European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 23 July 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
RESOLOR

International Nonproprietary Name (INN): ***prucalopride***

On 23 July 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Resolor,1mg and 2mg, film coated tablets intended for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief The applicant for this medicinal product is Movetis NV.

The active substance of Resolor is prucalopride, a serotonin ($5\text{-}HT_4$) receptor agonist (ATC-Code: A03AE04) which is likely to explain its enterokinetic effects.

The benefits with Resolor are illustrated by its effect on the main propulsive force to defecation. As shown in the clinical studies, the proportion (%) of subjects that reached normalisation of bowel movements defined as an average of three or more spontaneous, complete bowel movements (SCBM) per week over the 12-week treatment period, significantly increased. Also, these patients noted an increased degree of satisfaction with treatment and with bowel habits, physical and psychosocial comfort and had fewer worries and concerns. The most common side effects are headache and gastrointestinal symptoms (abdominal pain, nausea or diarrhoea), which tend to occur predominantly at the start of therapy and usually disappear within a few days with continued treatment. Uncommonly, new onset of palpitations was recorded during therapy.

A pharmacovigilance plan for Resolor, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief."
Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Resolor and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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