Pfizer

PP-NGE-GBR-0864
Date of Preparation: November 2024

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Image is an actor portrayal

ngenla® (somatrogon) injection ▼ Genotropin® somatropin (rbe)

Help your patients REACH THEIR GROWTH POTENTIAL

Tap here to start your journey

Prescribing information for NGENLA (somatrogon) and Genotropin (somatropin) is available from this stand.

NGENLA is indicated for the treatment of paediatric growth hormone deficiency in children and adolescents aged 3 years or older.[1]

Genotropin is indicated for the treatment of paediatric growth hormone deficiency, growth disturbance associated with Turner syndrome or chronic renal insufficiency, Prader-Willi syndrome, for improvement of growth and body composition and children born small for gestational age.[2,3]

This promotional material has been developed and funded by Pfizer and is intended for healthcare professionals only.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Pfizer Medical Information on 01304 616161.

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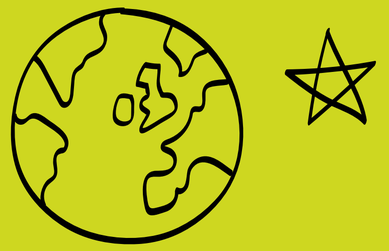

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Tailored support and resources for your NGENLA and Genotropin patients and their families

NGENLA and Genotropin are about more than just treatment. At Pfizer, we put your patients first, providing them with a variety of different platforms and services they can utilise for support and resources in addition to their treatment plans

- **Standard Homecare Services**
- **GroSupport** For Genotropin patients
- **Dedicated Patient Helpline**
- **Homecare Plus**
- **NGENLA Starter Kits**
- **Genotropin Starter Kits**

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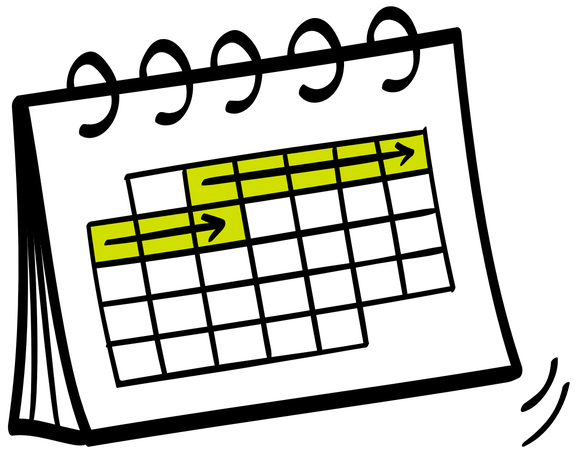
How to switch to NGENLA

1. **Prescribe NGENLA and ensure relevant device training has taken place.**
2. **Start patients on NGENLA the day after daily growth hormone is discontinued.**
3. **Administer NGENLA weekly thereafter.**



Dosing[1]

The recommended dose is 0.66 mg/kg of body weight administered once weekly by subcutaneous injection.

The dose of NGENLA may be adjusted as necessary, based on growth velocity, adverse reactions, body weight and serum IGF-1 concentrations.

Dose may be rounded up or down based on the physician's expert knowledge of the individual patient's needs.

Each prefilled pen is capable of setting and delivering the dose prescribed by the physician.

24 mg Pen
For doses up to 12 mg
(body weight <18 kg)

0.2 mg dose increments

0.5 mg dose increments

60 mg Pen
For doses ≥12 mg
(body weight >18 kg)

For full dosing details, refer to the Summary of Product Characteristics for NGENLA.

IGF-1, insulin-like growth factor 1.

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NGENLA can provide flexible and convenient once-weekly administration at any time of the day[1]

Administration site
NGENLA is to be injected in the abdomen, thighs, buttocks or upper arms. To reduce injection site pain, the site of injection should be rotated at each administration. Injections to the upper arms and buttocks should be given by the caregiver.

Changing the dosing day
The day of weekly administration can be changed if necessary, as long as the time between 2 doses is at least 3 days. After selecting a new dosing day, the once-weekly dosing should be continued.

MISSED DOSE CALENDAR

Managing a missed dose
Patients should maintain their regular dosing day.

WITHIN 3 days of missed dose
As soon as possible, and then the usual once-weekly dosing schedule should be resumed.

AFTER 3 days of missed dose
Skip dose and administer next dose on the regularly scheduled day.

In each case, patients can then resume their regular once-weekly dosing schedule.

Over 90% of patients and caregivers (N=87) did not miss any injections with NGENLA in the 4 weeks prior to questionnaire completion, compared to 67.4% with Genotropin (N=86).[2,3]

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Missed dose calendar

Your scheduled dosing day			Last day you can inject if you have missed a dose			
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday
Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday
Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday
Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday
Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Inject your dose as soon as you remember

Skip your dose and inject the next dose on your scheduled dose day

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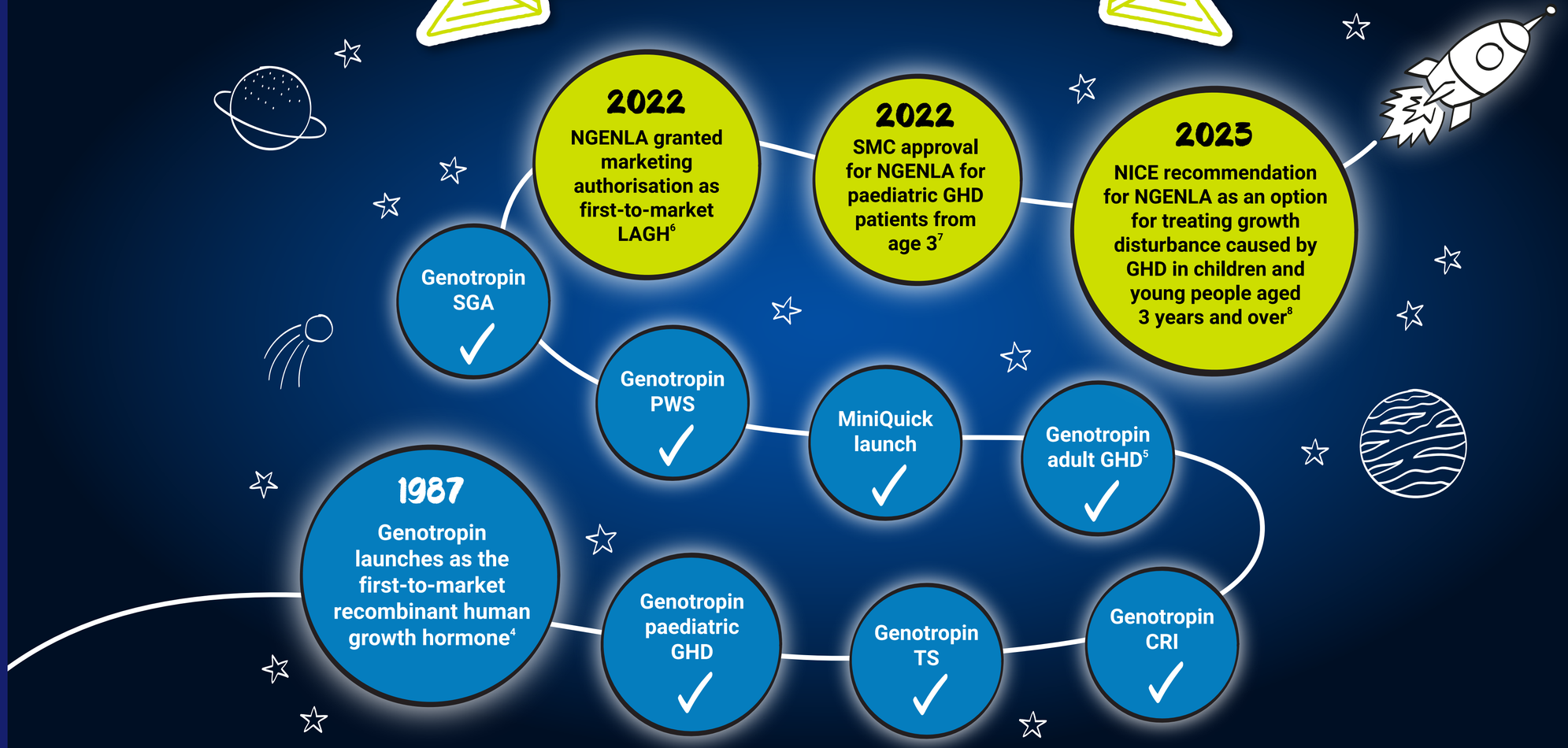
PFIZER'S COMMITMENT TO OVER 35 YEARS OF GROWTH



✓ denotes NICE-recommended treatment for a specified indication.

