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Short communication

Real-World Evidence on a Diosmectite-Based Medical Device: Safety and Efficacy Outcome From Pediatricians and Gastroenterologists.

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Abstract

Background: Diarrhea, both acute and chronic, is a common gastrointestinal condition that significantly affects patients' quality of life (QoL).
Aim of the data collection: In this investigation, a diosmectite-based medical device (MD), was evaluated as part of Post-Marketing Surveillance (PMS) in compliance with European Medical Device Regulation 2017/745 (MDR). The objective was to assess its efficacy and safety in real-world clinical settings (Real-World Evidence, RWE).
Material and method: The study comprised two distinct data sets: (A) aggregated data from pediatricians involving 1,558 pediatric patients with acute or chronic diarrhea, and (B) aggregated data from gastroenterologists concerning 743 patients with chronic-recurrent diarrhea. All data were provided in aggregate form by participating physicians, based on retrospective analysis of patient medical records.
Results: In both RWE settings, the MD demonstrated effectiveness in improving stool consistency and reducing evacuation frequency within a few days of treatment, with excellent tolerability.
Conclusions: These findings, consistent with existing literature on diosmectite, support the use of the product as a safe and effective therapeutic option for managing diarrhea in both pediatric and adult populations—particularly in acute cases, with promising utility in chronic-persistent diarrhea of different etiologies.

Keywords : Acute Diarrhea, Chronic Diarrhea, Diosmectite, Pediatric, Gastroenterology.

INTRODUCTION

Diarrhea is a prevalent gastrointestinal disorder characterized by a reduction in stool consistency (soft or semiliquid stools) and/or an increase in the frequency of bowel movements (≥3 per 24 hours), often accompanied by an elevated total fecal output (>200 g/day). Clinically, diarrhea is classified by duration: acute diarrhea resolves within 14 days, persistent diarrhea lasts more than two weeks, and chronic diarrhea persists for over four weeks. Acute diarrhea is typically self-limiting and mild, often resulting from viral infections, food poisoning, or environmental changes (e.g., traveler's diarrhea). In contrast, chronic diarrhea may signal an underlying intestinal or systemic pathology, with causes ranging from chronic infections to inflammatory or iatrogenic origins. Effective management of diarrhea is essential to prevent complications such as dehydration, enhance patient comfort, and reduce the strain on healthcare resources. Among the treatment options, diosmectite-based products have demonstrated efficacy in both acute and chronic cases. Diosmectite exerts its therapeutic effect through its adsorptive and mucoprotective properties, forming a protective barrier over the intestinal mucosa, thereby limiting irritation, toxin absorption, and fluid loss [1,2].

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MATERIAL AND METHODS

Product used in the study

Retrospective data were collected to verify the efficacy and safety of a diosmectite-based medical device (MD) (CE 0426 – manufactured by PharmaLine S.r.l.) commercially available in Italy under the brand name *Catidral* Plus and distributed in other countries under various private labels. The medical device is indicated for the treatment of both acute and chronic diarrhea, as well as for alleviating gastrointestinal discomfort and associated painful symptoms.

Aim of the project and study design

The collected data originates from structured post-marketing surveillance activities, as mandated by European Medical Device Regulation 2017/745 (MDR). The surveillance was designed to encompass different clinical settings and patient populations, with the objective of gathering practical, real-world insights. These findings are intended to inform and support clinical decision-making, optimize therapeutic strategies, and ultimately contribute to improving the quality of life in patients affected by diarrhea.

Two distinct datasets has been collected using a uniform methodology:

- ***Collection A:*** Aggregated data from pediatricians on children with acute or chronic diarrhea.
- ***Collection B:*** Aggregated data from gastroenterologists on patients with chronic-recurrent diarrhea.

For both data collections, pediatricians (Collection A) and gastroenterologists (Collection B) were selected among physicians across Italy who routinely prescribe the diosmectite-based medical device under investigation. Participating clinicians contributed with aggregated data retrospectively extracted from patient medical records, enabling the realization of a non-interventional observational study based on real-world evidence (RWE).. In addition to clinical data extracted from patient records, evidence were collected regarding physicians' personal experience with the product. As part of the data sharing, all physicians provided informed consent for the processing of their personal data by PharmaLine S.r.l. and ensured the complete anonymity of any patient data submitted, in compliance with applicable privacy regulations.

