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To the Minister for Medical Care and Sport
PO Box 20350
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2019059073

Our reference
2019059073

Date 17 December 2019
Subject Hidrasec (racecadotril)

Dear Mr Bruins,

In the letter of September 2019 (CIBG-19-08761), you asked the National Health Care Institute to assess whether racecadotril (Hidrasec®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed the substantive assessment.

Racecadotril (Hidrasec®) is available as 10 mg granules for oral suspension (Hidrasec baby) and as 30 mg (Hidrasec junior) granules for oral suspension. It is registered as an adjunctive symptomatic treatment for acute diarrhoea in infants (over three months of age) and children, together with oral rehydration and the usual supportive measures, if these alone are not sufficient to control the patient's clinical disorder and if causal treatment is not possible. If causal treatment is possible, then racecadotril can be administered as an adjunctive treatment.

The National Health Care Institute has been advised by the Dutch College of General Practitioners and the Dutch Paediatric Society regarding the placement of this treatment. Both of these professional groups are of the opinion that medical management has no place in the treatment of acute diarrhoea in infants and children, other than the prescription of medicinal products for rehydration such as ORS (oral rehydration solution). If the pathogen has been identified then antibiotics might be prescribed. In the case of vomiting, another medicinal product (ondansetron) can be prescribed, if necessary.

Based on these opinions, the National Health Care Institute has informed the manufacturer that the professional groups feel that there is no place for medical management with regard to the registered indication. Accordingly, there is no place for racecadotril.

On 11 November, the manufacturer responded to this by informing the National Health Care Institute that they wish to withdraw the reimbursement application.

Advice

Based on the above, the National Health Care Institute will not proceed with the assessment of the medicinal product racecadotril. Furthermore, the National Health Care Institute advises you not to include racecadotril 10 mg granules for oral suspension (Hidrasec baby) and 30 mg (Hidrasec junior) in the Medicine Reimbursement System.

Please do not hesitate to contact me should you have any further questions.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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