CRI, chronic renal insufficiency; GHD, growth hormone deficiency; LAGH, long-acting growth hormone; NICE, National Institute for Health and Care Excellence; PWS, Prader-Willi syndrome; SGA, small for gestational age; SMC, Scottish Medicines Consortium; TS, Turner syndrome.

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Give patients 313 injection-free days with NGENLA*

NGENLA is approved as a treatment option in 56 countries.[9]

EFFICACY YOU EXPECT

The efficacy you expect from daily GH, but with **313 injection-free days.**

In the phase 3 non-inferiority study, NGENLA delivered an **annual height velocity that was non-inferior to daily Genotropin** (somatropin).[1]

The commonly reported adverse reactions after treatment with NGENLA are ISRs (25.1%), headache (10.7%) and pyrexia (10.2%).

For full information and descriptions of selected adverse reactions. please refer to the Summary of Product Characteristics.[1]

ADMINISTERED IN 3 STEPS

The NGENLA pen is a prefilled, multidose device with no need for reconstitution that can be administered in 3 simple steps.[1,10]

NGENLA is **administered in a prefilled, multidose pen.**

Once primed, NGENLA can be administered in 3 steps:

- **Attach the needle**
- **Adjust the dose**
- **Inject**

TREATMENT EXPERIENCE FAVOURED BY PATIENTS

A treatment experience favoured by patients and caregivers.[11]

In a phase 3 crossover study versus Genotropin, NGENLA demonstrated **significant reduction in treatment burden.**[11]

*Assumes that patients will take their medication as prescribed: every day for 365 days per year for daily GH and one day per week for 52 weeks for NGENLA.
GH, growth hormone; ISR, injection site reaction.

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NGENLA is designed for your patients' ease of use

NGENLA is administered in a prefilled, multidose pen.[12]

NO RECONSTITUTION REQUIRED

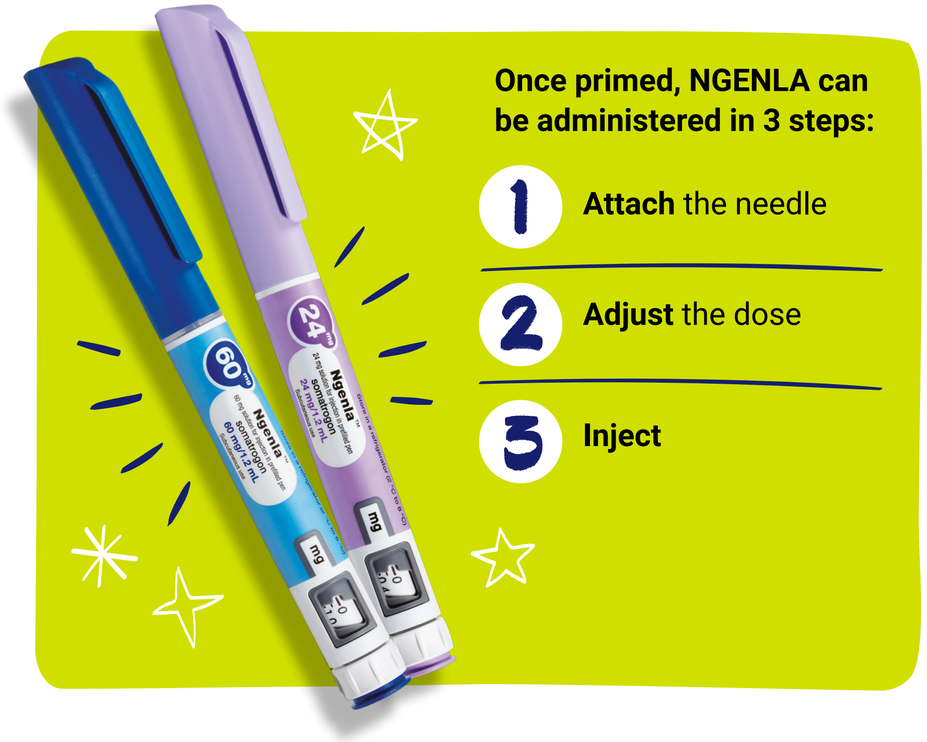
Once-weekly administration, at any time of the day.

- Ready-to-use pen with audible and tactile dose adjustments[12]
- Small needle gauge [30G–32G][10]

Once-weekly dosing is based on 0.66 mg/kg of body weight.[1]

DOSING | ADMINISTRATION

LEARN ABOUT NGENLA'S MODE OF ACTION



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Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday
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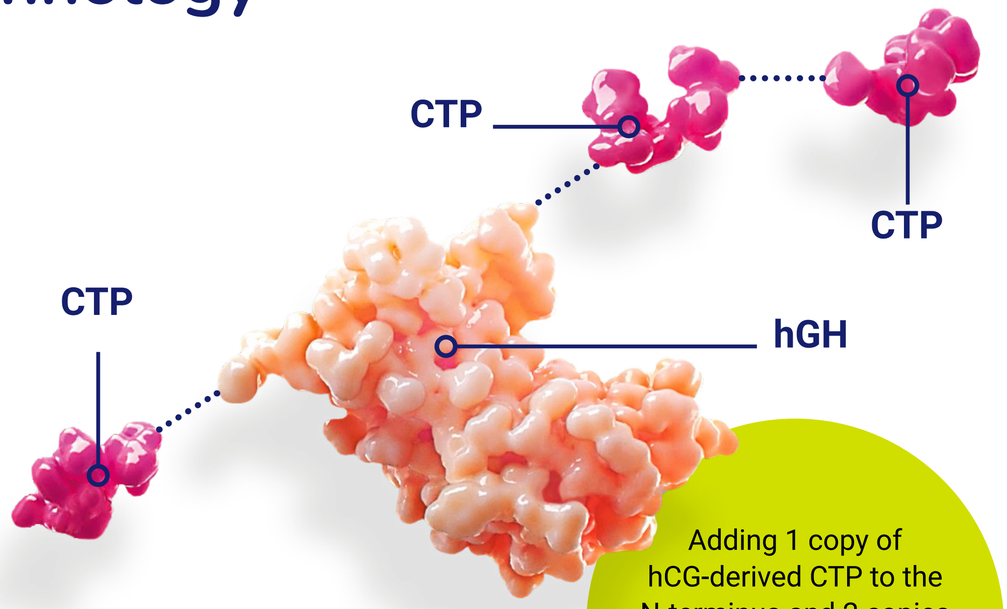
Once-weekly dosing achieved through C-terminal peptide technology

Somatrogon is composed of a human growth hormone (hGH) molecule fused with C-terminal peptide (CTP) from naturally occurring human chorionic gonadotropin (hCG)[1,13]

- C-terminal peptides provide hCG with required longevity, but do not impact interaction with hCG and its receptor[13]
- Like hGH, somatrogon binds to the GH receptor and initiates a cascade leading to changes in growth and metabolism.[1]



Adding 1 copy of hCG-derived CTP to the N-terminus and 2 copies to the C-terminus of hGH **extends half-life for somatrogon.**[1]

CTP, C-terminal peptide; GH, growth hormone; hCG, human chorionic gonadotropin; hGH, human growth hormone.