RESULTS

Collection A: data from pediatricians

Between May and October 2024, a total of 24 Italian pediatricians participated in the study, providing retrospective aggregated data from their pediatric patients to whom the diosmectite-based medical device (MD) had been prescribed within the previous 12 months. Data were collected for 1,558 children: 837 patients aged 2–6 years and 721 patients aged 7–12 years.

Medical device effectiveness

Of the 24 pediatricians, 23 used the MD primarily for the treatment of acute diarrhea, while only one physician indicated primary use in chronic-recurrent cases. Overall, the MD was prescribed for acute diarrhea in 87.2% of cases and for chronic diarrhea in 12.8%.

In cases of acute diarrhea:

- 54% of pediatricians administered 6 g/day (2 sachets/day) until symptom resolution.
- 29% used 12 g/day (4 sachets/day) for the first 3 days, followed by a reduced dose until resolution.
- 17% used an intermediate dose of 9 g/day (3 sachets/day).

For chronic diarrhea, the most common administration regimen was 3–6 g/day (1–2 sachets/day), typically administered in 8-week cycles.

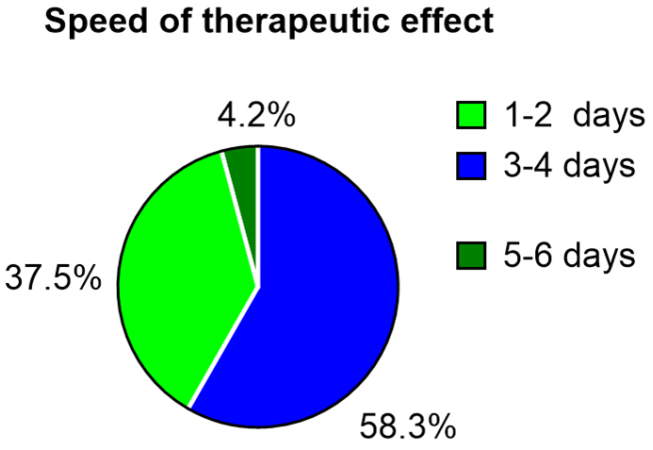
Onset of Action

To evaluate the speed of therapeutic effect, pediatricians were asked to extrapolate from patients' medical records the average duration of therapy required to normalize stool frequency and consistency:

- 58.3% reported improvement within 3–4 days
- 37.5% observed results within 1–2 days
- 4.2% indicated that 5–6 days were needed.

These results confirm both the efficacy and rapid onset of action of the MD in pediatric settings (**Figure 1**).

Figure 1. Speed of therapeutic effect. Pie chart depicting the speed with which the therapeutic effect occurs in pediatric patients.



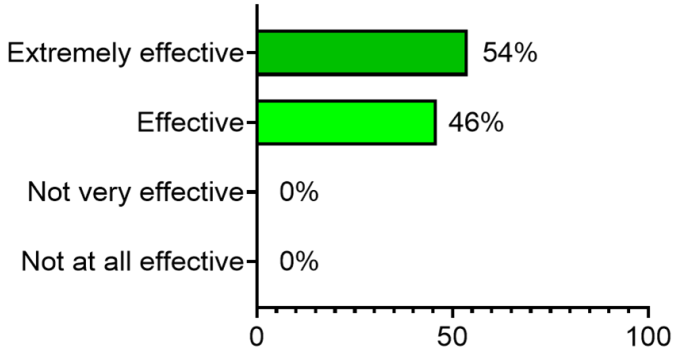
Safety Profile

No adverse events due to DM use were reported across the entire pediatric cohort (n=1,558), even in cases involving continuous use over extended periods (e.g., 8-week cycles for chronic diarrhea).

Overall Physician Assessment

Pediatricians were asked to rate the overall effectiveness of the MD on a four-point scale: not at all effective, not very effective, effective, or extremely effective, based on their personal experience. As shown in **Figure 2**, all respondents rated the treatment as either "effective" or "extremely effective", resulting in a 100% positive evaluation.

Figure 2. Pediatricians' overall assessment of MD effectiveness.



Conclusion – Data collection A

The pediatric data confirm that the diosmectite-based MD is both effective and well tolerated in children with acute and chronic diarrhea. Most notably, its rapid action, with symptom relief typically occurring within a few days, and the absence of reported adverse effects, underscore its utility as a frontline treatment in pediatric gastroenterology.

