

August 21, 2006

To whom it may concern

Maruho Co., Ltd.
Banyu Pharmaceutical Co., Ltd.

An additional indication of "Stromectol[®] Tablets 3mg" (basically indicated for strongyloidiasis) was approved by the Health Authorities of Japan for oral drug of scabies

Today, Banyu Pharmaceutical Co., Ltd. and Maruho Co., Ltd. will announce that an additional indication of Stromectol[®] Tablets 3mg (generic name: ivermectin; basically administered for strongyloidiasis) was given by the Health Authorities of Japan for the treatment of scabies for the first time as an oral drug and that the administration for scabies was indeed out of the NHI-system, but was taken into this system.

Banyu Pharmaceutical Co., Ltd. filed an additional application for the indication of Stromectol[®] to treat scabies in March 2005 and this medicine was approved at that time under the Extra NHI-system with only the medication cost to be paid by patients. From April 2006 on, Banyu Pharmaceutical Co., Ltd. has continues to have the approval for manufacturing and selling of Stromectol[®] in Japan, but the right for selling has been transferred from Banyu Pharmaceutical Co., Ltd. to Maruho Co., Ltd.

Stromectol[®] joins selectively and strongly with glutamatergic chloride ion channels which exist in nerve and muscle cells of invertebrates, so that it leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of nerve or muscle cells, resulting in paralysis and death of parasites. Stromectol[®] may also interact with gamma-aminobutylatergic (GABAergic) chloride ion channels. Stromectol[®] has already been approved for the treatment of scabies in France, the Netherlands and Mexico. It is now used as a remedy and has been confirmed that it shows a high efficacy. In overseas clinical studies, the following adverse reactions were reported as possibly probably, or definitely related to Stromectol[®] (more than 1% of incidence); dizziness (2.8%), pruritus (2.8%), diarrhea(1.8%), nausea(1.8%)

Scabies is a skin infection caused by the mite *Sarcoptes scabies*, a parasite of the stratum corneum of human skin. In most cases, scabies is associated with severe itching and with specific clinical features such as scabies burrow and reddish papule on the abdomen, chest, armpits, thighs and arms inside. So far, there are no effective oral medicines approved for treating scabies in Japan. Therefore, the approval of an additional indication of Stromectol[®] Tablets 3 mg for the treatment of scabies was strongly requested by various medical-scientific societies.

We will make every effort to provide medical information so that the approval of this medicine for the treatment of scabies can be of assistance to physicians and all other medical personnel.

Registered Trademark of Merck & Co., Inc., Whitehouse Station, N.J., U.S.A.

【Product Profile】

Product name	STROMEKTOL Tablets 3mg
Dosage	Ivermectin 3mg
Indications	Strongyloidiasis, Scabies
NHI Price	3mg, 1 Tablet 764.40yen
Effect mechanism	<p>Ivermectin is a member of the avermectin class of broad-spectrum antiparasitic agents which have a unique mode of action.</p> <p>Stromectol[®] joins selectively and strongly with glutamatergic chloride ion channels which exist in nerve and muscle cells of invertebrates, so that it leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of nerve or muscle cells, resulting in paralysis and death of parasites. Stromectol[®] may also interact with gamma-aminobutylatergic (GABAergic) chloride ion channels.</p>