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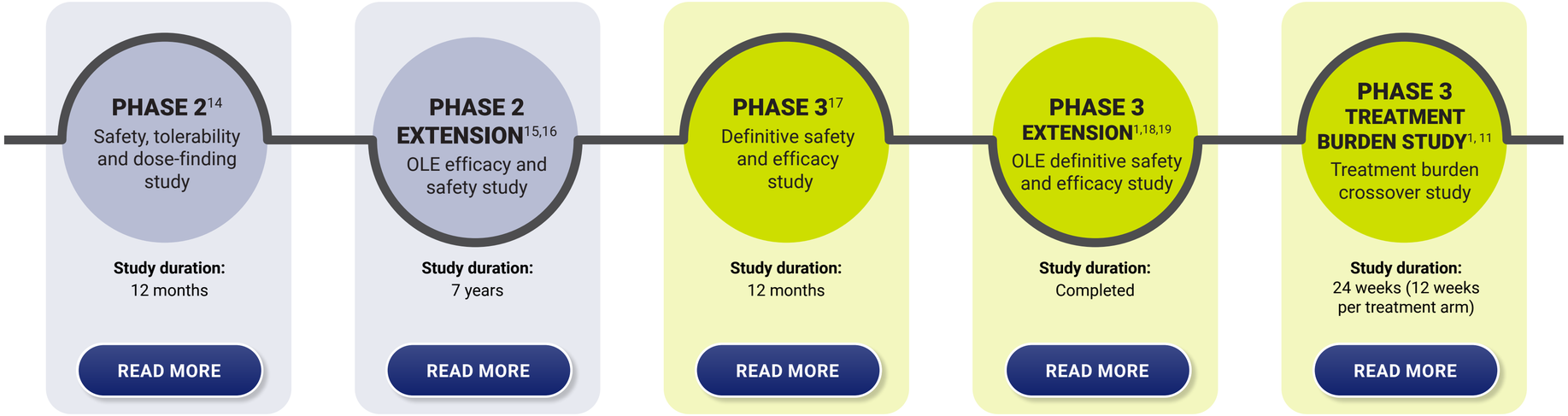

OLE, open-label extension.

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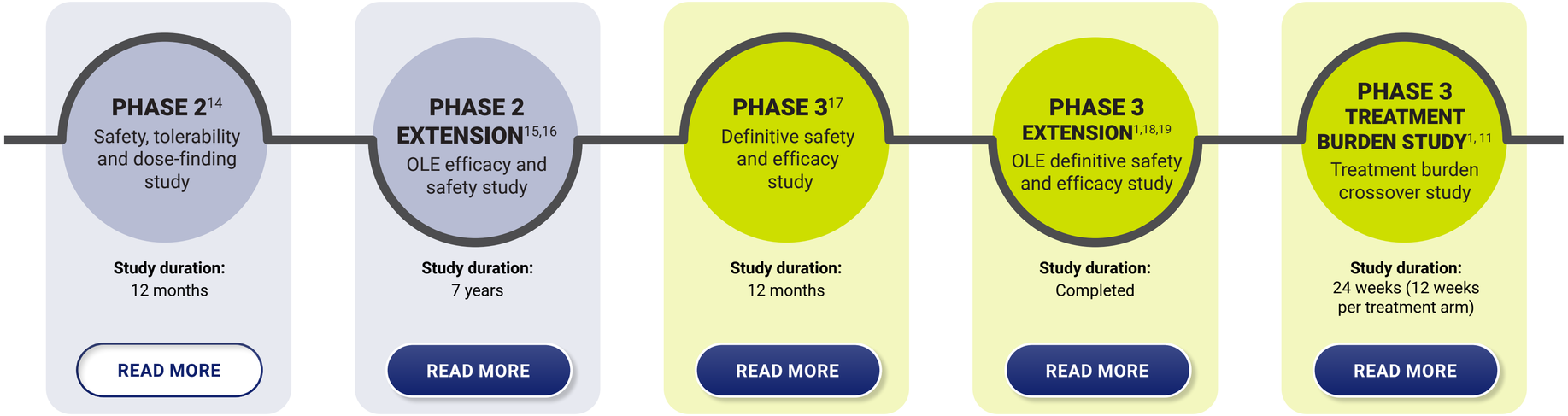

Phase 2 – Key outcome[14]:

Somatrogon 0.66 mg/kg/week elicited a comparable response outcome (height velocity SDS and height SDS at 12 months) to daily somatropin.

Open-label, randomised, active-controlled study comparing three dose levels of NGENLA administered weekly to daily GH (Genotropin 0.034 mg/kg/day; N=53).

GH, growth hormone; OLE, open-label extension; SDS, standard deviation score.

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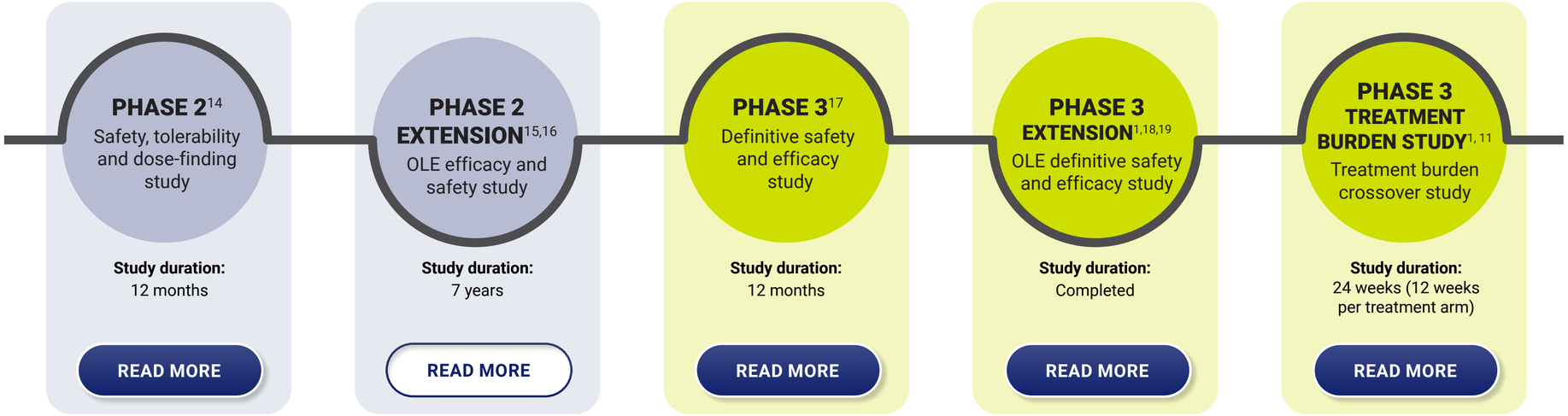

Phase 2 extension – Key outcome[15,16]:
Somatrogon administered once weekly for up to 7 years after the main study was generally well tolerated and participants showed sustained improvement in annual height velocity, height SDS, and delta height SDS.

