

Paediatric Pharmacotherapy for Common Obesity: Position Statement of a Tertiary Multidisciplinary Paediatric Rehabilitation Centre for Chronic Diseases

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Introduction

Childhood and adolescent obesity has reached epidemic proportions, representing one of the most pressing chronic health challenges worldwide. In our tertiary multidisciplinary paediatric rehabilitation centre, more than 50% of the admitted children present with obesity as part of their complex care needs. These children often belong to a subgroup that responds poorly to ambulatory lifestyle interventions (LI) alone. Indeed, the IMI-SOPHIA study showed that ambulatory LI have a limited effect in older children and adolescents with severe obesity who come from disadvantaged socioeconomic backgrounds and have a history of migration (1).

Our own results, as a tertiary paediatric rehabilitation centre illustrate the effectiveness of intensive LI in a residential setting. In a cohort of 295 adolescents 12-18 years (mean age: 14.9 ± 1.7 years) with obesity treated in 2023-2024, the average weight loss was 17.5 ± 11.6 kg, corresponding to a $15.3 \pm 8.7\%$ reduction from baseline weight and a body mass index (BMI) reduction of -6.5 ± 4.1 . Fat mass percentage also decreased significantly: in patients with a stay of less than 10 months, the average body fat percentage decreased from 50% to 43% (-7%), and in patients with a stay of more than 10 months, it decreased from 53% to 41% (-12%).

These results are in sharp contrast to outpatient programmes whose outcomes vary significantly depending on the age of the population. Indeed long-term, multidisciplinary LI can significantly improve BMI and cardio-metabolic health parameters in children

with severe obesity, while adolescents show less pronounced benefits—highlighting the importance of early intervention (2-5). A recent longitudinal study confirmed this, showing that children responded significantly better than adolescents to a tailored lifestyle programme, both in terms of BMI reduction and metabolic improvements (6). Systematic review reported that adolescents in intensive outpatient LI programmes (>26 contact hours) achieved an average weight loss of only 1.9 kg over a median period of 6 months (7). Residential LI such as ours therefore offers significantly greater benefits.

However, intensive lifestyle intervention programmes do not always lead to meaningful results or outcomes that patients perceive as significant. Moreover, weight regain is often observed in the longer term—further emphasising the chronic and relapsing nature of obesity. So other strategies should also be considered.

Rather than viewing treatment as a stepwise process, current guidelines recommend the use of obesity management medication (OMM) along with lifestyle intervention, motivational interviewing and psychosocial support to optimize outcomes for children living with obesity aged 12 years or older (8,9). In this context, Glucagon-like peptide-1 receptor agonists (GLP-1 RAs) have emerged as promising therapeutic options, and our centre is preparing to implement them in a structured manner, aligned with national and international guidance.

Other medications such as orlistat, phentermine have already been approved in the US for use in adolescents with obesity over the age of 12, but not in Europe

(10). Setmelanotide is reserved to specific monogenic or syndromic (Bardet-Biedl) obesities and will not be discussed here. For this reason, we will limit ourselves to GLP-1 Ras.

In this paper, we first review the literature, then we describe our own vision.

Efficacy of GLP-1 Receptor Agonists in Adolescents

When combined with lifestyle changes, both liraglutide and semaglutide have been shown to be successful in inducing weight loss in adolescents. The STEP-TEENS study reported an average BMI reduction of 16.1% with semaglutide, compared with a change of 0.6% in BMI in the placebo group after 68 weeks, with 44.9% versus 12.1% of patients achieving normalisation of BMI, respectively (11,12). Liraglutide also showed a significant but more modest 5% reduction in BMI in the SCALE-TEEN study (13). Moreover, greater BMI reduction appears to be achieved when treatment is initiated early in life, as liraglutide induced a -7.4% BMI reduction in children aged 6–12 years compared with a -4.6% reduction in adolescents aged 12–18 years (14).

Furthermore, in the STEP-TEENS study, improvements in cardio-metabolic risk factors (waist circumference, glycated haemoglobin, lipids [except high-density lipoprotein cholesterol] and alanine aminotransferase) were greater with semaglutide than with placebo. These findings are clinically relevant, as BMI, triglycerides and total cholesterol levels have all been identified as childhood risk factors associated with later cardiovascular events in adulthood. In addition, an improvement in weight-related quality of life was observed, mainly due to an improved Impact of Weight on Quality of Life – Kids (IWQOL-Kids) score for physical comfort, which was not observed in the previous study of liraglutide in adolescents with obesity. It is important to note that the effects of these medications on weight loss and obesity-related comorbidities are observed in combination with lifestyle intervention. There is insufficient evidence to support OMM as monotherapy in adolescents, i.e. without a multidisciplinary treatment strategy, as was demonstrated once again in a recent study (15).

