Revestive®▼ (teduglutide) in paediatric patients with short bowel syndrome with intestinal failure (SBS-IF)[1]

Revestive is indicated for the treatment of patients 4 months corrected gestational age and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.[1]

Adverse events should be reported.
Reporting forms and information can be found at:
www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Takeda at:
AE.GBR-IRL@takeda.com

Prescribing information for the United Kingdom can be found by scanning this QR code, or by visiting www.emcpi.com/grp/60.

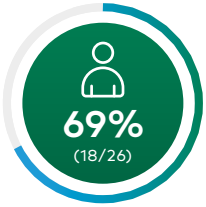
Revestive®▼
powder and solvent for solution for injection
teduglutide

C-APROM/GB/REV/0277 | February 2025

Efficacy: Paediatric patients with SBS-IF

In paediatric patients with SBS-IF, Revestive reduced PN/IV requirements[1,2]

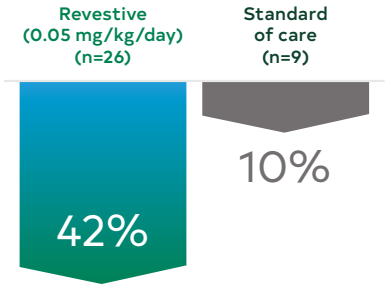
In a 24-week, Phase 3 trial including 59 paediatric patients with SBS-IF[2*]



A larger proportion of Revestive patients achieved 20% PN/IV volume reduction compared with SOC[2]

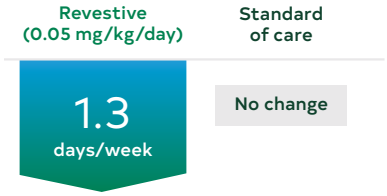
At Week 24, 69% (18/26) of patients treated with Revestive 0.05 mg/kg/day achieved ≥20% reduction from baseline in weekly PN/IV volume vs 11% (1/9) with SOC

Revestive resulted in a larger mean reduction in PN/IV volume vs. SOC[2]



From baseline to Week 24, the mean percentage changes in PN/IV volume were –42% with Revestive 0.05 mg/kg/day vs –10% in SOC arm

Revestive reduced the number of days/week on PN/IV[2]



At baseline, PN/IV requirement was 6.6 days/week in Revestive and SOC groups.

Mean reduction in PN/IV in the Revestive group was 1.3 day/week compared with no change with SOC.

At Week 24, 3/26 paediatric patients treated with Revestive were independent from PN/IV vs 0/9 with SOC

The recommended dose of teduglutide is 0.05 mg/kg body weight once daily.

*Patients in the teduglutide treatment arm were randomised 1:1 into two parallel-dose groups to receive a once daily SC injection of 0.025 mg/kg (off label) or 0.05 mg/kg teduglutide. The results here show data from the 0.05 mg/kg and SOC treatment arms only.

Real-world evidence

Use of Revestive in the real-world: Paediatric Spanish cohort[3]

Study design

17 children* with SBS-IF

Treated with teduglutide

Evaluation

Adverse events

Efficacy: Reduction in parenteral nutrition (PN/IV)

RWE: Efficacy[3]

Patients with 20% reduction in PN requirements[3]

93% (14/15) of patients **experienced reduced PN requirements** (decrease of ≥20%) at 12 months†,‡

3 months	6 months	12 months
7/15 patients	13/15 patients	14/15 patients

Patients achieving PN independence[3]

66% (10/15) **patients had achieved PN independence within 12 months†**

3 months

Enteral autonomy **3 patients**

No enteral autonomy

14 patients decreased their parenteral fluid (average 18%) and **calorie needs (average 20%)**

6 months

Enteral autonomy **7 patients**

No enteral autonomy

6 patients decreased their parenteral fluid (average 28%) and **calorie needs (average 30%)**

3 patients showed **no changes**

12 months

Enteral autonomy **10 patients**

No enteral autonomy

4 patients decreased their **support needs (decrease of ≥20%)**

1 patient showed **no change**

*Children received Revestive SC at a dose of 0.05 mg/kg/day. One patient discontinued treatment after 4 months because of cardiac decompensation; they resumed treatment 11-12 months later and were weaned off PN after 3 months. Another patient received treatment for only 6 months. †15 out of 17 patients were treated for at least 12 months. ‡A patient in whom the PN support could be reduced by 20% or more was considered a "responder".

Safety

Revestive was generally well tolerated in paediatric patients with SBS-IF[1]

Very common adverse events (≥1/10) include respiratory tract infection, headache, abdominal distension and pain, nausea, vomiting, injection-site reaction and gastrointestinal stoma complication.[1] **Please refer to the Summary of Product Characteristics for a full list of AEs.**

In two completed clinical trials in 86 paediatric patients aged 1–17 years old with SBS-IF treated with Revestive for up to 6 months: [2,3]

- No patient discontinued the studies due to AEs
- Most TEAEs were mild to moderate in severity
- The overall safety profile (type and frequency of events) was similar to that reported in adults

No new safety signals were seen in long-term pooled paediatric data of 89 patients treated with Revestive for up to 51.7 weeks (median; range 5.0–94.7) and followed up for a median of 83 weeks[4]

Real-world evidence:[3]

- Revestive was well-tolerated, with mild abdominal pain in some patients
- Two patients reported relevant AEs — one patient developed an episode of cholecystitis and one patient with pre-existing cardiac disease developed fluid overload

Takeda provides a fully funded comprehensive homecare service, delivered by HealthNet or Sciensus.

To find out more information, please reach out to:
Charlie Reed, National Key Account Manager, Takeda
Email: Charlie.Reed@Takeda.com, Mobile: 07468 698 576

For further information on SBS-IF materials (e.g., patient diaries), please visit: **sbs-ifhub.co.uk, or scan the QR code on the right. This Takeda website is for healthcare professionals only.**

AE, adverse event; **HCP**, healthcare professional; **PN/IV**, parenteral nutrition/intravenous fluid; **RWE**, real-world evidence; **SBS-IF**, short bowel syndrome with intestinal-failure; **SC**, subcutaneous; **SOC**, standard of care; **TEAE**, treatment-emergent adverse event.

References: 1. Revestive 1.25 mg and 5 mg Summary of Product Characteristics; **2.** Kocoshis SA, et al. *JPEN J Parenter Enteral Nutr* 2020;4:621–631; **3.** Ramos Boluda E, et al. *J Pediatr Gastroenterol Nutr* 2020;71:734–739; **4.** Hill S, et al. *JPEN J Parenter Enteral Nutr* 2021;45:1456–1465.