** Revised in April 2016 (8th edition)
* Revised in April 2012

**S t o r a g e :** Store at room temperature.
After opening the inner package, store in a tight container protected from light.
**Expiration Date:** 1 year and 3 months(Use before the expiration date indicated on the outer case.)

| Standard Commodity Classification No. of Japan |
|---|
| 8 7 3 2 5 9 |

**Elemental diet**

# ELENTAL®

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| Approval No. | 22100AMX00868 |
| Entry in NHI Drug Price List | September 2009 |
| Initial Marketing | September 1981 |
| Reexamination Results | December 1986 |

D0209311

**[Contraindications (Elental® Is Contraindicated in the Following Patients.)]**
1. Patients who have a history of hypersensitivity to any component of the present drug.
2. Among patients who have severe diabetes mellitus or are receiving high dose steroids, those patients who are suspected of having glucose metabolism disorder. (Hyperglycemia may develop.)
3. Administration of 5000 IU per day or more of vitamin A to women in the first 3 months of pregnancy or women who want to become pregnant. (See the section **5 "Administration to pregnant women, parturient women, nursing women, etc.**")
4. Patients with amino acid metabolism disorder. (Elental® may cause hyperaminoacidemia etc.)

## * [Composition and Description]

### 1. Composition

| Component | In 100 g (375 kcal) | In 1 bag or 1 bottle (80 g) (300 kcal) |
|---|---|---|
| L-isoleucine | 803 mg | 642 mg |
| L-leucine | 1124 mg | 899 mg |
| L-lysine hydrochloride | 1110 mg | 888 mg |
| L-methionine | 810 mg | 648 mg |
| L-phenylalanine | 1089 mg | 871 mg |
| L-threonine | 654 mg | 523 mg |
| L-tryptophan | 189 mg | 151 mg |
| L-valine | 876 mg | 701 mg |
| L-histidine hydrochloride hydrate | 626 mg | 501 mg |
| L-arginine hydrochloride | 1406 mg | 1125 mg |
| L-alanine | 1124 mg | 899 mg |
| Magnesium/potassium L-aspartate | 1295 mg | 1036 mg |
| Sodium L-aspartate monohydrate | 1084 mg | 867 mg |
| L-glutamine | 2415 mg | 1932 mg |
| Glycine | 631 mg | 505 mg |
| L-proline | 788 mg | 630 mg |
| L-serine | 1449 mg | 1159 mg |
| L-tyrosine | 138 mg | 110 mg |
| Dextrin | 79.26 g | 63.41 g |
| Sodium citrate dehydrate | 770 mg | 616 mg |
| Potassium chloride | 188 mg | 150 mg |
| Calcium glycerophosphate | 1031 mg | 825 mg |
| Ferrous gluconate dihydrate | 19.4 mg | 15.5 mg |
| Zinc sulfate hydrate | 9.85 mg | 7.88 mg |
| Manganese sulfate pentahydrate | 1.63 mg | 1.30 mg |
| Copper sulfate | 1.03 mg | 0.82 mg |
| Potassium iodide | 24.5 μg | 19.6 μg |
| Thiamine hydrochloride | 242 μg | 194 μg |
| Riboflavin sodium phosphate | 320 μg | 256 μg |
| Pyridoxine hydrochloride | 334 μg | 267 μg |
| Cyanocobalamin | 0.9 μg | 0.7 μg |
| Calcium pantothenate | 1.49 mg | 1.19 mg |
| Nicotinamide | 2.75 mg | 2.20 mg |
| Folic acid | 55 μg | 44 μg |
| Biotin | 49 μg | 39 μg |
| Choline bitartrate | 22.41 mg | 17.93 mg |
| Ascorbic acid | 9.75 mg | 7.80 mg |
| Retinol acetate | 810 IU | 648 IU |
| Tocopherol acetate | 4.13 mg | 3.30 mg |
| Ergocalciferol | 1.6 μg | 1.3 μg |
| Phytonadione | 11 μg | 9 μg |
| Soybean oil | 636 mg | 509 mg |

Elental® contains potassium sorbate, polysorbate 80, aspartame (an L-phenylalanine compound), flavor, soy lecithin, citric acid hydrate, lactose hydrate, and carmellose sodium as additives.

### 2. Product Description

This drug is a white powder with a slight characteristic odor and a characteristic taste. Dissolve this drug in the proper amounts of water or lukewarm water, the solution becomes slightly turbid.

**[Indications]**

This drug is a very low residual, easily absorbable high-calorie enteral nutrient called elemental diet or elemental nutrition, which consists of ingredients requiring minimum digestion. Generally, the drug is used preoperatively or postoperatively in patients in whom managing nutrition is difficult when tube feeding nutrition containing undigested proteins. In particular, the drug is used for the following purposes:
1. Postoperative nutritional management in patients in whom the use of tube feeding nutrition containing undigested proteins is difficult.
2. Nutritional management in patients with a disease that requires clean intestines.
3. Nutritional management in the immediate postoperative period.
4. Nutritional management in patients with abnormal gastrointestinal conditions (such as ruptured suture, short bowel syndrome, and various gastrointestinal fistulae).
5. Nutritional management in patients with special gastrointestinal diseases (such as Crohn's disease, ulcerative colitis, dyspepsia syndrome, pancreatic disease, and protein-losing enteropathy).
6. Nutritional management in patients in whom the use of intravenous hyperalimentation is difficult (such as patients with extensive burns).