In adults, GLP-1 RAs associated with LI have been shown to enhance weight loss and to maintain weight loss for 2 years, but weight rebound was observed after discontinuation of the medication (16). Therefore, GLP-1 RAs may need to be continued long-term to support a chronic disease management paradigm similar to that of hypertension or diabetes. Encouragingly, real-world data from Qatar, presented at the European Congress on Obesity 2025, show that adolescents treated with liraglutide achieved significant reductions in BMI and maintained weight loss even after discontinuing treatment, with no significant difference in outcomes between those who adhered to therapy (BMI -6.5 ± 17.2) and those who discontinued (-3.9 ± 16.5) (17). In adults as in adolescents with obesity,

semaglutide appears to offer a significantly greater chance of greater reduction in actual weight and BMI compared to placebo and liraglutide (18,19). A recent review confirmed semaglutide as being the most effective and safe option of four GLP-1 RAs tested (semaglutide, exenatide, liraglutide and dulaglutide) in children and adolescents with type 2 diabetes or obesity. Such evidence in youth with obesity without diabetes is more limited, though preliminary data also suggest beneficial effects (20).

In addition, the once-weekly administration of semaglutide offers greater convenience and potentially better adherence compared to the daily administration required for liraglutide. The oral form of semaglutide has been shown to be safe and effective in adults, but unfortunately, there is no information available on its use in adolescents.

Although dual agonists such as tirzepatide (Mounjaro®) have demonstrated even greater weight loss in adults compared to semaglutide, paediatric trials are still ongoing and regulatory approval for this population is still pending. Until more evidence becomes available, semaglutide remains our preferred option for the pharmacological treatment of adolescents with common obesity and liraglutide for 6-12y old children living with obesity.

Changes in food preferences and eating behaviour after GLP-1 Therapy

GLP-1 RAs not only reduce appetite but also influence reward behaviour and food preferences. Functional MRI studies in adults have shown that during the weight loss phase of treatment with GLP-1 RAs neuronal responses to signals from high-calorie foods in the insula, amygdala, putamen and orbitofrontal cortex decrease (21). Adolescents report less craving for dairy and starchy food, smaller meal sizes and a reduced preference for energy-dense foods (22,23).

While these effects in weight loss phase are promising, few data on the persistence of these effects in the weight maintenance phase are available. Reward-based eating—reinforced by an immature prefrontal cortex—remains a challenge in adolescence. This underscores the need for additional and ongoing behavioural and nutritional counselling in addition to pharmacotherapy. Our centre integrates cognitive behavioural therapy as a fundamental pillar of our obesity care which also includes psychosocial support, self-regulation strategies, and motivational interviewing.

Safety, Side Effects, and Long-Term Considerations

The GLP-1 RAs are generally well tolerated. Gastrointestinal symptoms - including nausea, vomiting, constipation, diarrhoea - are the most reported, particularly during the dose escalation phase (11-13). Serious adverse events appear to be rare but there are currently only relatively short-term data available.

However, caution is advised. A higher risk of intestinal obstruction, gastroparesis and pancreatitis was demonstrated in adults living with obesity receiving GLP-1 RAs. Concerns have been raised about an increase in thyroid neoplasia and hyperplasia in adults with diabetes treated with GLP-1 RAs compared with those receiving sodium-glucose cotransporter (SGLT)-2 inhibitors, but more recent data do not confirm an increased risk of thyroid tumours with GLP-1 RAs exposure (24-26). There is a strong need for observational data in children and adolescents to investigate whether these observations in adults may also be relevant for children and adolescents. Therefore, it is crucial that OMM data from practice are documented in registries for children and adolescents with obesity at national and international level. Little is known about the long-term effects. Starting treatment for OMM at this crucial stage of life can have various effects on healthy growth, such as brain development, and on possible future health risks, such as mental disorders or cancer.

