

The reported efficacy of racecadotril is based on the results of only two studies, both supported by the industry. The results of one of the study (including both boys and girls with diarrhoea) are questionable because collection of stool uncontaminated with urine is difficult to obtain in girls therefore compromising the most important primary outcome measure.

There is no data available demonstrating the safety of this drug. Furthermore, trial deviates in the reported studies are more frequent in children receiving racecadotril than in those receiving placebo. This aspect of the results is not discussed and should be further investigated.

Finally, we are aware that a multi centre study was conducted by the company to further evaluate the efficacy of racecadotril. However, the results of that multi-centre (multi-national) study were never published. This clearly raises the issue that the scientific evidence shown to us is not the total evidence obtained through clinical trials and may represent selective presentation of trials.

For all these reasons we do not support the use of racecadotril in the management of diarrhoea in children.

A handwritten signature in black ink, appearing to read 'O. Fontaine', enclosed within a large, stylized, handwritten oval or loop.

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