Collection B: data from gastroenterologists

Between July and October 2024, 16 Italian gastroenterologists contributed with retrospective aggregate data on patients to whom the diosmectite-based medical device (MD) had been prescribed within the previous 12 months for the treatment of chronic-recurrent diarrhea. The dataset included 80 pediatric patients (aged 2–12 years) and 663 patients aged over 12 years, for a total of 743 individuals.

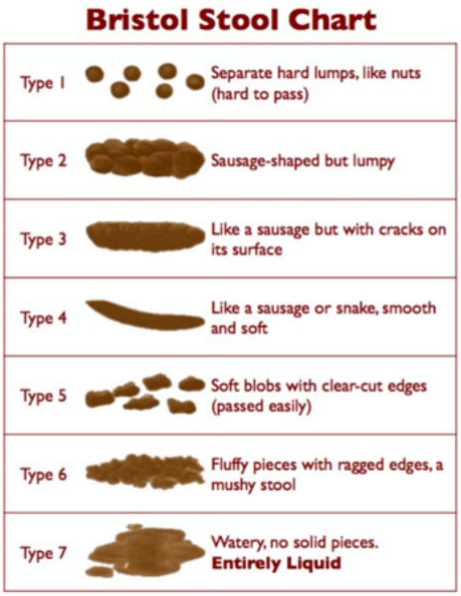
Etiology of Chronic-Recurrent Diarrhea

The underlying causes of chronic-recurrent diarrhea were heterogeneous. The most commonly reported condition was Irritable Bowel Syndrome (IBS), accounting for approximately 50% of cases. Other etiologies included chronic intestinal diseases, persistent infections, dysbiosis, food intolerances, malabsorption syndromes, side effects from radiotherapy or chemotherapy, and functional diarrhea.

Medical device effectiveness

To assess efficacy, gastroenterologists reported the patients' average number of daily bowel movements and stool consistency, measured using the Bristol Stool Scale (**Figure 3**), both before and after treatment with the DM.

Figure 3. Bristol Stool Chart.



Among patients over 12 years of age:

- In 69% of cases 3–6 g/day (1–2 sachets daily) has been prescribed in 8-week cycles.
- In the remaining 31% of cases, 9 g/day (3 sachets daily) for 10-day cycles per month has been prescribed.

Before treatment, patients had:

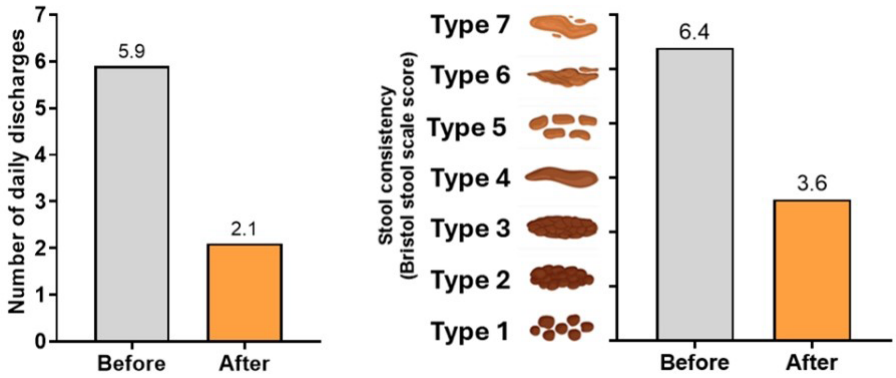
- An average of 5.9 daily evacuations (range: 3–10).
- Average stool consistency between types 6 and 7 on the Bristol scale (mean: 6.4), consistent with chronic diarrhea.

After treatment:

- The average number of daily evacuations decreased to 2.1 (range: 1–5).
- Stool consistency improved to an average Bristol type 3–4 (mean: 3.6).

These findings indicate a substantial improvement in both bowel movement frequency and stool form (see **Figure 4**). Graphical representation of the mean value of the number of daily discharges (left graph) and mean stool consistency based on Bristol Stool Scale score (right graph).

Figure 4. Impact of Diosmectite-Based Medical Device on Stool Frequency and Consistency.