Nutritional and Functional Implications

When combined with the new OMM, the focus of LI may shift from solely promoting weight loss through calorie restriction to encouraging healthier food choices and increased physical activity. This approach supports optimal changes in body composition, enhances overall health and contributes to improved quality of life for patients. For LI in combination with OMM, some evidence and guidance are available for adults but are lacking for adolescents. Nutritional recommendations for healthcare providers supporting adults with obesity who are receiving OMM were recently published (27). According to these guidelines, it is advised to identify any pre-existing nutritional risk factors early on to help prevent adverse outcomes such as malnutrition or the development of eating disorders. During OMM treatment, patients should be closely monitored to address potential deficiencies in fluid or (micro)nutrient intake and to better manage side effects. For instance, it is recommended to avoid high-fat foods, such as fried items, to reduce gastrointestinal discomfort.

Maintaining or even increasing skeletal muscle mass during weight reduction is crucial for overall health, metabolic function, and long-term weight loss maintenance (28). The potential loss of muscle mass during GLP-1 RAs treatment remains a concern. Recent meta-analysis suggests that reductions in fat-free mass (FFM) account for approximately 25–39% of the total weight loss observed with GLP-1 RAs and GLP-1/GIP (Glucose-dependent Insulinotrophic Polypeptide) receptor co-agonists (29,30). This is consistent with the reported percentage of FFM loss with other forms of weight loss (diet-induced or bariatric surgery-induced), indicating that GLP-1 RAs do not exert an additional effect on the proportion of FFM lost (31,32). However, FFM, which is usually measured by dual-energy x-ray absorptiometry (DEXA) in these studies, is

only a crude surrogate for skeletal muscle mass. FFM encompasses not only muscle mass but also organs, bone, fluids, and water in fat tissue and it does not capture muscle function or volume. Therefore, the clinical relevance of these changes remains uncertain (33).

At the time of writing, there are no data to establish whether treatment with GLP-1 RAs is associated with physical frailty or sarcopenia (28). No paediatric randomized controlled trials have yet been conducted in which changes in muscle mass, strength or physical performance during GLP-1 RAs therapy have been directly measured. Given the existing research gaps, it is advisable when initiating GLP-1 RAs therapy such as semaglutide in children and adolescents, to monitor body composition (e.g., via DEXA or bioimpedance) and muscle function (e.g. strength testing) in addition to body weight.

Moreover, preservation of muscle mass should be regarded as a key therapeutic objective, parallel to the goals of reducing adiposity and weight-related complications. Beyond appetite regulation, sustainable weight loss requires strategies that support energy expenditure, fat oxidation and lean mass preservation. This underscores the importance of integrating resistance exercise and adequate protein intake alongside pharmacotherapy (34). As demonstrated in older adults, combining protein-rich nutrition with resistance training can help mitigate potential muscle loss (35). Participants randomized to liraglutide 3.0 mg daily plus resistance exercise for one year exhibited a lower percentage FFM loss compared with those receiving drug therapy alone (24.7% vs. 38.6%) (36). Thus, a multidisciplinary approach involving a dietitian and a physical therapist should be integrated into OMM therapy to optimize outcomes, prevent weight cycling and consequently reducing the risk of developing sarcopenic obesity (37). New medications such as selective androgens receptor modulators (SARM) or myostatin-activin pathways inhibitors are currently under development to help preserve skeletal muscle mass (38).

However, the observed loss of FFM may also reflect a reduction in intramuscular fat rather than true loss of contractile muscle tissue, as FFM reductions associated with GLP-1 RAs have not been linked to declines in physical performance (39). In line with these findings, a recent study using MRI to assess muscle volume and composition showed that GLP-1/GIP agonist therapy reduced intramuscular fat infiltration in individuals with type II diabetes after 52 weeks of treatment, without evidence of increased muscle loss (40). Another MRI-based sub-study assessed muscle quality in 128 women living with obesity but without diabetes. They found that, compared with placebo, liraglutide reduced (thigh) muscle fat by 7.8% from baseline, and that the presence of adverse muscle composition (high muscle fat and low muscle mass) decreased compared to controls (41). In fact, excessive deposition of adipose tissue within skeletal muscle (intramuscular adipose tissue, IMAT) also referred as myosteatorsis, is a known cardiovascular risk

factor and is associated with insulin resistance, aging, poor muscle quality and reduced mobility. Thus, GLP-1 RAs may improve muscle composition despite concomitant reductions in muscle mass.

Evidence-based recommendations on how to adapt LI to different phases of OMM treatment along the obesity treatment chain are warranted.

