

April 22, 2009

Ajinomoto Co., Inc.
Dainippon Sumitomo Pharma Co., Ltd.

Acquisition of an additional indication relating to pretreatment for barium enema X-ray examination by concomitant use of NIFLEC® and GASMOTIN®

Ajinomoto Co., Inc. (Headquarters: Tokyo, Japan; President: Norio Yamaguchi; hereinafter called “Ajinomoto”) and Dainippon Sumitomo Pharma Co., Ltd. (Headquarters: Osaka, Japan; President: Masayo Tada; hereinafter called “DSP”) have obtained an approval for an additional indication and new dosing regimen relating to pretreatment for barium enema X-ray examination by concomitant use of NIFLEC® and GASMOTIN® (GASMOTIN® Tablets 2.5 mg, GASMOTIN® Tablets 5 mg, and GASMOTIN® Powder) in Japan as of April 22, 2009.

NIFLEC®, launched in 1992, is an orally-available gastrointestinal lavage solution. This product is widely used in pretreatment for colonoscopic examination as well as in pretreatment for colon surgery because it has an excellent cleansing effect on the digestive system and furthermore does not require diet restrictions which are usually necessary until the day before examination.

GASMOTIN® (generic name: mosapride citrate hydrate), launched in 1998, is one of DSP’s proprietary compounds, with efficacy of improving gastrointestinal motility (selective serotonin 5-HT₄ receptor agonist). This product has thus far been used extensively to cure “digestive symptoms (heartburn, nausea, and vomiting) associated with chronic gastritis” based on its stimulant effects on motility function of upper gastrointestinal tract (stomach and duodenum), while it has also been expected pharmacologically to stimulate a motility function of lower gastrointestinal tract (colon).

In a barium enema X-ray examination, after the colon is cleaned up, barium (a contrast agent) and air are injected into the colon through the anus for X-ray radiation. A procedure to clean up the colon in advance for an easier examination is called “pretreatment”. Currently, more than 90% of pretreatments are done according to the modified Brown’s method (diet restriction for 1-2 days and dosing of plural purgative drugs), but this procedure is not necessarily regarded as a satisfactory pretreatment

due to too heavy physical burdens to an examinee.

Meanwhile, in the past there was no case of single application of NIFLEC® to pretreatment for barium enema X-ray examination because of possible stay of the NIFLEC® solution in the intestinal tract.

Recently it has been found that concomitant use of GASMOTIN® with NIFLEC® ensures an excellent barium enema X-ray image as a result of reduction of the amount of the NIFLEC® solution remaining in the intestinal tract by effects of GASMOTIN® based on improvement of motility in the lower intestine. In addition, an examinee has less physical burdens, being relieved from such pressures as diet restrictions and dosing of more than one purgative drug, because the pretreatment with NIFLEC® and GASMOTIN® can be completed within the day of examination under this concomitant use.

Ajinomoto and DSP expect improvements in examination environments for both healthcare providers and examinees and contribution to earlier detections of colon diseases as a result of acquisition of the approval of the above-mentioned additional indication and new dosing regimen

[Please see the separate sheet for an outline of the approved additional indication and dosage and administration.]

<Separate Sheet>

1. Outline of NIFLEC®

[Brand Name]	NIFLEC®
[Generic Name]	No generic name; NIFLEC® is a pharmaceutical combination preparation.
[Indication] (<u>The underline indicates the added part.</u>)	Cleansing of gastrointestinal tract for pretreatment of colonoscopy, <u>barium enema X-ray examination</u> and colon operation.
[Dosage and Administration]	Patient must not eat or drink anything but water on the morning of the procedure. Start administration at about six hours prior to the procedure. The usual adult dosage for oral use is 20 mg of mosapride citrate with a solution of NIFLEC® (approx. 180 mL) at the initiation of administration of NIFLEC® solution, and 20 mg of mosapride citrate with a small amount of water after completion of the administration of NIFLEC® solution.
[Manufacturer and Distributor]	Ajinomoto Co., Inc.

2. Outline of GASMOTIN®

[Brand Name]	GASMOTIN® Tablets 5 mg, GASMOTIN® Tablets 2.5 mg, and GASMOTIN® Powder
[Generic Name]	Mosapride citrate hydrate
[Indication] (addition only)	Adjunctive treatment to the pretreatment with orally gastrointestinal lavage solution for barium enema X-ray examination
[Dosage and Administration] (addition only)	The usual adult dosage for oral use is 20 mg of mosapride citrate with the oral gastrointestinal lavage solution (approx. 180 mL) at the initiation of administration of the lavage solution, and 20 mg of mosapride citrate with a small amount of water after completion of administration of the lavage solution.
[Manufacturer and Distributor]	Dainippon Sumitomo Pharma Co., Ltd.