

June 14, 2018

Otsuka Pharmaceutical Factory launches the antiseptics for external use “Olanedine[®] 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[®] Antiseptic Solution 1.5% OR,” “Olanedine[®] Solution 1.5% OR Antiseptic Applicator 10 mL,” and “Olanedine[®] 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[®] Antiseptic Solution 1.5% OR (200 mL),” and two kinds of applicators, “Olanedine[®] Solution 1.5% OR Antiseptic Applicator 10 mL” and “Olanedine[®] 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)	:	http://www.otsukakj.jp/en/