

NEWS RELEASE

September 16, 2015

Otsuka Pharmaceutical Factory launches the antiseptics for external use "Olanedine" on September 16, 2015

Otsuka Pharmaceutical Factory, Inc. (Head Office; Naruto, Tokushima, Japan: President; Shinichi Ogasawara) launches the antiseptics for external use "Olanedine_® Antiseptic Solution 1.5%," "Olanedine_® Solution 1.5% Antiseptic Applicator 10 mL," and "Olanedine_® Solution 1.5% Antiseptic Applicator 25 mL" on September 16, 2015.

Antiseptics play an important role in the measures to prevent postoperative infections. Recently, some bacteria including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant enterococci (VRE), and *Pseudomonas aeruginosa*, which are resistant to marketed antiseptics for external use, have been reported, and the development of new antiseptic for external use which is effective for such bacteria has been desired.

Olanedine Antiseptic Solution is a novel biguanide-based antiseptic^{*} of which active ingredient is olanexidine gluconate. *In vitro* efficacy studies in mice shows that it exerts a significant bactericidal effect against the bacteria that are regarded as antiseptic-resistant such as MRSA, 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 addition to the bottled antiseptic "Olanedine_® Antiseptic Solution 1.5%," two kinds of applicators, "Olanedine_® Solution 1.5% Antiseptic Applicator 10 mL, 25 mL" which can be used easily and hygienically, are launched. All these products are expected to be highly useful as new antiseptics.

Antiseptics commonly used in Japan are as follows. Alcohol-based antiseptics, iodine-based antiseptics, biguanide-based antiseptics including chlorhexidine gluconate, and quaternary-ammonium-ion based antiseptics.

Product Information

| Brand name | Olanedine Antiseptic Solution 1.5% | | |
|--|---|--|--|
| | Olanedine Solution 1.5% Antiseptic Applicator 10 mL | | |
| | Olanedine Solution 1.5% 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 | Olanedine Antiseptic Solution 1.5%: | 200 mL, 20 bottles/case | |
| | Olanedine Solution 1.5% Antiseptic App | licator 10 mL: 10 mL, 30 units/case | |
| | | | |
| | Olanedine Solution 1.5% Antiseptic App | licator 25 mL: | |
| | | 25 mL, 30 units/case | |
| Storage | Store at room temperature | | |
| Expiration date | 3 years after the manufacturing | | |
| Date of approval for manufacturing and marketing | July 3, 2015 | | |
| Date of insurance coverage | August 31, 2015 | | |

| 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 | : | September 1, 1921 |
|-------------------------|---|--|
| Capital | : | 80 million yen |
| President | : | Shinichi Ogasawara, President and Representative Director |
| Head Office | : | 115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima 772-8601, Japan |
| Employees | : | 2,356 (as of December 31, 2014) |
| Business Description | : | Manufacture and sale of pharmaceutical and nutrition products |
| URL | : | http://www.otsukakj.jp/ |