Patient Selection and Clinical Integration of GLP-1 RAs Therapy in our Paediatric Rehabilitation Centre

A. For adolescents (≥ 12 years) who were not taking GLP-1 RAs upon admission to our rehabilitation centre, GLP-1 RAs therapy should be considered during hospitalization:

1) After 3 months of intensive LI if:

a) Persistent obesity, is present, defined as:

- i) BMI $\geq$ IOTF35 (International Obesity Task Force threshold corresponding approximately to adult BMI ≥ 35) or
- ii) BMI $\geq$ IOTF30 with ongoing obesity-related comorbidities such as (42):
 - (1) insulin resistance, defined as HOMA-IR $> P90$ for age (43).
 - (2) metabolic dysfunction-associated steatotic liver disease (MASLD), defined according to the NASPGHAN clinical practice guidelines (44).
 - (3) obstructive sleep apnoea (OSA) diagnosed by polysomnography (45,46).
 - (4) hypertension defined as blood pressure values above the 95th percentile (47).

b) Satiety phenotype is identified, characterized by abnormal satiety (i.e., reduced duration of fullness after meals) (48).

2) At any time beyond 3 months during the stay, if:

- a) Weight loss plateaus AND
- b) BMI remains $\geq$ IOTF 30.

In practice: all patients (≥ 12 years) admitted to our rehabilitation centre without prior pharmacotherapy begin with an intensive LI program.

After 3 months, weight evolution is evaluated. If pre-defined criteria are met, semaglutide initiation is considered with dosage titrated guided by clinical response and tolerability, up to a maximum of 2.4 mg/week. Dose escalation to the maximal dose is not mandatory if adequate weight loss and improvement of obesity status are achieved at lower doses. The rate of weight loss, side effects, and achievement of a BMI

within the normal range for age and sex are considered during titration. During the maintenance phase, tapering may be considered if increased physical activity and sustained weight loss are achieved (35).

Before starting treatment, realistic goals, expectations, and potential side effects will be discussed with the patient and their family. The patient's motivation and overall wellbeing will be carefully considered in the decision-making process.

Beyond its metabolic benefits, the LI program offers significant psychopedagogical value: it fosters self-awareness, builds coping strategies, and promotes long-term behavioural change. This holistic approach not only supports physical health but also enhances emotional resilience and quality of life (49,50). Importantly, lifestyle intervention will always remain the cornerstone of our treatment strategy, regardless of pharmacological support.

Upon initiation of the medication, patients will be informed of the importance of attending regular follow-up consultations after their stay in our centre. These follow-ups will focus on clinical and behavioural monitoring, including assessments of weight, side effects, and treatment adherence. It will also be clearly communicated that GLP-1 RAs therapy is a long-term treatment strategy, with significant financial implications. Monthly costs may typically range from 145 to 190 euros which may represent a significant long-term financial challenge for most families (51). This information is essential to support informed decision-making and ensure sustained engagement with the treatment plan. Financial feasibility is a key determinant. If the family cannot afford to continue therapy for at least 6–12 months post-discharge, initiation may be postponed to avoid early discontinuation and rebound weight gain.

B. Adolescents (≥ 12 years) who were already receiving GLP-1 RAs upon admission and had achieved a decrease of $\geq 4\%$ in BMI or BMI-z-score after 3 months on the medication preceding admission to the Zeepreventorium, will continue the medication during their hospitalisation. For patients who did not achieve a significant reduction in BMI during previous GLP-1 RAs therapy, the care team will evaluate treatment adherence and assess whether the appropriate therapeutic dose was reached, with the aim of considering a potential reinitiation of the treatment.

Our Institutional Commitment

As a tertiary care centre, we support the continuation of GLP-1 RAs therapy initiated by second-line paediatric obesity centres (PMOCs). Conversely, when treatment is initiated within our rehabilitation centre, we ensure a structured transition back to secondary care. This includes the transfer of DEXA scan results, progress metrics, and a comprehensive multidisciplinary follow-up plan. Shared decision-making and transparent communication with families remain essential throughout all stages of care.

We advocate for a cautious, guideline-driven implementation within specialized care settings and highlight the need for longitudinal outcome research, especially in pre-adolescent and adolescent populations.

We recognize our multifaceted role in clinical care, conducting research studies, contributing to national policy committees, and disseminating knowledge.

