

August 28, 2020

Otsuka Pharmaceutical Factory obtains approval of new labeling including “prevention of deterioration of or recovery from dehydration” and “heatstroke with dehydration” for its Oral Rehydration Solution OS-1® Series (individually evaluated food for persons with medical conditions) from the Consumer Affairs Agency

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara) has obtained new labeling approval on its Oral Rehydration Solution OS-1®, OS-1® Jelly, and OS-1® Powder from the Consumer Affairs Agency on August 27, 2020. OS-1 products are approved as individually evaluated food for persons with medical conditions, and are categorized as food for special dietary use by the Consumer Affairs Agency.

We applied for new labeling approval to clearly describe the circumstances using OS-1 in a manner that is easier for users and healthcare professionals to understand and approval was subsequently granted by the Consumer Affairs Agency. We hope that the changes in labeling will help users better understand the use of oral rehydration therapy and OS-1.

The main differences from the current labeling are as follows:

- Dehydration is described as a disease covered by OS-1, a food for persons with medical conditions.
- Describes that OS-1 can be used to prevent the deterioration of or recover from dehydration caused by three conditions, (Diarrhea, vomiting, or fever associated with infectious enteritis or the common cold / Insufficient oral intake in elderly persons / Excessive perspiration), etc.
- Describes that OS-1 can be used to provide or maintain water and electrolytes in the three conditions, etc., even after the recovery from dehydration.
- Describes that this product can be used for heatstroke with dehydration.

* We plan to start distributing products with the new label around the spring of 2021. In the meantime, we will continue to sell products with the current label (the shipment time will differ depending on the product).

* There are no changes in composition, taste, concentrations of ingredients contained, or raw materials used between the current labeling and new labeling.

Based on the corporate philosophy of “Otsuka-people creating new products for better health worldwide,” the Otsuka Group is dedicated to contributing to the health of people around the world.

<Approved labeling of OS-1>

<OS-1>

| Currently approved labeling | Newly approved labeling |
|--|---|
| <p>OS-1 is an oral rehydration solution that contains carbohydrates and electrolytes in balanced concentrations. This product is approved as a food for persons with medical conditions and is intended to provide water and electrolytes in order to maintain proper water and electrolyte balance in persons with mild-to-moderate dehydration. Specifically, OS-1 is useful for dehydration due to diarrhea, vomiting, or fever associated with infectious enteritis or the common cold, as well as for dehydration resulting from insufficient oral intake in elderly persons or excessive perspiration.</p> | <p>OS-1 is an oral rehydration solution used in dietary therapy (oral rehydration therapy) for dehydration. This product is approved as a food for persons with medical conditions and is intended to provide water and electrolytes in order to maintain proper water and electrolyte balance in persons with mild-to-moderate dehydration. Use this product to prevent the deterioration of or recover from dehydration caused by the following conditions, or to provide or maintain water and electrolytes in the following conditions even after the recovery from dehydration</p> <ul style="list-style-type: none"> ● Diarrhea, vomiting, or fever associated with infectious enteritis or the common cold ● Insufficient oral intake in elderly persons ● Excessive perspiration <p>This product can also be used for heatstroke accompanied by dehydration.</p> |

<OS-1 Jelly>

| Currently approved labeling | Newly approved labeling |
|---|--|
| <p>OS-1 Jelly is an oral rehydration solution in jelly form that contains carbohydrates and electrolytes in balanced concentrations. This product is approved as a food for persons with medical conditions and is intended to provide water and electrolytes in order to maintain the proper water and electrolyte balance in persons with mild-to-moderate dehydration.</p> <p>Specifically, OS-1 Jelly is useful for dehydration due to diarrhea, vomiting, or fever associated with infectious enteritis or the common cold, as well as for dehydration resulting from insufficient oral intake in elderly persons or excessive perspiration. Although this product can be consumed by persons who have difficulty chewing or swallowing, a physician should be consulted before its use.</p> | <p>OS-1 Jelly is an oral rehydration solution used in dietary therapy (oral rehydration therapy) for dehydration. This product is approved as a food for persons with medical conditions and is intended to provide water and electrolytes in order to maintain proper water and electrolyte balance in persons with mild-to-moderate dehydration. Use this product to prevent the deterioration of or recover from dehydration caused by the following conditions, or to provide or maintain water and electrolytes in the following conditions even after the recovery from dehydration</p> <ul style="list-style-type: none"> ● Diarrhea, vomiting, or fever associated with infectious enteritis or the common cold ● Insufficient oral intake in elderly persons ● Excessive perspiration <p>This product can also be used for heatstroke accompanied by dehydration.</p> <p>Although this product can be consumed by persons who have difficulty chewing or swallowing, a physician should be consulted before its use.</p> |

<OS-1 Powder>

| Currently approved labeling | Newly approved labeling |
|--|--|
| <p>OS-1 Powder is a powder for oral rehydration solution that contains carbohydrates and electrolytes in balanced concentrations, which is dissolved in water for use. This product is approved as a food for persons with medical conditions and is intended to provide water and electrolytes in order to maintain proper water and electrolyte balance in persons with mild-to-moderate dehydration. Specifically, OS-1 is useful for dehydration due to diarrhea, vomiting, or fever associated with infectious enteritis or the common cold, as well as for dehydration resulting from insufficient oral intake in elderly persons or excessive perspiration.</p> | <p>OS-1 Powder is a powder for oral rehydration solution used in dietary therapy (oral rehydration therapy) for dehydration. Dissolve it in water for use. This product is approved as a food for persons with medical conditions and is intended to provide water and electrolytes in order to maintain proper water and electrolyte balance in persons with mild-to-moderate dehydration. Use this product to prevent the deterioration of or recover from dehydration caused by the following conditions, or to provide or maintain water and electrolytes in the following conditions even after the recovery from dehydration</p> <ul style="list-style-type: none"> ● Diarrhea, vomiting, or fever associated with infectious enteritis or the common cold ● Insufficient oral intake in elderly persons ● Excessive perspiration <p>This product can also be used for heatstroke accompanied by dehydration.</p> |

Company Profile

Otsuka Pharmaceutical Factory, Inc.

Established : October 7, 1969 (founded September 1, 1921)
Capital : 80 million yen
Representative : Shinichi Ogasawara, President and Representative Director
Head Office : 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan
Employees : 2,247 (as of December 31, 2019).
Business : Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc.
Description :
URL : <https://www.otsukakj.jp/en/>