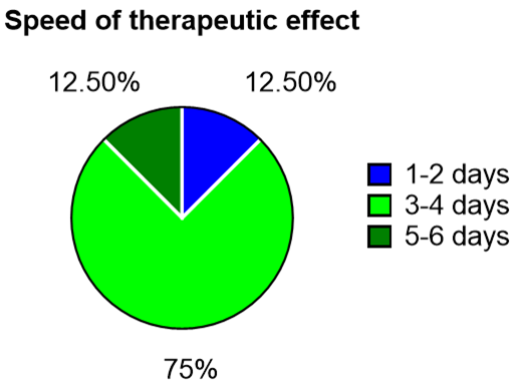


Speed of therapeutic effect

To evaluate onset of action, gastroenterologists were asked to extrapolate from patients' medical records the average duration of therapy required to normalize stool frequency and consistency:

- 75% reported improvement typically occurring within 3–4 days (see **Figure 5**), demonstrating the rapid therapeutic effect of the DM.

Figure 5. Speed of therapeutic effect. Pie chart depicting the speed with which the therapeutic effect occurs in gastroenterological patients.



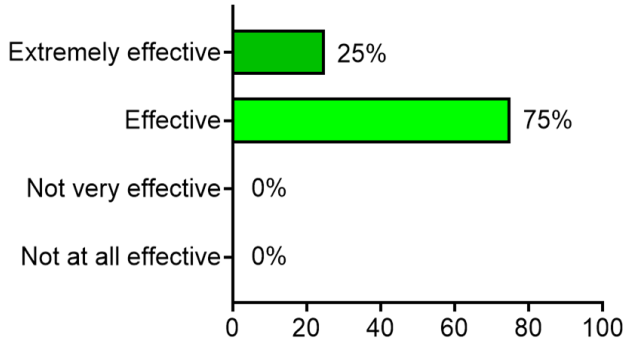
Safety

No adverse events due to MD use were reported among the 743 patients included in this dataset, despite the extended treatment duration in many cases.

Physician evaluation and confidence in product use

Gastroenterologists were also asked to provide an overall assessment of the product's efficacy using a four-point scale: *not at all effective, not very effective, effective, or extremely effective*. As shown in **Figure 6**, 100% of physicians rated the MD as either "effective" or "extremely effective" for the treatment of chronic-recurrent diarrhea.

Figure 6. Gastroenterologists' overall assessment of MD effectiveness.



Furthermore, physicians were asked about the confidence in the use of the product in clinical practice:

- 50% of gastroenterologists (8 physicians) routinely advised patients to continue or cyclically repeat treatment on their own, due to the MD's favorable safety and tolerability profile.
- 31% (5 physicians) endorsed unsupervised continuation only in selected cases, further supporting the device's ease of use and low risk profile.

Conclusion – data Collection B

Data from this real-world, retrospective analysis confirm that the diosmectite-based medical device is effective, safe, and well tolerated in both pediatric and adult patients with chronic-recurrent diarrhea of various etiologies.

Across the 743 patients evaluated, DM use led to a significant reduction in stool frequency and normalization of stool consistency, typically within 3–4 days of treatment.

The absence of adverse events, even during extended 8-week treatment cycles, further supports the product's safety in real-world use. Moreover, many specialists reported that the MD could be safely self-administered by patients over time, reinforcing its practicality of use and suitability for long-term

management of chronic-recurrent diarrhea, including self-administration by patients.