Open-label, randomised, multicentre, dose-finding, and safety study of different NGENLA dose levels in prepubertal patients with GHD following 7 years of treatment. In Extension Year 1, patients taking NGENLA continued their assigned dose. Patients taking Genotropin were assigned to 1 of 3 NGENLA doses. In Extension Years 2 and beyond, patients were transitioned to NGENLA (0.66 mg/kg/week; N=48).

GHD, growth hormone deficiency; OLE, open-label extension; SDS, standard deviation score.

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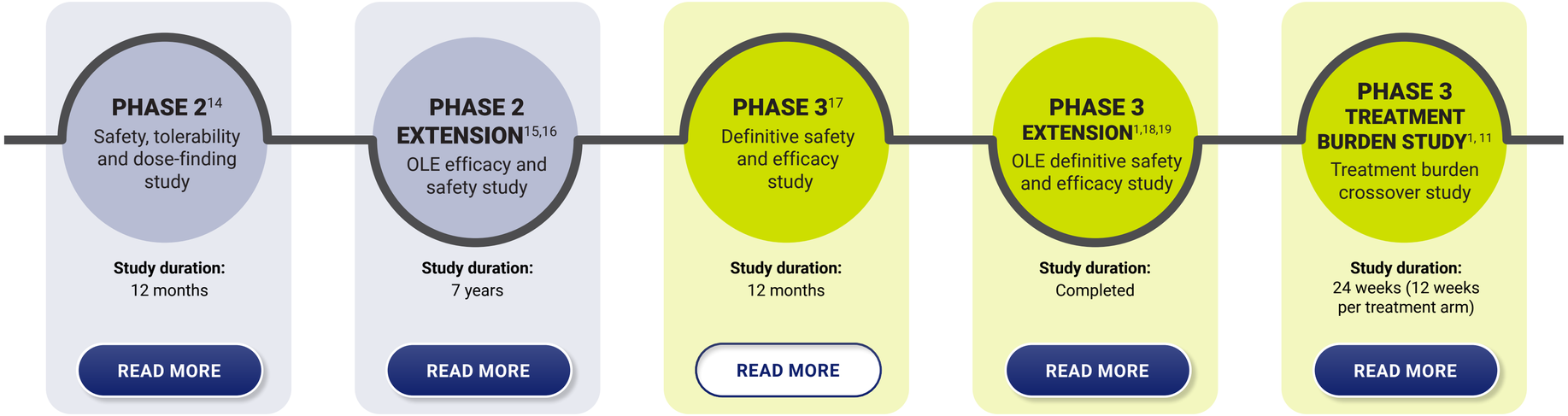

Phase 3 – Key outcome[17]:
The efficacy (annual height velocity) of once-weekly somatrogon was non-inferior to once-daily somatropin, with comparable safety and tolerability profiles.

Open-label, multicentre, randomised, active-controlled, parallel-group study in prepubertal children with GHD. Patients were randomised to weekly doses of NGENLA (0.66 mg/kg/week; n=109) or daily administration of Genotropin (0.034 mg/kg/day; n=115; N=224).

GH, growth hormone; OLE, open-label extension.

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PHASE 2[14]
Safety, tolerability and dose-finding study

Study duration:
12 months

READ MORE

PHASE 2 EXTENSION[15,16]
OLE efficacy and safety study

Study duration:
7 years

READ MORE

PHASE 3[17]
Definitive safety and efficacy study

Study duration:
12 months

READ MORE

PHASE 3 EXTENSION[1,18,19]
OLE definitive safety and efficacy study

Study duration:
Completed

READ MORE

PHASE 3 TREATMENT BURDEN STUDY[1, 11]
Treatment burden crossover study

Study duration:
24 weeks (12 weeks per treatment arm)

READ MORE

Phase 3 extension – Key outcome[18,19]**:**

Following up to 5 years of somatrogon treatment, children with pGHD continued to demonstrate catch-up growth, with a mean increase in height SDS (from baseline) of 1.94 observed in OLE Year 4.

Extension study to evaluate the long-term efficacy and safety of somatrogon. Patients who completed the main study were eligible for inclusion. Those who received NGENLA in the main study continued to receive NGENLA once weekly at the same dose (0.66 mg/kg/week) while patients who received Genotropin in the main study were switched to NGENLA once weekly (0.66 mg/kg/week; N=212).

OLE, open-label extension; pGHD, paediatric growth hormone deficiency; SDS, standard deviation score.

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Study duration:
12 months

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PHASE 3 EXTENSION[1,18,19]
OLE definitive safety and efficacy study

Study duration:
Completed

READ MORE

PHASE 3 TREATMENT BURDEN STUDY[1, 11]
Treatment burden crossover study

Study duration:
24 weeks (12 weeks per treatment arm)

READ MORE

Phase 3 treatment burden study – Key outcome[11]**:**

Once-weekly NGENLA had a lower treatment burden and was associated with a more favourable treatment experience than once-daily somatropin.

Open-label, multicentre, 2-period, crossover study assessing patient perception of treatment burden. Patients were randomised in a 1:1 ratio to either 12 weeks of NGENLA once-weekly followed by 12 weeks of Genotropin once daily or 12 weeks of Genotropin once daily followed by 12 weeks of NGENLA once weekly (N=87). Twelve of the patients in the somatrogon arm of the experiment (n=109) required a dose adjustment due to two consecutive measurements with IGF-1 SDS >2.

IGF-1, insulin-like growth factor 1; OLE, open-label extension; SDS, standard deviation score.

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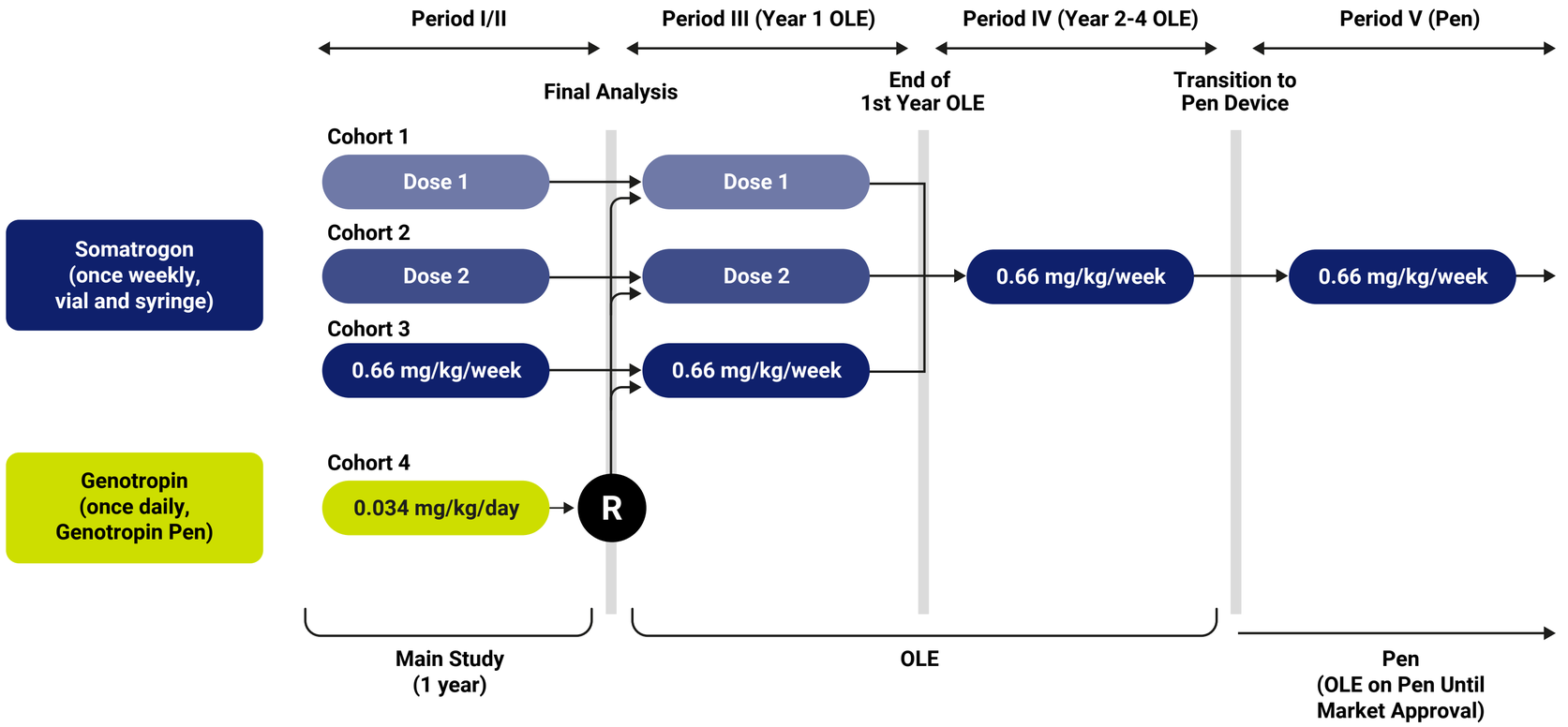
Design of somatrogon phase 2 study[16]



