



## Corporate Press Release

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### **Clinical Trial Results : Evaluation of Acceptability, Tolerability, Safety and Efficacy of MOVIPREP® Orange (NRL0706-01/2009)**

With the continued expansion of Bowel Cancer Screening programmes worldwide, the performance of elective colonoscopy is expected to increase for asymptomatic patients. The procedure, including the preparation, needs to be safe, uncomplicated and well tolerated to achieve satisfactory subject compliance to ensure the colon is sufficiently clean to allow effective cancer screening, or detection of abnormalities. Conventional methods for gut cleansing prior to colonoscopy have involved the use of high volume of gut lavage solutions (e.g. 4 litres) or lower volume hyperosmotic preparations.

MOVIPREP® has been developed and marketed successfully in both EU and US as a reduced volume cleansing solution (2 litres) in routine colon cleansing prior to colonoscopies. MOVIPREP® contains macrogol 3350, electrolytes, which include sodium sulphate, sodium ascorbate, and ascorbic acid. NRL0706 (MOVIPREP® Orange) is a new orange flavoured formulation of MOVIPREP®. The objective of this study was to assess the acceptability, tolerability, safety and efficacy of this new formulation.

The study was conducted in five specialised gastroenterology units in private practice or ambulatory care centres in Germany in consenting subjects aged between 40-75 years old undergoing an elective complete colonoscopy for colon cancer screening. Each subject was instructed to take 1 litre of MOVIPREP® Orange in the evening ahead of the colonoscopy and 1 litre early in the morning on the day of the colonoscopy. Each dose of MOVIPREP® Orange was followed by at least 0.5 litre of any additional clear fluid.

Subjects recorded their tolerance in relation to the gut cleansing preparation using taste evaluation, acceptability assessments and any occurrence of predefined symptoms. The efficacy of cleansing was measured using a 5-grade scale for each of the predefined colon areas resulting into a final grading of the overall quality of gut preparation (A or B: "success" versus C or D: "failure") using the previously established Harefield Cleansing scale\*.

A total of 121 subjects were enrolled, of which 118 were eligible to be randomised. 55 subjects (46.6%) were female and 63 subjects (53.4%) were male with a mean age of 58.6 years (SD 8.72). All 118 patients were assigned to treatment with MOVIPREP® Orange.

The colon preparation was considered as successful (Grade A and B) by the investigator in 114 subjects (96.6%).



The main criterion used to assess the tolerability of MOVIPREP® Orange was a 100mm visual analogue scale where tolerance was rated from “extremely poorly tolerated” (0) to “perfectly well tolerated” (100) and overall acceptance was rated from: “totally unacceptable” (0) to “fully acceptable” (100). For the overall tolerability and overall acceptance of the subjects, mean values of 72.7mm and 68.7mm respectively were calculated. The majority of subjects in the ITT population rated the tolerability of the intake as acceptable or better (good/very good); 95.8% and 89.8% of subjects for the first and second litres respectively. Acceptability was assessed using a 4 point visual rating scale. The majority of subjects (92.4%) in the ITT population rated consumption of MOVIPREP® Orange as “easy” or “very easy”.

Overall, 12 (10.2%) patients experienced adverse events (unwanted side effects) following treatment administration. 21 individual episodes were reported, of which 15 (71.4%) were considered related to the administration of MOVIPREP® Orange. The most commonly reported drug-related adverse event was abdominal pain (6 [5.1%] patients). No significant changes were observed on vital signs or physical examination.

| Adverse Event        | MOVIPREP® Orange       |                                       |
|----------------------|------------------------|---------------------------------------|
|                      | Number of Subjects (%) | Number of Reported Adverse Events (%) |
| Abdominal Pain       | 6 (5.1)                | 7 (33.3)                              |
| Nausea               | 4 (3.3)                | 4 (19.0)                              |
| Abdominal Discomfort | 3 (2.5)                | 3 (14.3)                              |
| Vomiting             | 1 (0.8)                | 1 (4.8)                               |

\* A total of 118 subjects randomised

\* A total of 21 adverse events were reported.

Gastrointestinal disorders (abdominal pain, nausea, abdominal distension and anal discomfort) are well known side effects of bowel preparations. The same profile was observed for the use of MOVIPREP® Orange (NRL0706).

In conclusion, it was shown in a population undergoing colon cancer screening that MOVIPREP® Orange was well tolerated. In addition, a high rating of successful cleansing (96%) similar to rates shown by the parent product was observed, supporting the use of MOVIPREP® Orange for colon cleansing prior to colonoscopic procedures.

**ENDS**



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\*The Harefield Cleansing scale is copyright of the Norgine group of companies.

### **About Norgine**

Norgine is an independent, successful European specialty pharmaceutical company that has been established for over 100 years and has a presence in all major European markets. In 2011, Norgine's net product sales were €260 million. The Company employs over 1,200 people.

Norgine's focus is the development and marketing of pharmaceutical products that address significant unmet clinical needs in therapeutic areas such as gastroenterology, hepatology and supportive care. The Company currently markets a range of products in various markets in its key therapeutic areas e.g., MOVICOL<sup>®</sup> for the treatment of constipation and faecal impaction, MOVIPREP<sup>®</sup> a bowel cleansing preparation, KLEAN-PREP<sup>®</sup> for large bowel preparation prior to colonoscopy or surgery, XIFAXAN<sup>®</sup> for the treatment of traveller's diarrhoea and ORAMORPH<sup>®</sup> for the treatment of moderate to severe pain associated with cancer.

Norgine is active in research and development and currently has products in various stages of clinical development. Norgine manufactures most of its own products in Hengoed, UK and Dreux, France. For more information: [www.norgine.com](http://www.norgine.com)

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