DISCUSSION

Diosmectite is a natural aluminosilicate clay characterized by a lamellar crystalline structure that confers adsorbent properties. Following oral administration, it remains confined to the intestinal lumen, exerting its effects locally without systemic absorption. Its mechanism of action is multifaceted: diosmectite adsorbs bacterial toxins, viruses, and other potentially noxious agents; it acts as a mucosal protector by binding to enteric mucoproteins, altering mucus viscosity, and inhibiting pathogen-induced mucolysis. Through its interaction with mucins, diosmectite limits the translocation of toxins across the mucus layer, thereby shielding the intestinal epithelium from inflammatory damage. Moreover, it helps preserve the structural integrity of enterocytes and restores epithelial barrier function by promoting ion absorption and limiting excessive water loss, a hallmark of diarrheal disease[1-2].
Due to its lack of systemic absorption, diosmectite is well tolerated, even in very young children. Its excellent safety profile has contributed to its widespread use for managing diarrhea in both pediatric and adult populations, particularly in Europe, as well as in parts of Asia and Africa. It is frequently administered alongside oral rehydration solutions (ORS), the cornerstone of acute diarrhea management. Importantly, diosmectite does not interfere with ORS absorption or efficacy[1-3], making the combination both clinically effective and safe.
Randomized controlled trials (RCTs) in children with mild to moderate acute diarrhea have demonstrated that diosmectite significantly reduces stool volume, duration and frequency of diarrhea, and improves stool consistency while also decreasing the rate of prolonged diarrhea cases. (>7 days)[2].
A Cochrane systematic review confirmed these findings, reporting that diosmectite shortens the duration of diarrhea by approximately one day and increases the likelihood of recovery by day three, while also reducing total stool output[4].
In adults, diosmectite has also shown clinical benefit. A placebo-controlled trial demonstrated that diosmectite, administered at a dosage of 6 g three times daily, was effective and well tolerated in reducing recovery time during episodes of acute watery diarrhea of infectious origin[5].
Following these findings, the use of diosmectite has been investigated in the treatment of chronic diarrhea of different etiologies. Increasingly, chronic diarrhea is known to result not only from ongoing disease processes, but also from disruptions in intestinal barrier function, dysbiosis, and low-grade mucosal inflammation. In this context, the role of mucosal protectants such as diosmectite has garnered growing attention for their ability to support intestinal homeostasis[6].
Clinical studies have demonstrated efficacy of diosmectite in patients with diarrhea-predominant irritable bowel syndrome (IBS-D), where 8-week treatment regimens using 3 g three times daily resulted in reduced bowel movement frequency and improved stool consistency[7]. Similar outcomes were observed in patients with functional diarrhea, where 28-day treatment led to significant improvements that persisted for up to two weeks after therapy discontinuation[8].
Recurrent diarrhea, common in patients with IBS or chronic inflammatory bowel disease, substantially impairs quality of life. In addition to controlling symptoms, effective treatments should aim to improve psychosocial well-being. Diosmectite has shown promise in this regard, with evidence indicating improvements in patient-reported outcomes and psychosocial adjustment in individuals with chronic functional diarrhea[9,10].
In summary, a strong set of clinical evidence supports the use of diosmectite across a spectrum of diarrheal conditions, both acute and chronic. It offers rapid symptom relief, sustained clinical benefits, and an excellent safety profile.
While RCTs remain the gold standard for evaluating therapeutic efficacy, their findings may be limited by narrowly defined inclusion criteria and ideal study conditions. Thus, real-world evidence (RWE) is essential for complementing RCT data, as it reflects routine clinical practice and different patient populations. RWE provides valuable insights into the generalizability of therapeutic outcomes and helps to establish a more comprehensive benefit-risk profile. In accordance with European Medical Device Regulation 2017/745 (MDR), these post-marketing surveillance data collections are indispensable for ensuring ongoing patient safety and optimizing clinical decision-making[11,12].

CONCLUSION

The real-world evidence (RWE) presented in this study, derived from observational data on patients with several different clinical and demographic profiles, offers valuable insights that complement findings from randomized clinical trials (RCTs). By incorporating input directly from pediatricians and gastroenterologists across Italy, this analysis provides a detailed understanding of the everyday use of a diosmectite-based medical device (DM) under real-world conditions—outside the strictly controlled and ideal parameters of clinical studies.
Such an approach allows for the identification of treatment effects and safety signals that may not be fully captured in RCTs, where inclusion criteria are highly selective and protocols rigid. Moreover, RWE facilitates the evaluation of therapeutic outcomes across broader, more representative patient populations, enhancing the generalizability of the results and applicability to general population.
The findings support the therapeutic role of diosmectite in

both acute and chronic diarrhea management. Data from pediatricians (Collection A) and gastroenterologists (Collection B) consistently demonstrated that the DM significantly improves stool consistency and reduces the frequency of bowel movements—typically within just a few days of treatment. Importantly, no adverse effects were reported across more than 2,300 patients, underscoring the product's excellent tolerability.

These results reinforce the positioning of this diosmectite-based DM as a safe, effective, and well-tolerated option for managing diarrhea of various etiologies, both in children (aged ≥2 years) and adults. Very good physician-reported efficacy and high tolerability profile validate its use in routine clinical practice and support its continued integration into therapeutic protocols for gastrointestinal care.

Furthermore, in line with the requirements of European Medical Device Regulation 2017/745 (MDR) on post-marketing surveillance, this RWE study contributes to the broader understanding of the product's benefit–risk profile, offering practical insights to clinicians and more individualized guidance for patients.

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