Unlicensed doses were used in dose trialling portions of this trial; these doses will not be discussed further.
OLE, open-label extension; R, randomisation.

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Once-weekly NGENLA delivered sustained growth and maintained a consistent safety profile over 8 years[15,16,20]

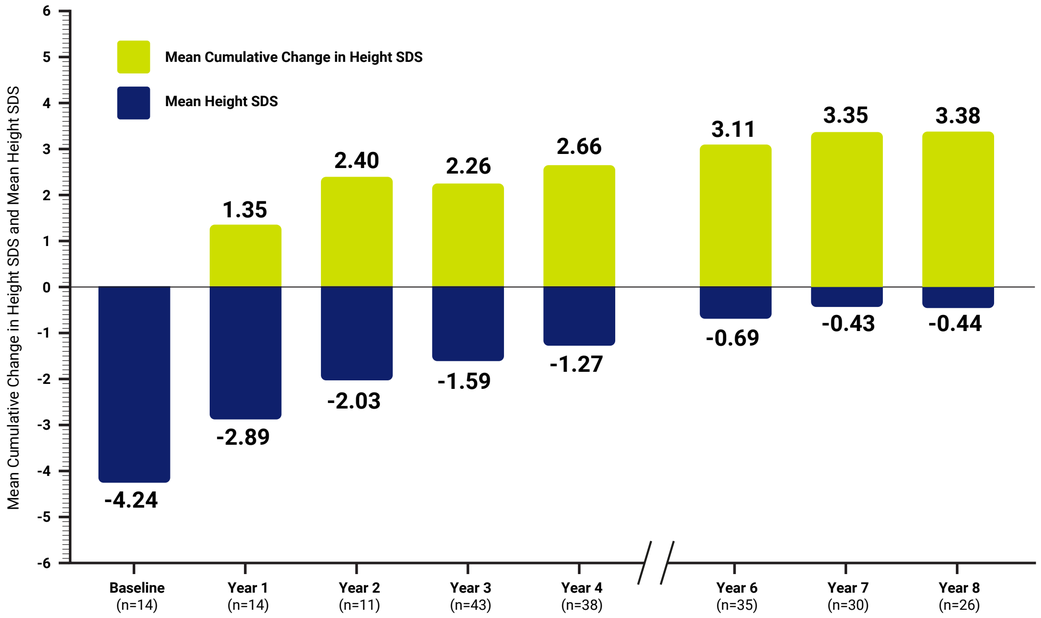
Key findings over 8 years:

- 91% of patients (N=48) chose to continue in the phase 2 OLE when given the choice to continue with somatrogon[15]
- Following up to 8 years of somatrogon treatment, including 7 years of the OLE, patients demonstrated continued growth, 4 of whom achieved final height, and somatrogon maintained a consistent safety profile[16]
- Progressive gains in height velocity SDS were achieved[15]

Data limitations

The first 3 years of this trial were the dose trialling portion so used unlicensed doses. Therefore, the full data from these years cannot be presented. Data are shown only for the cohort taking the approved dose of NGENLA, 0.66 mg/kg/week.

- In Year 1 there were 3 different NGENLA doses and 1 dose of Genotropin.
- In Year 2, those patients taking NGENLA remained on their original dose, and Genotropin recipients were randomised to one of the 3 NGENLA doses.
- From Year 3, all patients received NGENLA 0.66 mg/kg/week.
- Graph does not include Year 5 data as most patients switched from single-use vials to a multidose pen during this year. Only 1 patient completed the whole of Year 5 using single-use vials.



Data above: Year 1 is the main phase 2 study (duration 12 months). Year 2 onwards is the phase 2 extension study.
Data adapted from Pfizer data on file: PP-NGE-GBR-0633 and PP-NGE-GBR-0421.

CLINICAL TRIAL PROGRAMME OVERVIEW

IGF-1 12 months

Unlicensed doses were used in dose trialling portions of this trial; these doses will not be discussed further.
IGF-1, insulin-like growth factor 1; OLE, open-label extension; SDS, standard deviation score.

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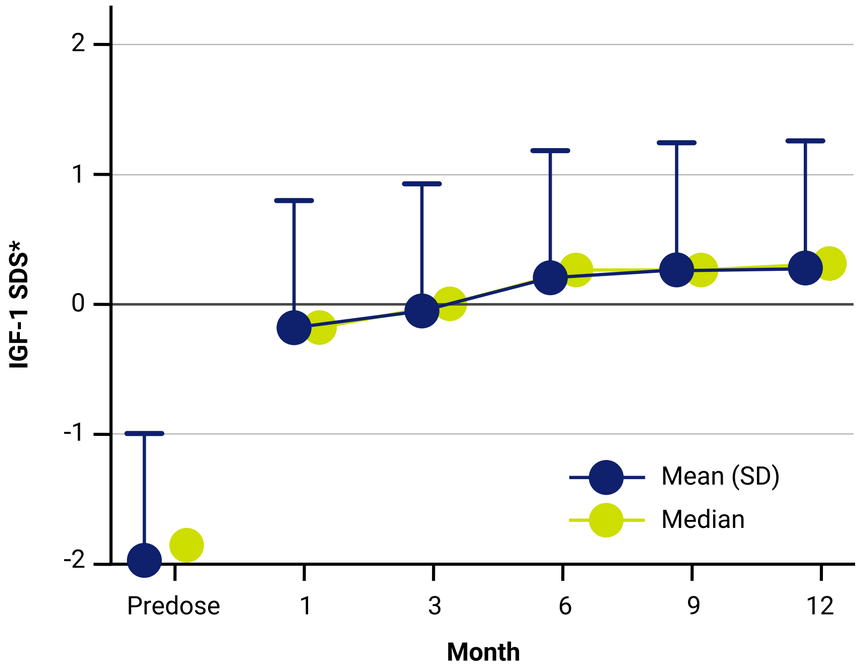
Mean and median IGF-1 values normalised at 1 month of treatment with NGENLA[1]

Post hoc analysis of IGF-1 SDS during 12 months of treatment with NGENLA[21]



*Based on observed (predose) or modelled 4 days postdose mean values.
IGF-1, insulin-like growth factor 1; SDS, standard deviation score.

