

For Immediate Release

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Daiichi Sankyo Launches new Cravit[®] Formulations in Japan

TOKYO, Japan (July 7, 2009) – Daiichi Sankyo Company, Limited (TSE: 4568), today launched new formulations of Cravit[®] (generic name: Levofloxacin Hydrate), a broad-spectrum oral anti-bacterial agent. These formulations are 500mg and 250mg tablets, and a 10% fine granular preparation in Japan. The company obtained manufacturing and marketing approval on April 22. The drug price listing was on June 19.

Daiichi Sankyo drew on PK-PD theory (see note below) to develop the once-daily dosage for the 500mg Cravit[®] tablet. This tablet lifts the maximum blood concentration and is significantly more bactericidal than the 100mg formulation, taken three times daily, suppressing the development of drug-resistant bacteria. The once-daily dosage of the Cravit[®] 500mg tablet is an approved standard in more than 120 countries and territories.

Since its introduction in December 1993 in Japan, Cravit[®] has gained approval for treating 43 indications and 32 bacteria. This agent continues to offer outstanding efficacy, and has won accolades for its safety profile. Daiichi Sankyo is confident that its concept of a once-daily dosage of a 500mg tablet will win broad acceptance for improved efficacy and a better suppression of strong bacteria. The company will cultivate this product as a worthy contributor to long-term treatment.

Note: PK-PD theory

This is a scientifically proven concept for design the optimal administrations of anti-bacterial agents.

This anti-bacterial efficacy and safety assessment concept combines pharmacokinetics (PK), which shows how anti-bacterial agent concentration changes within human body, and pharmacodynamics (PD), considers the actions of anti-bacterial agents within organisms.

Overview of new products

(Launch date: Tuesday, July 7, 2009)

Classification	Broad-spectrum oral anti-bacterial agent
Product names	Cravit [®] 500mg and Cravit [®] 250mg tablets and Cravit [®] 10% fine granular preparation (generic name: Levofloxacin Hydrate)
Prices	Cravit [®] 500mg: ¥547.20 per tablet Cravit [®] 250mg: ¥304.50 per tablet Cravit [®] 10% fine granular preparation: ¥138.20 per 5g dose (Prices as disclosed on June 19, 2009)
Effects and efficacy	<p>[Indications] <Strains(32)> Cravit-susceptible strains of Staphylococcus sp., Streptococcus sp., Streptococcus pneumonia, Enterococcus sp., Neisseria gonorrhoeae, Moraxella (Branhamella) catarrhalis, Bacillus anthracis, Escherichia coli, Shigella, Salmonella sp., Salmonella typhi, Salmonella paratyphi, Citrobacter sp., Klebsiella sp., Enterobacter sp., Serratia sp., Proteus sp., Morganella morganii, Providencia sp., Yersinia pestis, Vibrio cholerae, Haemophilus influenzae, Pseudomonas aeruginosa, Acinetobacter sp., Legionella sp., Brucella sp., Francisella tularensis, Campylobacter sp., Peptostreptococcus sp., Propionibacterium acnes, Q fever rickettsia (Coxiella burnetii), and Trachoma chlamydia (Chlamydia trachomatis)</p> <p><Indications(43)> Superficial skin infections, deep skin infections, lymphangitis/lymphadenitis, chronic pyoderma, acne (with suppurative inflammation), secondary infection in trauma, burns, operative wound, etc., mastitis, perianal abscess, laryngopharyngitis, tonsillitis (including peritonsillitis, peritonsillar abscess), acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic disease), epididymitis, urethritis, cervicitis, cholecystitis, cholangitis, infectious enteritis, typhoid fever, paratyphoid, cholera, Bartholin's glanditis, intrauterine infection, uterine adnexitis, dacryocystitis, hordeolum, tarsal glanditis, otitis externa, otitis media, sinusitis, suppurative sialadenitis, periodontitis, pericoronitis, gnathitis, anthrax, brucellosis, plague, tularemia, Q fever.</p>
Usage and dosages	Normally, an adult patient would orally take one 500mg dose of the Levofloxacin Hydrate (one 500mg or two 250mg tablets or one 5g dose of 10% fine granular preparation) per day. Dosage would be reduced appropriately according to the patient's illness or symptoms. For typhoid or paratyphoid sufferers, the Levofloxacin Hydrate administration would be one 500mg dose orally (one 500mg or two 250mg tablets or one 5g dose of 10% fine granular preparation) per day for 14 days.
Manufacturer and seller	Daiichi Sankyo Company, Limited