**[Dosage and Administration]**

Usually, 80 g of Elental® is dissolved in water or lukewarm water to make 300 mL (1 kcal/mL), and the resulting solution is continuously infused into the duodenum or jejunum through a nasogastric tube, gastrostomy tube, or enterostomy tube at an infusion rate of 75 to 100 mL per hour. If necessary, the solution may be orally administered in single or divided doses.
The standard dose for adults is 480 to 640 g (1800 to 2400 kcal) per day. The dose is appropriately adjusted depending on age, body weight, and symptoms. Generally, a solution of about one-eighth (60 to 80 g) of the daily dose is administered at a concentration that is about one-half (0.5 kcal/mL) of the specified concentration as the initial dose. The concentration and the dose are gradually increased depending on the condition of the patient until the standard dose is reached 4 to 10 days later.

**<Method of Preparation>**

Preparation of 1 kcal/mL solution from a bag of Elental® (80 g)
Add a bag of Elental® to about 250 mL of water or lukewarm water in a container and stir immediately. After dissolution, the quantity of the solution should be about 300 mL (1 kcal/mL).

Preparation of 1 kcal/mL solution from a bottle of Elental® (80 g) in a plastic container
Add water or lukewarm water to the container and dissolve the contents to prepare about 300 mL of a solution as measured by the scale (salient).

**<Precautions Regarding Dosage and Administration>**
The solution prepared from this drug **must not be administered intravenously**.

**[Precautions]**

**1.Careful Administration (This drug should be administered with care to the following patients:)**

Patients with short bowel syndrome caused by extensive resection of the small intestine. (Be especially careful not to cause diarrhea. Since the absorptive ability of the intestinal tract may have been particularly lowered after this surgery, start administration carefully—about 4 days after the surgery as a rough standard.)

**2.Important Basic Precaution**

(1) Supply vitamins, electrolytes, and trace elements as needed because these nutrients may become insufficient. Selenium deficiency (reduced cardiac function, white discoloration of nails, muscular weakness, etc.) has been reported during long-term administration.

(2) In patients receiving this drug through feeding tubes, dumping syndrome-like hypoglycemia may occur after administration when the dosing concentration or the rate of administration is too high. Thus, carefully select the dosing concentration and the rate of administration (see Dosage and Administration).

**3.Adverse Reactions**

A total of 2339 adverse reactions were reported in 8170 patients who were surveyed in clinical studies that had been conducted up to the time of approval and in post-marketing drug use-results surveys. Common adverse reactions included diarrhea in 1057 patients (12.9%), bloating in 359 patients (4.4%), increased blood AST (GOT)/ALT (GPT)/Al-P in 301 patients (3.7%), nausea in 168 patients (2.1%), vomiting in 134 patients (1.6%) and abdominal pain in 123 patients (1.5%) (as of the time when reexamination was completed).

When the following adverse reactions occur, take appropriate precautions, such as discontinuation of administration, dose reduction, or change to administration at a lower concentration or a lower rate of administration.

**** (1) Clinically significant adverse reactions**

**1) Shock/anaphylaxis**(unknown frequency): Since this drug may cause shock/anaphylaxis, observe the patient closely. When decreased blood pressure, disturbed consciousness, dyspnea, cyanosis, nausea, chest discomfort, flushed face, itching, sweating, etc., occur, immediately discontinue administration and take appropriate precautions.

**2) Hypoglycemia** (less than 0.1%): Dumping syndrome-like hypoglycemia (malaise, sweating, cold sweat, facial pallor, convulsion, decreased consciousness, etc.) may occur after administration. When these symptoms occur, take appropriate precautions (see Dosage and Administration).

**(2) Other adverse reactions**

| | Not less than 5% | Not less than 0.1% and less than 5% | Less than 0.1% |
|---|---|---|---|
| **Digestive organs** | Diarrhea | Abdominal distension, nausea, vomiting, abdominal pain | |
| **Liver** | | Increased blood AST (GOT), increased blood ALT (GPT), increased blood AL-P | Increased LDH, increased γ-GTP |
| **Kidney** | | Increased blood urea nitrogen | |
| **Carbohydrate/lipid metabolism** | | Increased blood glucose level | Increased triglyceride levels |
| **Autonomic nervous system** | | | Sweating |
| **Skin** | | | Rash |
| **Others** | | Pyrexia | |

**4.Use in the Elderly**

Since the elderly generally have reduced physiological function, carefully select the rate of administration when administering to the elderly.

**5.Use During Pregnancy, Delivery, or Lactation**

An overseas epidemiologic study has estimated that malformation mainly in the cranial neural crest increased in children born from women who ingested 10,000 IU per day or more of vitamin A starting 3 months before pregnancy through the first trimester of pregnancy. Thus, when administering to women within the first trimester or women who wish to become pregnant, carefully select the dosage and take the necessary precautions, such as limiting the dose of vitamin A that is administered through this drug to less than 5000 IU per day.