The mean and median of the modelled mean IGF-1 SDS values gradually increased in the first 6 months of the study and remained stable thereafter.

IGF-1 should be monitored regularly to ensure that levels remain within the normal range.

In patients whose serum IGF-1 concentrations exceed the mean reference value for their age and sex by more than 2 SDS, the dose of somatrogon should be reduced by 15%. More than one dose reduction may be required in some patients.[1]

IGF-1, insulin-like growth factor 1; OLE, open-label extension; SDS, standard deviation score.

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Summary of TEAEs[16]

	Study Years							
n (%)	Year 1 n=42	Year 2 n=48	Year 3 n=44	Year 4 n=43	Year 5 n=38	Year 6 n=40	Year 7 n=35	Year 8 n=31
TEAEs	30 (71.4)	25 (52.1)	22 (50.0)	18 (41.9)	17 (44.7)	23 (57.5)	15 (42.9)	11 (35.5)
Serious TEAEs	0 (0.0)	2 (4.2)	1 (2.3)	0 (0.0)	1 (2.6)	0 (0.0)	1 (2.9)	0 (0.0)
Treatment-related TEAEs	9 (21.4)	0 (0.0)	1 (2.3)	1 (2.3)	2 (5.3)	3 (7.5)	0 (0.0)	2 (6.5)
TEAEs leading to treatment withdrawal	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.9)	0 (0.0)
TEAEs leading to dose reduction or interruption	1 (2.4)	0 (0.0)	1 (2.3)	0 (0.0)	2 (5.3)	0 (0.0)	1 (2.9)	1 (3.2)
TEAEs leading to study discontinuation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	1 (2.5)	1 (2.9)	0 (0.0)
Deaths	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

In Year 8:

- Incidence of TEAEs was lower than in Years 1–7 (range: 41.9–71.4%)
- **No serious TEAEs or TEAEs leading to somatrogon withdrawal occurred**
- Treatment-related TEAEs occurred in 2 patients: keeled chest acquired and scoliosis (n=1) and arthralgia (n=1)

Following up to **8 years of treatment** with NGENLA, patients demonstrated **continued growth**.

NGENLA maintained a **favourable safety profile** at the end of Year 8, **similar to earlier timepoints**.

Unlicensed doses were used in dose trialling portions of this trial; these doses will not be discussed further.
TEAEs, treatment-emergent adverse events.

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Genotropin somatropin (rbe)

References

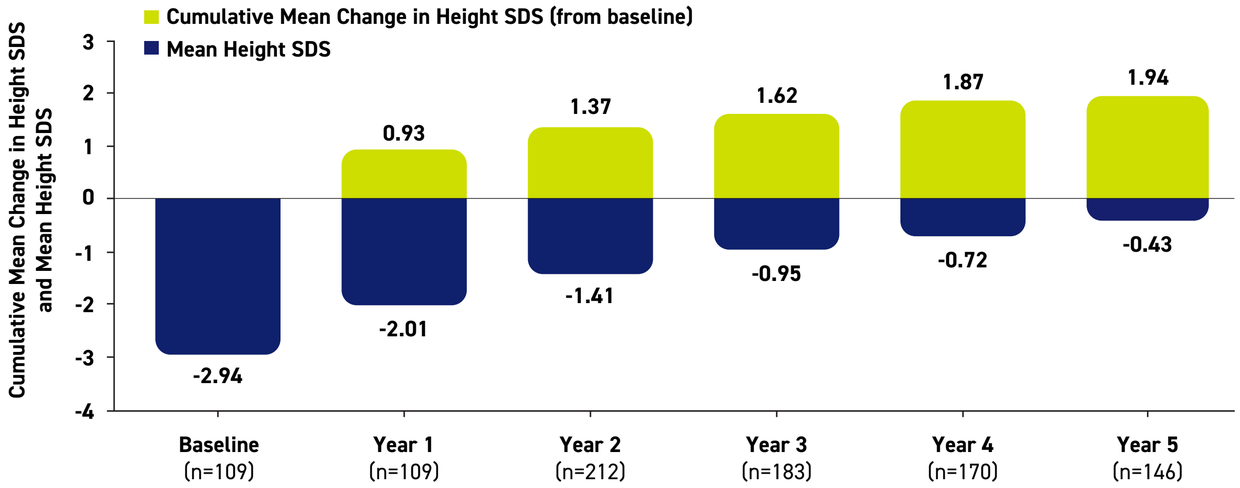
Once-weekly NGENLA delivers the efficacy you expect from daily Genotropin[17,19,24]

Efficacy demonstrated annual height velocity non-inferior to Genotropin at 1 year (N=224)[1,17]

- Mean annual height velocity: NGENLA 0.66 mg/kg/week, 10.1 cm/year; Genotropin 0.034 mg/kg/day, 9.78 cm/year (95% CI: -0.24, 0.89)[1,17]

Following up to 5 years of NGENLA (0.66 mg/kg/week), children with pGHD continued to demonstrate catch-up growth[1,17,19]

- Mean increase in height SDS (from baseline) of 1.94 observed after five years (OLE 4 Year)[19]



CI, confidence interval; GH, growth hormone; OLE, open-label extension; pGHD, paediatric growth hormone deficiency; SDS, standard deviation score.

Study Design[17,19]

Phase 3 study to assess the efficacy and safety of NGENLA administered once weekly in children with GHD following up to 4 years of NGENLA treatment. For the 12-month main study period, prepubertal paediatric patients were randomized 1:1 to receive NGENLA (n=109) or Genotropin (n=115).

Patients who completed the main study period were eligible to enrol in an OLE during which NGENLA-treated patients continued to receive NGENLA and Genotropin-treated patients switched to NGENLA (n=108).

CLINICAL TRIAL PROGRAMME OVERVIEW

IGF-1 12 months

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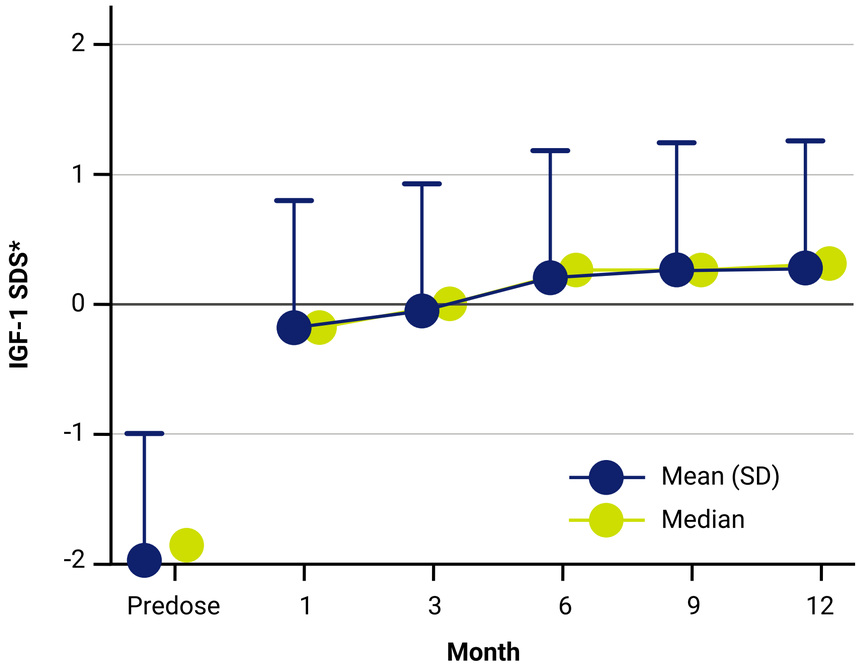
Mean and median IGF-1 values normalised at 1 month of treatment with NGENLA[1]

Post hoc analysis of IGF-1 SDS during 12 months of treatment with NGENLA[21]



*Based on observed (predose) or modelled 4 days postdose mean values.
IGF-1, insulin-like growth factor 1; SDS, standard deviation score.