We commit to:

- Integrating pharmacotherapy in alignment with the latest clinical guidelines.
- Contributing to national registries and advancing real-world outcome research.
- Collaborating with academic institutions to address data gaps in paediatric obesity care.
- Collaborating with second-line PMOCs and first-line providers through joint care pathways.
- Advocating for reimbursement for OMM in paediatric care within specialized centres. Initiation of OMM should always occur under the supervision of an experienced healthcare professional.

Conclusion

When embedded within a patient-centred, comprehensive care model, grounded in behavioural, nutritional, physical, and psychosocial support, GLP-1 pharmacotherapy represents a pivotal advancement in the management of paediatric obesity. In our setting, these medications can play a valuable role in supporting adolescents with severe obesity as they engage in lifestyle interventions.

This pharmaco-therapeutic approach must be individualized and sustained over time to maximize benefit and minimize the risk of rebound. It also reflects our centre's broader commitment to equitable access, long-term continuity of care, and improved health trajectories for children and adolescents with complex obesity.

As a rehabilitation centre, we recognize our responsibility in guiding the safe and equitable use of long-term GLP-1 RAs therapy. These treatments should be initiated only in specialized (second or third line) centres that offer a multidisciplinary LI program. Furthermore, given the high cost and potential financial barriers for families, we are committed to rigorously assessing medical necessity, supporting families in navigating access and reimbursement processes, and advocating for broader systemic solutions to ensure that effective treatment is not restricted by socioeconomic status.

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Prijs terugbetaald (GZ)	12,80€
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BESCHERM

ALLE BABY'S* TEGEN RSV†

†LAGERE-LUCHTWEG AANDOENINGEN VEROORZAAKT DOOR RSV



Patiëntweergave. Dit is een fictief patiëntgeval, uitsluitend bedoeld ter illustratie.

Plan Beyfortus® idealiter vóór aanvang van het RSV-seizoen:

- ✓ Eenmalige injectie voor het hele seizoen (ten minste 5-6 maanden)
- ✓ Dosering op basis van gewicht: 50mg (<5kg) of 100mg (≥5kg)
- ✓ Terugbetaald voor alle baby's in hun eerste RSV-seizoen** en voor kwetsbare kinderen in hun tweede seizoen

SOPHIA

- Geboortedatum: 15 augustus (vóór het RSV-seizoen)
- Geboortestatus: A terme (39 weken), normaal geboortegewicht
- Woont samen met beide ouders en een broer van 3 jaar
- Ging binnen drie maanden na de geboorte naar de crèche
- Was niet beschermd tegen RSV
- Werd in december opgenomen in het ziekenhuis wegens RSV-LRTD

Beyfortus® is het eerste direct langwerkend antilichaam ontwikkeld voor alle baby's†



Voor al uw vragen scan de QR-code of
contacteer: Beyfortus.Belgium@sanofi.com

Beyfortus® is geïndiceerd voor de preventie van lagere-luchtwegaandoeningen veroorzaakt door RSV bij:
i. Pasgeborenen en zuigelingen tijdens hun eerste RSV-seizoen.
ii. Kinderen tot 24 maanden oud die kwetsbaar blijven voor ernstige RSV-ziekte tijdens hun tweede RSV-seizoen.

