

Santen Files Manufacturing/Marketing Approval of its Broad Spectrum Anti-Infective Ophthalmic Solution DE-108 (Generic name: Levofloxacin, high concentration)

March 2, 2010, Osaka, Japan -- Santen Pharmaceutical Co., Ltd. announced that it had filed manufacturing and marketing approval in Japan of its broad spectrum anti-infective ophthalmic solution DE-108 (Generic name: Levofloxacin) with the Japanese Ministry of Health, Labour and Welfare as of February 10, 2010.

DE-108, in-licensed from Daiichi Sankyo Co., Ltd., is broad spectrum anti-infective ophthalmic solution developed by Santen with the concentration of its active ingredient, Levofloxacin, tripled to 1.5% from 0.5% of Cravit[®] Ophthalmic Solution, now marketed in Japan. Cravit[®] Ophthalmic Solution 0.5% has been highly recognized among medical experts for its excellent therapeutic effect on external ocular infections and high safety since its release in April, 2000.

Santen expects DE-108 (Levofloxacin ophthalmic solution, high concentration) will contribute to the treatment of external ocular infections more than Cravit[®] Ophthalmic Solution 0.5%.

About DE-108

Development code :	DE-108
Generic name :	Levofloxacin
Dosage form :	Aqueous ophthalmic solution
Indication :	<applicable bacterial stains> LVFX suseptable Staphylococcus sp., Streptococcus sp., S. pneumoniae, Enterococcus sp., Micrococcus sp., Moraxella sp., Corynebacterium sp., Klebsiella sp., Enterobacter sp., Serratia sp., Proteus sp., Morganella morganii, Hemophilus influenzae, Haemophilus Aegyptius (bacillus Koch-Weeks), Pseudomonas sp., Pseudomonas aeruginosa, Stenotrophomonas (Xanthomonas) maltophilia, Acinetobacter sp. and Propionibacterium

acnes

<Applicable indications>

Blepharitis, Dacryocystitis, Hordeolum, Conjunctivitis,
Meibomianitis, Corneitis (including Keratohelecosis) and
preoperative sterilization

Dosage

Basically 1 drop / time, 3 times a day

Its frequency can be appropriately increased or decreased
depending on the condition.

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