The mean and median of the modelled mean IGF-1 SDS values gradually increased in the first 6 months of the study and remained stable thereafter.

IGF-1 should be monitored regularly to ensure that levels remain within the normal range.

In patients whose serum IGF-1 concentrations exceed the mean reference value for their age and sex by more than 2 SDS, the dose of somatrogon should be reduced by 15%. More than one dose reduction may be required in some patients.[1]

CI, confidence interval; GH, growth hormone; OLE, open-label extension; pGHD, paediatric growth hormone deficiency; SDS, standard deviation score.

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Safety profile[1]

Safety data are derived from the phase 2, multicentre safety and dose-finding study, and the pivotal phase 3, multicentre non-inferiority study in paediatric patients with GHD. The data reflect exposure of 265 patients to NGENLA administered once weekly (0.66 mg/kg/week).

In the phase 2, multicentre safety and dose-finding study, 31 patients received up to 0.66 mg/kg/week of NGENLA for up to 7.7 years.

The commonly reported adverse reactions after treatment with NGENLA are injection site reactions (25.1%), headache (10.7%) and pyrexia (10.2%).

System Organ Class	Very Common	Common	Uncommon	Rare	Very Rare	Frequency Not Known
Blood and lymphatic system disorders		Anaemia Eosinophilia				
Endocrine disorders		Hypothyroidism	Adrenal insufficiency			
Nervous system disorders	Headache					
Eye disorders		Conjunctivitis allergic				
Skin and subcutaneous tissue disorders			Rash generalised			
Musculoskeletal and connective tissue disorders		Arthralgia Pain in extremity				
General disorders and administration site conditions	Injection site reactions* Pyrexia					

For full information and description of selected adverse reactions refer to the Summary of Product Characteristics for NGENLA.

Safety data from phase 3 main study period

Safety data from phase 3 extension study

*Injection site reactions include the following: injection site pain, erythema, pruritus, swelling, induration, bruising, haemorrhage, warmth, hypertrophy, inflammation, deformation, urticaria.
Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) or frequency not known (cannot be estimated from the available data).
GHD, growth hormone deficiency.

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NGENLA demonstrated a safety profile comparable to Genotropin[17]

Based on a phase 3, 12-month, open-label, randomised study comparing the safety and efficacy of NGENLA and once-daily Genotropin, the incidence of all-causality TEAEs was comparable between the somatrogon (84.4%) and somatropin groups (78.3%).[17]

Preferred Term	Somatrogon (n=109)	Genotropin (n=115)
Injection site pain*	43 (39.4%)	29 (25.2%)
Nasopharyngitis	25 (22.9%)	29 (25.2%)
Headache	18 (16.5%)	25 (21.7%)
Pyrexia	18 (16.5%)	16 (13.9%)
Cough	9 (8.3%)	9 (7.8%)
Injection site erythema*	9 (8.3%)	0
Vomiting	8 (7.3%)	9 (7.8%)
Anaemia	7 (6.4%)	7 (6.1%)
Hypothyroidism	7 (6.4%)	3 (2.6%)
Pharyngitis	7 (6.4%)	5 (4.3%)
Arthropod bite	6 (5.5%)	1 (0.9%)

Preferred Term	Somatrogon (n=109)	Genotropin (n=115)
Rhinitis	6 (5.5%)	1 (0.9%)
Injection site pruritus*	6 (5.5%)	0
Oropharyngeal pain	6 (5.5%)	4 (3.5%)
Arthralgia	5 (4.6%)	8 (7.0%)
Tonsillitis	5 (4.6%)	6 (5.2%)
Otitis media	4 (3.7%)	7 (6.1%)
Bronchitis	3 (2.8%)	9 (7.8%)
Abdominal pain upper	2 (1.8%)	6 (5.2%
Blood creatine phosphokinase increased	2 (1.8%)	8 (7.0%)
Ear pain	2 (1.8%)	7 (6.1%)

*Local injection site reactions tended to be transient, occurred mainly in the first 6 months of treatment and were mild in severity.[1]
TEAEs, treatment-emergent adverse events.

available data).
GHD, growth hormone deficiency.

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Summary of AEs experienced by patients receiving NGENLA[19,24]

During the phase 3 study (including the 12-month main study period and 4 years of an open-label extension), most AEs experienced by NGENLA-treated patients were mild to moderate in intensity.[19]

	Total NGENLA (Baseline until Year 5)
n (%)	**n=217**
AEs	3359
Patients with AEs	192 (88.5)
Patients with serious AEs	17 (7.8)
Patients with severe AEs	21 (9.7)
Patients discontinued from study due to AEs	10 (4.6)
Patients discontinued study drug due to AE and continued study	0
Patients with dose reduced or temporary discontinuation due to AEs	18 (8.3)

AE, adverse event.

available data).
GHD, growth hormone deficiency.

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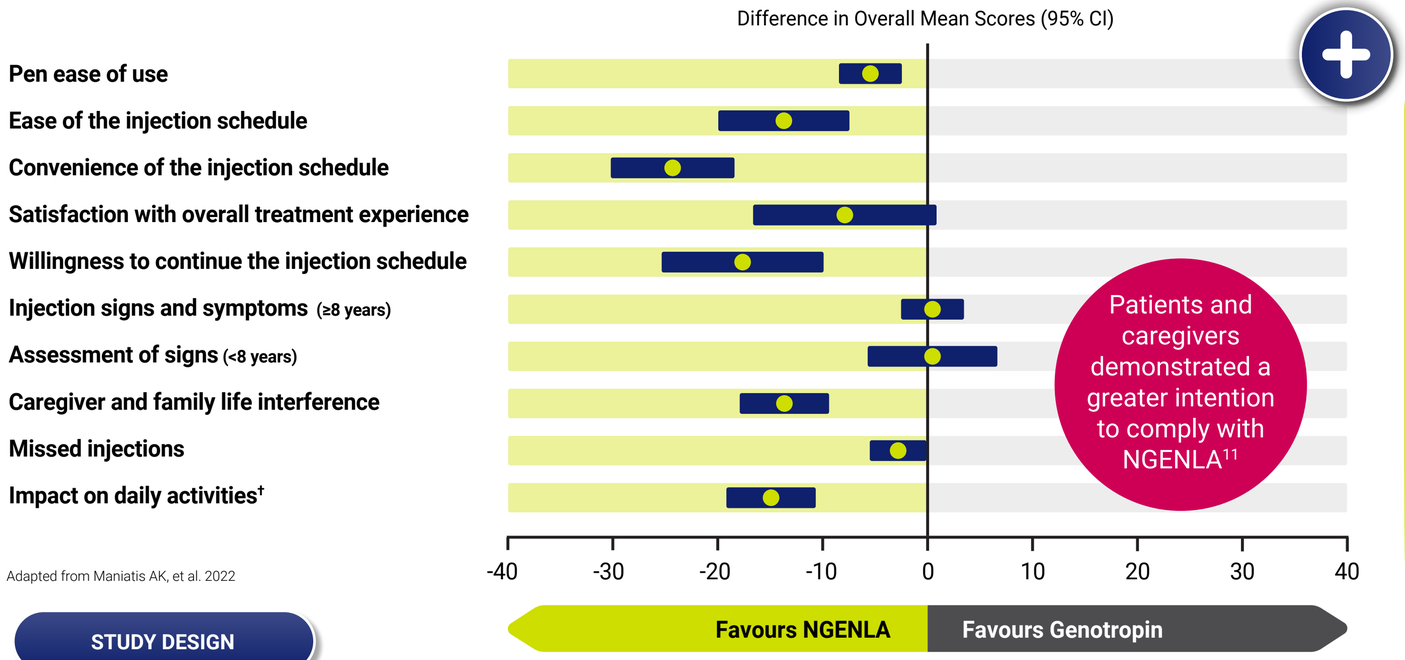
Once-weekly NGENLA delivered a treatment experience favoured by patients and caregivers*

In a phase 3 crossover study versus Genotropin, NGENLA demonstrated a significant reduction in treatment burden*,[11]



Adapted from Maniatis AK, et al. 2022

STUDY DESIGN

Have you considered switching your eligible pGHD patients from daily GH to NGENLA?

