



## News Release

September 28, 2015  
Maruho Co., Ltd.

### **Maruho receives manufacturing and marketing approval for quinolone anti-microbial topical treatment Zebiax<sup>®</sup> Lotion 2%**

Osaka (Japan), September 28, 2015 – Maruho Co., Ltd (“Maruho”, Head Office: Osaka, Japan, President and CEO: Koichi Takagi) announces that the product submitted for a new drug approval on July 23, 2014, Zebiax<sup>®</sup> Lotion (Zebiax) (INN: ozenoxacin), has received manufacturing and marketing approval from the Ministry of Health, Labour and Welfare (MLWH) for the treatment of superficial skin infections and acne (accompanied by purulent inflammation).

Zebiax is a topical antimicrobial agent developed by Toyama Chemical Co., Ltd. with the quinolone compound ozenoxacin as its active ingredient. Ozenoxacin inhibits deoxyribonucleic acid (DNA) synthesis in bacteria by trapping gyrase-DNA and topoisomerase IV-DNA complexes involved in cell replication, resulting in apoptosis. Ozenoxacin shows a strong antibacterial effect against various aerobic/anaerobic, gram positive/gram negative bacteria, and high antibacterial activity against superficial skin infections from *Staphylococcus aureus*, *Staphylococcus epidermidis* and *P. acnes*. With these properties, Maruho developed Zebiax as a new treatment option for superficial skin infections and acne.

As a pharmaceutical company specializing in dermatology, Maruho hopes to contribute a better treatment option for patients suffering from superficial skin infections and acne.



Product Profile: Zebiax<sup>®</sup> Lotion 2%

Product Name	Zebiax <sup>®</sup> Lotion 2%
INN	Ozenoaxicin
Formulation/Dose	Lotion formulation containing 1g of ozenoxacin per 20mg of lotion
Indication	<Indicated bacterial strains> Staphylococcus sensitive to ozenoaxicin, P. acnes <Indicated diseases> Superficial skin infections, Acne (accompanied by purulent inflammation)
Dosage and Administration	An appropriate amount of the drug should be applied to the affected area once daily. For facial acne, the drug should be applied to the affected area after washing the face.
Approval Requirements	A pharmaceutical risk management plan should be properly designed and implemented.

**About Superficial Skin Infections**

Superficial skin infection is a disease where bacteria, including Staphylococcus aureus enter the body through pores or cuts in the skin and cause inflammation. Sycosis (razor rash), purulent perioritis, contagious impetigo, folliculitis, etc. are collectively known as superficial skin infections.

**About Acne**

Excess sebum production as a result of hormone levels etc. can cause pores to become clogged and the inflammation of hair follicles and sebaceous glands resulting in a skin disease commonly known as acne or pimples. When hair follicles are clogged with sebum, P.acnes in the follicle can grow causing a red inflammation with pus. There is low recognition of acne as a skin “disease” and there is wide use of self-care with OTC, quasi-drugs and cosmetics. However, if infection gets worse pimples become purulent leaving acne scars. In such cases appropriate medical treatment is required.

**Maruho’s initiatives towards treatment for Acne**

Maruho markets acne vulgaris treatment agent Bepio Gel<sup>®</sup> 2.5% (INN: benzoyl peroxide), and acne with purulent inflammation antibacterial treatment oral penem antibiotic Farom<sup>®</sup> Tablets 150mg, Farom<sup>®</sup> Tablets 200mg (INN: faropenem sodium hydrate). Maruho also runs an information website to provide information to patients suffering from acne. [www.maruho.co.jp/kanja/nikibi](http://www.maruho.co.jp/kanja/nikibi) (As Maruho only markets Bepio Gel and Farom for customers in Japan, the information is only provided in Japanese).

**About Maruho**

Maruho Co., Ltd. has its headquarters in Osaka and leads Japan in research and development, manufacturing, and commercialization of dermatological products. Founded in 1915, Maruho has 1,297 employees (as of the end of September 2014), and net sales were approximately 63.3 billion yen in the previous fiscal year. Pursuing its long-term corporate vision of “Excellence in Dermatology,” Maruho is striving to improve the health and quality of life of people all over the world.

For more information about Maruho Co., Ltd., please refer to [www.maruho.co.jp/english](http://www.maruho.co.jp/english)

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