†Dit geneesmiddel is onderworpen aan aanvullende monitoring. Daardoor kan snel nieuwe veiligheidsinformatie worden vastgesteld. Beroepsbeoefenaren in de gezondheidszorg wordt verzocht alle vermoedelijke bijwerkingen te melden. Zie rubriek 4.8 voor het rapporteren van bijwerkingen. **NAAM VAN HET GENEESMIDDEL** Beyfortus 50 mg oplossing voor injectie in een voorgevulde spuit. Beyfortus 100 mg oplossing voor injectie in een voorgevulde spuit. **KWALITATIEVE EN KWANTITATIEVE SAMENSTELLING** Beyfortus 50 mg oplossing voor injectie in een voorgevulde spuit Elke voorgevulde spuit bevat 50 mg nirsevimab in 0,5 ml (100 mg/ml). Beyfortus 100 mg oplossing voor injectie in een voorgevulde spuit Elke voorgevulde spuit bevat 100 mg nirsevimab in 1 ml (100 mg/ml). Nirsevimab is een gehumaniseerd immunoglobuline G1 kappa (IgG1D) monokonaal antilichaam dat geproduceerd wordt uit ovariumcellen van de Chinese hamster (Chinese hamster ovary, CHO) met behulp van recombinant-DNA-technologie. Hulpstoffen met bekend effect: Dit middel bevat 0,1 mg polysorbaat 80 (E433) in elke doseringseenheid van 50 mg (0,5 ml) en 0,2 mg in elke doseringseenheid van 100 mg (1 ml) (zie rubriek 4.4). Voor de volledige lijst van hulpstoffen, zie rubriek 6.1. **FARMACEUTISCHE VORM** Oplossing voor injectie (injectie). Helder tot opalescente, kleurloze tot gele oplossing met een pH-waarde van 6,0. **THERAPEUTISCHE INDICATIES** Beyfortus is geïndiceerd voor de preventie van lagere-luchtwegaandoeningen veroorzaakt door het respiratoir syncytiaal virus (RSV) bij: - Pasgeborenen en zuigelingen tijdens hun eerste RSV-seizoen. - Kinderen tot 24 maanden oud die kwetsbaar blijven voor ernstige RSV-ziekte tijdens hun tweede RSV-seizoen (zie rubriek 5.1). Beyfortus dient te worden gebruikt in overeenstemming met officiële aanbevelingen. **DOSERING EN WIJZE VAN TOEDIENING** Dosering Zuigelingen tijdens hun eerste RSV-seizoen De aanbevolen dosering is een enkelvoudige dosis van 50 mg intramusculair toegediend voor zuigelingen met een lichaamsgewicht < 5 kg en een enkelvoudige dosis van 100 mg intramusculair toegediend voor zuigelingen met een lichaamsgewicht ≥ 5 kg. Beyfortus moet worden toegediend vanaf de geboorte voor zuigelingen die tijdens het RSV seizoen zijn geboren. Voor diegenen die buiten het seizoen geboren zijn, dient Beyfortus idealiter te worden toegediend voorafgaand aan het RSV-seizoen. De dosering bij zuigelingen met een lichaamsgewicht van 1,0 kg tot <1,6 kg is gebaseerd op extrapolatie. Hiervoor zijn geen klinische gegevens beschikbaar. Naar verwachting zal blootstelling bij zuigelingen van <1 kg hogere blootstellingen opleveren dan bij zuigelingen die meer wegen. De voordelen en risico's van het gebruik van nirsevimab bij zuigelingen van <1 kg moeten zorgvuldig worden afgewogen. Er zijn beperkte gegevens beschikbaar over extreem premature zuigelingen (zwangerschapsduur < 29 weken) jonger dan 8 weken. Er zijn geen klinische gegevens beschikbaar over zuigelingen met een postmenstruele leeftijd (zwangerschapsduur bij geboorte plus chronologische leeftijd) van minder dan 32 weken (zie rubriek 5.1). Kinderen die kwetsbaar blijven voor ernstige RSV-ziekte tijdens hun tweede RSV-seizoen De aanbevolen dosis is een enkelvoudige dosis van 200 mg intramusculair toegediend als twee injecties (2 x 100 mg). Beyfortus dient idealiter te worden toegediend voorafgaand aan aanvang van het tweede RSV-seizoen. Voor personen die een hartoperatie ondergaan met cardiopulmonale bypass, kan zodra de persoon stabiel is na de operatie een extra dosis toegediend worden om adequate nirsevimab-serumspiegels te garanderen. Als dit binnen 90 dagen na ontvangst van de eerste dosis Beyfortus plaatsvindt, dient de aanvullende dosis tijdens het eerste RSV-seizoen 50 mg of 100 mg te zijn, afhankelijk van het lichaamsgewicht, of 200 mg tijdens het tweede RSV-seizoen. Als er meer dan 90 dagen zijn verstreken sinds de eerste dosis, kan de aanvullende dosis een enkelvoudige dosis