**6.Pediatric Use**

Safety in low-birth-weight babies has not been established. (There are no use results.)

**7.Precautions Concerning Use**

**(1)At the time of administration**

1) Since this drug contains only a minimal amount of fat, fatty acid deficiency may rarely occur particularly when administering to children, when Elental® alone is administered for a long period of time, and when the total dose is low. In these cases, supplementation of fat is required.
2) Although this drug contains minimal amounts of electrolytes, the required amounts of electrolytes differ depending on the pathological conditions. Thus, administration of this drug may cause an excess of electrolytes. In such cases, take such precautions as adjusting the dose of the drug as needed.
3) When this drug is continuously infused through a nasogastric tube, reflux may rarely occur depending on the location of the placement of the tube end, the rate of infusion, and the condition of the patient. Thus, carefully select the location of the placement of the tube end and the rate of infusion.

**(2)Method of preparation:** This drug is prepared by dissolving in water or lukewarm water before use. Use the solution within 12 hours of preparation.

**(3)Dosing concentration and rate of administration:** The solution prepared from this drug has a standard concentration of 1 kcal/mL (80 g/300 mL) and is infused at a standard rate of 100 mL per hour. When administering to children or patients at an early stage of administration, it is desirable to use a low concentration and a low infusion rate at first and move up to the maintenance dose in steps.

In addition, dumping syndrome-like hypoglycemia may occur after administration when the dosing concentration or the rate of administration is too high. Thus, carefully select the dosing concentration and the rate of administration.

**(4)Others:** When nutrition sets, feeding tubes, etc., made of polyvinyl chloride containing DEHP (di-(2-ethylhexyl) phthalate) as a plasticizer are used, DEHP is eluted into the drug. Thus, it is desirable to use nutrition sets, feeding tubes, etc., containing no DEHP.

**[Pharmacokinetics]**

**(For information) Absorption, distribution, metabolism, and excretion in animals**

The present drug containing amino acids, dextrin, or vitamin $B_6$ that have been labeled with $^{14}C$ was administered to male Fisher rats. As a result, it was inferred that each component was rapidly absorbed and used normally as protein components, energy sources, etc.[1]

**[Clinical Studies]**

The present drug is effective mainly for the nutritional management in patients with reduced digestive ability or patients requiring high-calorie nutritional support.

The results of clinical studies involving a total of 606 patients showed response rates of 68.0% (complete response/effective) and 85.4% (slightly effective or better).

**[Pharmacology]**

1. An experiment in healthy rats demonstrated that the present drug has trophic effects that are equivalent to those of good-quality proteins.[2]
2. A free feeding experiment in rats that had undergone extensive resection of the small intestine showed that the group treated with the present drug was superior to the group treated with casein feed in body weight gain and nitrogen balance and produced an extremely small amount of feces.[3]
3. Comparison of administration of a commercial tube-feeding nutrients, administration of intravenous hyperalimentation, and administration of the present drug to rats that had undergone extensive resection of the small intestine revealed that the present drug was superior to the commercial tube-feeding nutrients in the ease of absorption and the amount of residue (low) and produced a smaller amount of feces.
   In addition, the present drug was equivalent to intravenous hyperalimentation in the effect on body weight gain and nitrogen balance.[4]
4. A study in rats that had undergone extensive resection of the small intestine showed no difference between intravenous hyperalimentation and the present drug in the pressure resistance of the small intestinal sutures. In addition, there was no difference between administration of high-calorie infusions and that of the present drug in the therapeutic effect on the skin wounds of rats that had undergone peeling.[5]
5. The present drug and a 50% solution of dried whole egg feed were administered to male Fisher rats aged 6 weeks through a stomach tube. The blood glucose level of hepatoportal blood reached maximum at 15 minutes after administration in both the group treated with the present drug and the group treated with dried whole egg feed. The amino acid level of hepatoportal blood reached maximum at 15 minutes after administration in the group treated with the present drug and 2 hours after administration in the group treated with dried whole egg feed. The blood amino acid pattern was similar in both groups.[6]

**[Packaging]**

80 g bag × 14 (1.12 kg)
80 g/plastic container/bag × 28 (2.24 kg)

**[References]**


1)Matsuzawa Y, et al. *Japanese Pharmacology and Therapeutics*. 1979;7(11):3445
2) Nakatsuji H, et al. *Japanese Pharmacology and Therapeutics*. 1979;7(11):3459
3) Nakatsuji H, et al. *Japanese Pharmacology and Therapeutics*. 1979;7(11):3471
4) Nakatsuji H, et al. *Japanese Pharmacology and Therapeutics*. 1979;7(11):3499
5) Nakatsuji H, et al. *Japanese Pharmacology and Therapeutics*. 1979;7(11):3547
6) Nakatsuji H, et al. *Japanese Pharmacology and Therapeutics*. 1979;7(11):3551


**** [Reference requests]**


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