

Racecadotril 10 & 30 mg sachet



Safe and effective product can be given to infants aged over 3 months

Key features

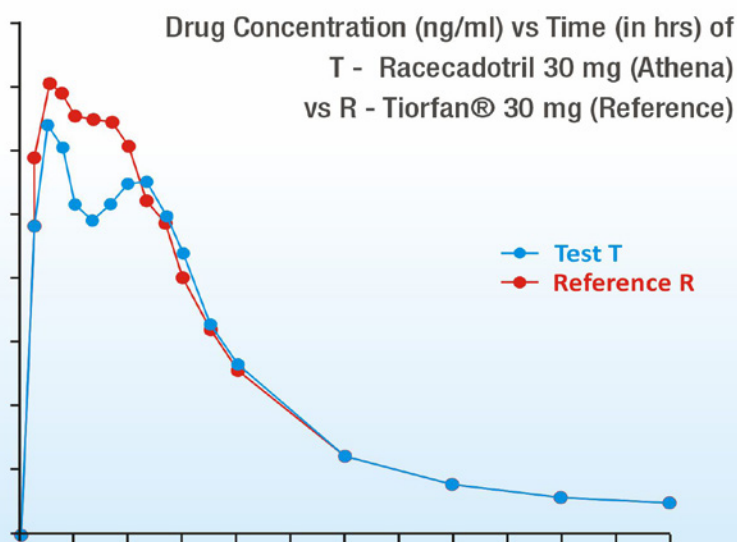
- Racecadotril is indicated for the symptomatic treatment of acute diarrhoea in infants aged over 3 months.

Competitive advantages

- Racecadotril is a guideline-recommended treatment to alleviate symptoms of acute diarrhoea^{1,2,3}. Safety profile is similar to that of placebo. Racecadotril inhibits the degradation of enkephalins, which in turn have potent antisecretory activity but only little effect on motility in the gut in contrast to loperamide (IMODIUM®)^{4,5,6}.
- Resolution of symptoms with racecadotril when compared to loperamide is associated with less rebound constipation and less abdominal discomfort⁷.
- Reduction of water and electrolytes losses in children suffering from acute diarrhoea^{8,9}.
- Racecadotril is indicated for the complementary symptomatic treatment of acute diarrhoea in infants aged over 3 months^{10,11}.

Regulatory status

- INN: Racecadotril
- ATC Code: A07XA04
- CAS registry number: 81110-73-8
- Reference compound: TIORFAN®, Bioprojet Pharma.
- BioEq. study
 - Patient population: 48 male and female fasting healthy volunteers.
 - Methodology: Randomized single-dose 2-way crossover (Test and reference administered with water).
 - Reference product: TIORFAN®, Bioprojet Pharma, France.
- Zone II & IV stability data available.
- CTD dossier available.
- Patent filled in USA, EU, Brazil, Mexico, Russia, China & Korea Regarding the pharmaceutical composition & process for preparation of racecadotril (PCT/IN2018/050085).



Racecadotril 10 & 30 mg

sachet 

GASTROENTEROLOGY

Information at a glance

- Commercial batch size (thousand doses) / strength: 10 mg: 330 | 30 mg: 110
- Dossier Batch size (thousand doses) / strength: 10 mg: 330 | 3 mg: 110
- Shelf-life: 3 years
- Storage conditions: Room temperature between 20-25°C
- Pack info: Heat sealed aluminium sachet. A soft tempered, silver coloured, one side shiny and other side opaque, printed alu. foil
- Sachet weight / strength: 10 mg: 1 000 mg | 30 mg: 3 000 mg

Market highlights

- Worldwide, 1.7 billion episodes of Acute Secretory Diarrhoea occur each year¹².
- Children's diarrhoea drug treatment account for the largest market share (63% in 2019)¹².
- Global antidiarrheal Drugs market is valued \$4,3 billion reaching \$5.8 billion by 2026 (CAGR: 4.5%)¹³.

Competitors' landscape

- Loperamide (IMODIUM®), bismuth subsalicylates (mostly OTC).

REFERENCES

1. Baldi F et al *World J Gastroenterol* 15(27): 3341-8 (2009)
2. Guarino A et al *J Pediatr Gastroenterol Nutr* 46(Suppl 2): S81-184 (2008)
3. Gutierrez Castrellon P et al *Ann Pediatr (Barc)* 73(3): 220 (2010)
4. Turvill J et al *Eur J Gastroenterol Hepatol* 9(9): 877-80 (1997)
5. Baumer et al *Gastroenterol Clin Biol* 13(11): 947-8 (1989)
6. Bergmann JF et al *Aliment Pharmacol Ther* 6(3): 305-13 (1992)
7. Vetel JM et al *Aliment Pharmacol Ther* 13(Suppl 6): 21-6 (1999)
8. Cezard JP et al *Gastroenterology* 120: 799-805 (2001)
9. Salazar-Lindo E et al *N Engl J Med* 343: 463-467 (2000)
10. NICE Guidance, Evidence summary of racecadotril (2013)
11. United Nations International Children's Emergency Fund (UNICEF) (2013)
12. Fischer Walker CL et al *BMC Public Health* 12:220 (2012)
13. Global Diarrhoea Drug Market Research report, Facts and Factors, 2020



Disclaimer: Athena if performed, will make available to potential customers its own IP assessment. Potential customers may on the basis thereof make their own independent assessment with respect to the absence of the violation of any intellectual property rights of any third party in the development and use of the regulatory dossier that could render unlawful the manufacture, import, marketing, sale, and/or distribution of the products in the relevant territory.

Key numbers

- 1.7 billion episodes of Acute Secretory Diarrhoea worldwide each year
- Global antidiarrheal Drugs market will reach \$5.8 billion by 2026

ASIA patil.amit@ddsathena.com

CANADA/USA hafid@tradepassrx.com

FRANCE francois.ribeaux@athenaips.com

GLOBAL hugues.benevent@athenaips.com
frederic.besancon@athenaips.com
awilliams@ddsathena.com

LATAM schauenberg.bruno@ddsathena.com

MENA patil.amit@ddsathena.com

OTHER contact@ddsathena.com