van 50 mg zijn, ongeacht het lichaamsgewicht, tijdens het eerste RSV-seizoen of 100 mg tijdens het tweede RSV-seizoen om de rest van het RSV seizoen te dekken. De veiligheid en werkzaamheid van nirsevimab bij kinderen in de leeftijd van 2 tot 18 jaar zijn niet vastgesteld. Er zijn geen gegevens beschikbaar. Wijze van toediening Beyfortus is alleen voor intramusculaire injectie. Het wordt intramusculair toegediend, bij voorkeur in de anterolaterale zijde van de dij. De gluteale spieren mogen niet routinematig als injectieplaats worden gebruikt vanwege het risico op beschadiging van de ischiaszenuw. Zijn er twee injecties nodig, gebruik dan twee verschillende injectieplaatsen. Zie rubriek 6.6 voor instructies inzake speciale hanteringsvereisten. **CONTRA-INDICATIES** Overgevoeligheid voor de werkzame stof of voor een van de in rubriek 6.1 vermelde hulpstoffen. **BIJWERKINGEN** Samenvatting van het veiligheidsprofiel De meest voorkomende bijwerking was rash (0,7%) die binnen 14 dagen na toediening optrad. Het merendeel van deze bijwerking was licht tot matig van intensiteit. Aanvullend werden pyrexie en injectieplaatsreacties binnen 7 dagen na toediening gemeld met een prevalentie van respectievelijk 0,5% en 0,3%. Injectieplaatsreacties waren niet ernstig. Lijst van bijwerkingen Hieronder staan de bijwerkingen die zijn gemeld bij 2.966 voldragen en premature zuigelingen (zwangerschapsduur, Gestational Age (GA) ≥ 29 weken) die nirsevimab kregen in klinische onderzoeken en tijdens het toezicht na het in de handel brengen (zie rubriek 4.4). De bijwerkingen die zijn gemeld in gecontroleerde klinische onderzoeken zijn ingedeeld volgens systeem/orgaanklasse (SOC) van MedDRA. Binnen elke SOC zijn voorkeurstermen gerangschikt op afnemende frequentie en vervolgens op afnemende ernst. De frequenties van optreden van bijwerkingen wordt gedefinieerd als: zeer vaak (≥ 1/10); vaak (≥ 1/100 tot <1/10); soms (≥ 1/1.000 tot <1/100); zelden (≥ 1/10.000 tot <1/1.000); zeer zelden (<1/10.000) en niet bekend (kan met de beschikbare gegevens niet worden bepaald). Immunsysteemaandoeningen - Niet bekend - Overgevoeligheidsaandoeningen uit spontane melding Huid- en onderhuidaandoeningen - Soms - Rash b Rash is gedefinieerd door de volgende gegroepeerde voorkeurstermen: rash, maculo-papulaire rash, vlekkeuze rash. Algemene aandoeningen en toedieningsplaatsstoornissen - Soms - Injectieplaatsreactie - Pyrexie c Injectieplaatsreactie is gedefinieerd door de volgende gegroepeerde voorkeurstermen: injectieplaatsreactie, injectieplaatspijn, injectieplaatsverharding, injectieplaatsoedeem, zwelling van injectieplaats Zuigelingen met een verhoogd risico op ernstige RSV-ziekte in hun eerste seizoen. De veiligheid is onderzocht in MEDLEY bij 918 zuigelingen met een verhoogd risico op ernstige RSV-ziekte, onder wie 196 extreem premature zuigelingen (GA < 29 weken) en 306 zuigelingen met chronische longziekte van prematuriteit of hemodynamisch significante aangeboren hartziekte die hun eerste RSV seizoen ingingen, die nirsevimab (n=614) of palivizumab (n=304) kregen. Het veiligheidsprofiel van nirsevimab bij zuigelingen die nirsevimab ontvingen in hun eerste RSV-seizoen was vergelijkbaar met het vergelijkende geneesmiddel palivizumab en consistent met het veiligheidsprofiel van nirsevimab bij voldragen en premature zuigelingen GA ≥ 29 weken (D5290C00003 en MELODY). Kinderen die kwetsbaar blijven voor ernstige RSV-ziekte in hun tweede seizoen De veiligheid werd beoordeeld in MEDLEY bij 220 kinderen met chronische longziekte van prematuriteit of hemodynamisch significante congenitale hartziekte die nirsevimab of palivizumab kregen in hun eerste RSV-seizoen en vervolgens nirsevimab kregen in hun tweede RSV-seizoen (180 proefpersonen kregen nirsevimab in zowel seizoen 1 als 2, 40 kregen palivizumab in seizoen 1 en nirsevimab in seizoen 2). Het veiligheidsprofiel van nirsevimab bij kinderen die nirsevimab kregen in hun tweede RSV-seizoen was consistent