

## **Santen Launches Broad-spectrum Antibacterial Ophthalmic Solution Cravit<sup>®</sup> Ophthalmic Solution 1.5% (High-concentration Levofloxacin Ophthalmic Solution)**

June 2, 2011, Osaka, Japan -- Santen Pharmaceutical Co., Ltd. announced today that it has launched its broad spectrum antibacterial ophthalmic solution, Cravit<sup>®</sup> Ophthalmic Solution 1.5% (Generic name: levofloxacin hydrate) in Japan.

Cravit<sup>®</sup> Ophthalmic Solution 1.5% is an ophthalmic solution with the concentration of levofloxacin, in-licensed from Daiichi Sankyo Co., Ltd., increased to 1.5%. Levofloxacin is the active ingredient of Cravit<sup>®</sup> Ophthalmic Solution 0.5%, a broad-spectrum antibacterial ophthalmic solution developed by Santen and now marketed in Japan, and has been highly recognized among medical experts for its excellent therapeutic effect in extraocular infections and high safety profile since its release in April, 2000. Cravit<sup>®</sup> Ophthalmic Solution 1.5% has been confirmed to show higher ocular tissue distribution, and therefore a more potent clinical efficacy can be expected.

Santen hopes Cravit<sup>®</sup> Ophthalmic Solution 1.5% will contribute to improving QOL (Quality of Life) of patients in extraocular infection treatment.

### Product Characteristics:

- Cravit<sup>®</sup> Ophthalmic Solution 1.5% is a high-concentration fluoroquinolone antibacterial ophthalmic solution developed based on the PK-PD theory\*.
- Cravit<sup>®</sup> Ophthalmic Solution 1.5% has higher ocular tissue distribution than Cravit<sup>®</sup> Ophthalmic Solution 0.5%.
- Cravit<sup>®</sup> Ophthalmic Solution 1.5% displays a broad antibacterial spectrum.
- Cravit<sup>®</sup> Ophthalmic Solution 1.5% was confirmed to have potent efficacy in clinical trials, and early disappearance of primary symptoms can be expected.
- No serious ocular or systemic adverse drug reactions have been found.

### \*PK-PD theory

The concept combines pharmacokinetics (PK) and pharmacodynamics (PD), and is under research in order to design a safe and effective administration method, based on “tissue distribution” and “pharmacological activity” of drug agents.

About Cravit<sup>®</sup> Ophthalmic Solution 1.5%

Product name	Cravit <sup>®</sup> Ophthalmic Solution 1.5%
Generic name (JAN)	Levofloxacin Hydrate
Dosage form:	Aqueous ophthalmic solution
Indication	<p>&lt;Bacterial stains&gt;</p> <p>Levofloxacin susceptible strains of <i>Staphylococcus</i> sp., <i>Streptococcus</i> sp., <i>S. pneumoniae</i>, <i>Enterococcus</i> sp., <i>Micrococcus</i> sp., <i>Moraxella</i> sp., <i>Corynebacterium</i> sp., <i>Klebsiella</i> sp., <i>Enterobacter</i> sp., <i>Serratia</i> sp., <i>Proteus</i> sp., <i>Morganella morganii</i>, <i>Haemophilus influenzae</i>, <i>Haemophilus Aegyptius</i> (<i>Koch-Weeks bacillus</i>), <i>Pseudomonas</i> sp., <i>Pseudomonas aeruginosa</i>, <i>Stenotrophomonas</i> (<i>Xanthomonas</i>) <i>maltophilia</i>, <i>Acinetobacter</i> sp. and <i>Propionibacterium acnes</i></p> <p>&lt;Approved indications&gt;</p> <p>Blepharitis, Dacryocystitis, Hordeolum, Conjunctivitis, Meibomianitis, Keratitis (including Corneal Ulcer) and perioperative sterilization</p>
Dosage method	<p>One drop at a time, 3 times daily</p> <p>Dosing frequency can be increased or decreased depending on the symptoms.</p>
Storage method	Store at room temperature with light protection.
Package	One carton contains 5mL×10 (5mL plastic ophthalmic bottles)
Price	138.10 JPY for 1mL
Date of approval	December 21, 2010
Date of NHI price listing	March 18, 2011
Date of launch	June 2, 2011



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