verified at end of shelf life.
- Children and pregnant women have their own standards, limits and reference patterns; adult amounts must not be extrapolated.

## 17 Bibliographic and regulatory references

1. ESPEN practical guideline Clinical Nutrition in cancer. Muscaritoli et al., Clinical Nutrition 2021. <https://pubmed.ncbi.nlm.nih.gov/33946039/>
2. ESPEN guideline on hospital nutrition. Thibault et al., Clinical Nutrition 2021. [https://www.espen.org/files/ESPEN-Guidelines/ESPEN\\_guideline\\_on\\_hospital\\_nutrition.pdf](https://www.espen.org/files/ESPEN-Guidelines/ESPEN_guideline_on_hospital_nutrition.pdf)

3. ESPEN practical guideline Ethical aspects of medical nutrition therapy. Cardenas et al., Clinical Nutrition 2026.  
<https://www.espen.org/guidelines-home/espen-guidelines>
4. WHO guideline on prevention and management of wasting and nutritional oedema. World Health Organization, 2023.  
<https://www.who.int/publications/i/item/9789240082830>
5. Updates on management of severe acute malnutrition in infants and children. World Health Organization, 2013.  
<https://www.who.int/publications/i/item/9789241506328>
6. Technical note on supplementary foods for moderate acute malnutrition 6 to 59 months. WHO, 2012.  
<https://iris.who.int/handle/10665/75836>
7. Guidelines for Ready to Use Therapeutic Foods CXS 95 2022. Codex Alimentarius, 2022. <https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/>
8. Standard for labelling of and claims for foods for special medical purposes CXS 180 1991. Codex Alimentarius.  
<https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/>
9. Standard for infant formula and formulas for special medical purposes intended for infants CXS 72 1981. Codex Alimentarius. <https://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/>
10. WHO recommendations on antenatal care for a positive pregnancy experience. World Health Organization, 2016 updated resources. <https://www.who.int/publications/i/item/9789241549912>
11. Vitamin and mineral requirements in human nutrition second edition. WHO and FAO, 2004.  
<https://www.who.int/publications/i/item/9241546123>
12. Dietary Reference Intakes collection. US National Academies. <https://www.nal.usda.gov/human-nutrition-and-food-safety/dri-calculator>
13. Regulation EU 2016 128 foods for special medical purposes. European Commission.  
[https://eur-lex.europa.eu/eli/reg\\_del/2016/128/oj](https://eur-lex.europa.eu/eli/reg_del/2016/128/oj)
14. Código Alimentario Argentino and food registration resources. ANMAT Argentina.  
<https://www.argentina.gob.ar/anmat/regulados/alimentos>
15. BioZate hydrolyzed whey protein. Agropur Ingredients. <https://www.agropuringredients.com/ingredients/branded-ingredients/biozate/>
16. Whey protein hydrolysates and medical nutrition ingredients. Arla Foods Ingredients.  
<https://www.arlafoodsingredients.com/our-ingredients/whey-protein-hydrolysate/>
17. Hydrolyzed whey protein product information. Hilmar Ingredients. <https://www.hilmar.com/ingredients/whey-protein/>
18. Amino acid solutions and quality grades. Ajinomoto Health and Nutrition.  
<https://www.ajihealthandnutrition.com/solutions/amino-acids/>
19. Albion chelated mineral ingredients. Balchem Human Nutrition and Health. <https://balchem.com/human-nutrition-health/hnh-products/albion-minerals/>

## 18 Review note

The phrase all existing literature is interpreted as a broad and traceable review of major guidelines, standards and primary sources within the forty page editorial limit. It is not an exhaustive systematic review of every worldwide publication. Before investment or clinical use, a PRISMA based systematic search and jurisdiction specific regulatory update are recommended.

## Compiler profile

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Nota editorial: se han incluido solamente antecedentes profesionales pertinentes para una publicación pública; se omiten datos personales sensibles, documentos de identidad, domicilios y otros datos de carácter privado.