met het veiligheidsprofiel van nirsevimab bij voldragen en premature zuigelingen GA ≥ 29 weken (D5290C00003 en MELODY). De veiligheid werd ook onderzocht in MUSIC, een open-label onderzoek zonder controlegroep met enkelvoudige dosis bij 100 immunocompromiteerde zuigelingen en kinderen ≤ 24 maanden die nirsevimab ontvingen in hun eerste of tweede RSV-seizoen. Dit omvatte deelnemers met ten minste een van de volgende aandoeningen: immunodeficiënte (gecombineerd, antilichaam of andere etiologie) (n=33); systemische behandeling met hoge doses corticosteroiden (n=29); orgaan- of beenmergtransplantatie (n=16); gebruik van immunosuppressieve chemotherapie (n=20); andere immunosuppressieve behandeling (n=15) en HIV-infectie (n=8). Het veiligheidsprofiel van nirsevimab was consistent met wat werd verwacht voor een populatie van immunocompromiteerde kinderen en met het veiligheidsprofiel van nirsevimab bij voldragen en premature zuigelingen GA ≥ 29 weken (D5290C00003 en MELODY). Het veiligheidsprofiel van nirsevimab bij kinderen tijdens hun tweede RSV-seizoen was consistent met het veiligheidsprofiel van nirsevimab dat werd waargenomen tijdens hun eerste RSV-seizoen. Voldragen en premature zuigelingen die hun eerste RSV-seizoen begonnen De veiligheid van nirsevimab werd ook beoordeeld in HARMONIE, een gerandomiseerd, multicenter open-label-onderzoek bij 8.034 voldragen en premature zuigelingen (GA ≥ 29 weken) die hun eerste RSV-seizoen begonnen (en niet geschikt waren voor palivizumab), die nirsevimab (n=4.016) of geen interventie (n=4.018) kregen ter preventie van ziekenhuisopname voor respiratoire syncytiale virusinfectie van de onderste luchtwegen (RSV LRTI). Het veiligheidsprofiel van nirsevimab toegediend in het eerste RSV-seizoen was consistent met het veiligheidsprofiel van nirsevimab in de placebogecontroleerde onderzoeken (D5290C00003 en MELODY). Melding van vermoedelijke bijwerkingen Het is belangrijk om na toelating van het geneesmiddel vermoedelijke bijwerkingen te melden. Op deze wijze kan de verhouding tussen voordelen en risico's van het geneesmiddel voortdurend worden gevolgd. Beroepsbeoefenaren in de gezondheidszorg wordt verzocht alle vermoedelijke bijwerkingen te melden via: België: Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten: www.fagg.be - Afdeling Vigilantie. Website: www.eenbijwerkingmelden.be - e-mail: adr@fagg.afmps.be **HOUDER VAN DE VERGUNNING VOOR HET IN DE HANDEL BRENGEN** Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, Frankrijk **NUMMER(S) VAN DE VERGUNNING VOOR HET IN DE HANDEL BRENGEN** EU/1/22/1689/001 - 50 mg, 1 voorgevulde spuit voor eenmalig gebruik EU/1/22/1689/002 - 50 mg, 1 voorgevulde spuit voor eenmalig gebruik met naalden EU/1/22/1689/003 - 50 mg, 5 voorgevulde spuiten voor eenmalig gebruik EU/1/22/1689/004 - 100 mg, 1 voorgevulde spuit voor eenmalig gebruik EU/1/22/1689/005 - 100 mg, 1 voorgevulde spuit voor eenmalig gebruik met naalden EU/1/22/1689/006 - 100 mg, 5 voorgevulde spuiten voor eenmalig gebruik **DATUM VAN EERSTE VERLENING VAN DE VERGUNNING/VERLENING VAN DE VERGUNNING** Datum van eerste verlening van de vergunning: 31 oktober 2022 **DATUM VAN HERZIENING VAN DE TEKST** Goedkeuringsdatum: 03/2026. Gedetailleerde informatie over dit geneesmiddel is beschikbaar op de website van het Europees Geneesmiddelenbureau <http://www.ema.europa.eu>

RSV, Respiratoir Syncytiaal Virus; **LRTD**, Lower Respiratory Tract Disease

**tijdens hun eerste RSV-seizoen **Eenmalige terugbetaling voor het eerste RSV-Seizoen en bij jonge kinderen (<2 jaar) die een hartoperatie ondergaan met cardiopulmonaire bypass in hun eerste of tweede RSV-seizoen, of jonge kinderen (<2 jaar) die kwetsbaar blijven voor ernstige RSV-ziekte tijdens hun tweede RSV-seizoen, (zoals beschreven in de aanbevelingen van de HGR (advies 9760)). Toediening voor de start van het RSV-seizoen of vanaf de geboorte voor zuigelingen geboren in het RSV-seizoen.

Referentie: 1. Beyfortus® SKP, 03/2026.