

June 14, 2018

Otsuka Pharmaceutical Factory launches the antiseptics for external use “Olanedine<sup>®</sup> Antiseptic Solution OR”

Otsuka Pharmaceutical Factory, Inc. (Head Office: Naruto, Tokushima, Japan; President and Representative Director: Shinichi Ogasawara; “OPF”) launches the antiseptics for external use “Olanedine<sup>®</sup> Antiseptic Solution 1.5% OR,” “Olanedine<sup>®</sup> Solution 1.5% OR Antiseptic Applicator 10 mL,” and “Olanedine<sup>®</sup> Solution 1.5% OR Antiseptic Applicator 25 mL” on June 14, 2018.




OPF obtained the marketing approval of a novel biguanide antiseptic\* of which active ingredient is olanexidine gluconate, “Olanedine Antiseptic Solution 1.5%,” in July 2015 and launched the product in September 2015. *In vitro* efficacy studies in mice show that it exerts a significant bactericidal effect against the bacteria that are regarded as antiseptic-resistant such as methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), *Pseudomonas aeruginosa*, *Serratia marcescens*, and *Burkholderia cepacia*, in addition to common bacteria including various Gram-positive and Gram-negative bacteria. In particular, the effect against Gram-positive bacteria is confirmed strong and immediate.

In response to a request from healthcare professionals, we developed a preparation which is orange-tinted Olanedine Antiseptic Solution 1.5% to clearly show the application area. The preparation contains the same active ingredient at the same concentration as that of Olanedine Antiseptic Solution 1.5%. The indications (preoperative skin preparation), and dosage and administration (apply appropriate amount of the drug) are also the same for both products.

The bottled antiseptic “Olanedine<sup>®</sup> Antiseptic Solution 1.5% OR (200 mL),” and two kinds of applicators, “Olanedine<sup>®</sup> Solution 1.5% OR Antiseptic Applicator 10 mL” and “Olanedine<sup>®</sup> Solution 1.5% OR Antiseptic Applicator 25 mL” which can be used easily and hygienically, are available. All these products are expected to be highly useful as new antiseptics in medical settings.

\* Antiseptics widely used in Japan are as follows: alcohol-based antiseptics, iodine antiseptics, biguanide antiseptics, and quaternary ammonium antiseptics. Olanedine Antiseptic Solution 1.5% is a biguanide antiseptic.

Product Information

Brand name	Olanedine® Antiseptic Solution 1.5% OR Olanedine® Solution 1.5% OR Antiseptic Applicator 10 mL Olanedine® Solution 1.5% OR Antiseptic Applicator 25 mL
Category	Antiseptic for external use
General name	Olanexidine gluconate
Indications	Preoperative skin preparation
Dosage and administration	Apply appropriate amount of the drug.
Packaging	<p>Olanedine® Antiseptic Solution 1.5% OR: 200 mL, 20 bottles</p>  <p>Olanedine® Solution 1.5% OR Antiseptic Applicator: 10 mL, 30 units</p>  <p>Olanedine® Solution 1.5% OR Antiseptic Applicator: 25 mL, 30 units</p> 
Storage	Store at room temperature.
Expiration date	2 years and 6 months after the manufacturing
Date of approval for manufacture and sale	April 13, 2018
Date of insurance coverage	May 30, 2018
Manufactured and distributed by	Otsuka Pharmaceutical Factory, Inc.
Co-marketed by	Otsuka Pharmaceutical Co., Ltd.

Note: These products are not listed in the NHI drug price listing; instead, are designated as the drugs which can be used for the health insurance treatment by the “Notice of notified issues” (“Notice of pharmaceutical products”).

## 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	:	2,297 (as of December 31, 2017)
Scope of Business	:	Manufacture, sale, import and export of clinical nutrition products and other pharmaceutical products, medical devices, functional foods, etc.
Website (URL)	:	<a href="http://www.otsukakj.jp/en/">http://www.otsukakj.jp/en/</a>