HOW TO SWITCH

* Data are based on patient/caregiver recall following each 12-week treatment period and at the end of the study. Caregivers completed the assessment for children under 8 years of age.[11]

† PGIS-IDA, Patient Global Impression Severity—Impact on Daily Activities

CI, confidence interval.

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Once-weekly NGENLA delivered a treatment experience favoured by patients and caregivers*

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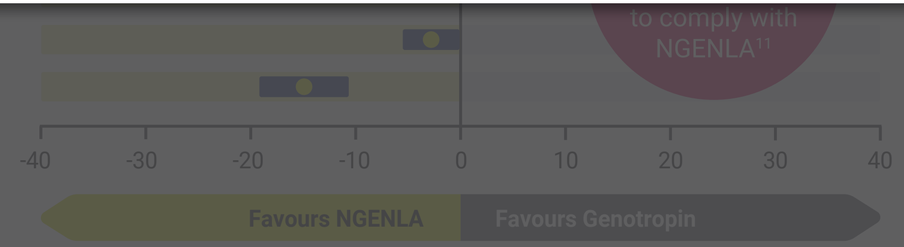
Adapted from Maniatis AK, et al. 2022

STUDY DESIGN



* Data are based on patient/caregiver recall following each 12-week treatment period and at the end of the study. Caregivers completed the assessment for children under 8 years of age.[11]
† PGIS-IDA, Patient Global Impression Severity—Impact on Daily Activities

CI, confidence interval.

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HOW TO SWITCH

Study design[11]

Patients and caregivers* (N=87) reported improved (lower) Life Interference Total Score after 12 weeks of once-weekly NGENLA treatment compared with once-daily GH.[1,11]

Phase 3, randomised, open-label, 2-period, crossover, multicentre study assessing patient perception of treatment burden with the use of NGENLA once weekly versus Genotropin once daily in children 3 to <18 years of age with GHD.[1,11]

* Data are based on patient/caregiver recall following each 12-week treatment period and at the end of the study. Caregivers completed the assessment for children under 8 years of age.[11]
GHD, growth hormone deficiency.

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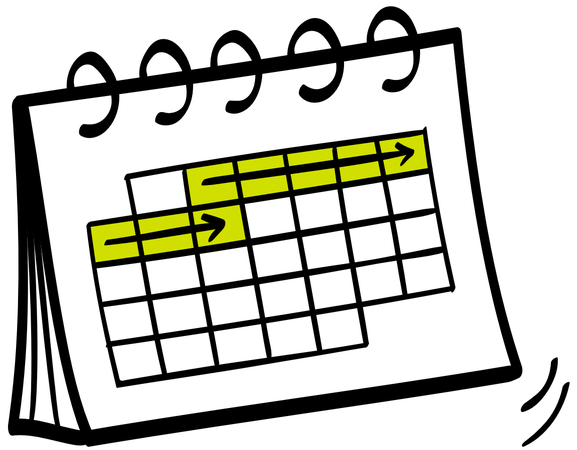
1. **Prescribe NGENLA and ensure relevant device training has taken place.**
2. **Start patients on NGENLA the day after daily growth hormone is discontinued.**
3. **Administer NGENLA weekly thereafter.**



CI, confidence interval.

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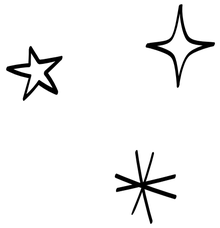
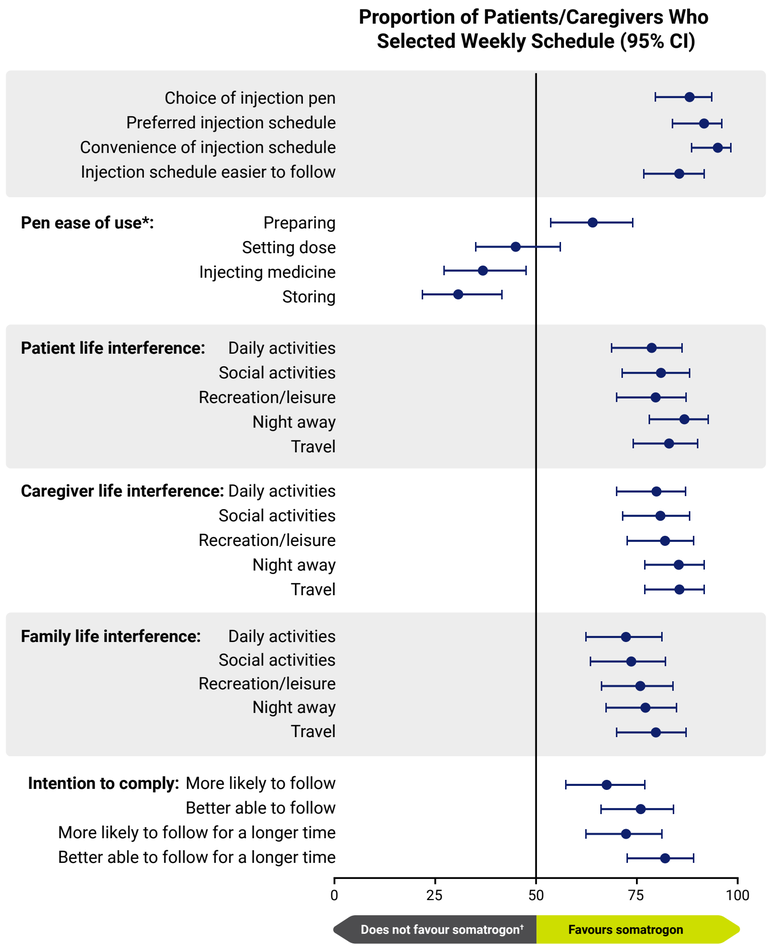
Patient and caregiver preference for weekly or daily injections (DCOA 2)[11]





*For the 3 items of the 'pen ease of use' domain where <50% of patients preferred somatrogon, a substantial proportion of patients had no preference (38.1%, 29.8% and 64.3%, for setting the dose, injecting the medicine, and storing the pen, respectively) between the injection schedules. †'Does not favour somatrogon' includes Genotropin and no preference/no difference.
CI, confidence interval; DCOA, Dyad clinical outcome assessment.

CI, confidence interval.

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IN CONCLUSION

Indicated for paediatric growth hormone deficiency in children and adolescents aged 3 years and older[1]

- The efficacy you expect from daily GH,[1] but with **313 injection-free days**
- Once primed, administered in **3 steps**
- Favoured by patients and caregivers, **and approved as a treatment option in 56 countries**[9]

HOW TO SWITCH

CI, confidence interval; GH, growth hormone; pGHD, paediatric growth hormone deficiency.

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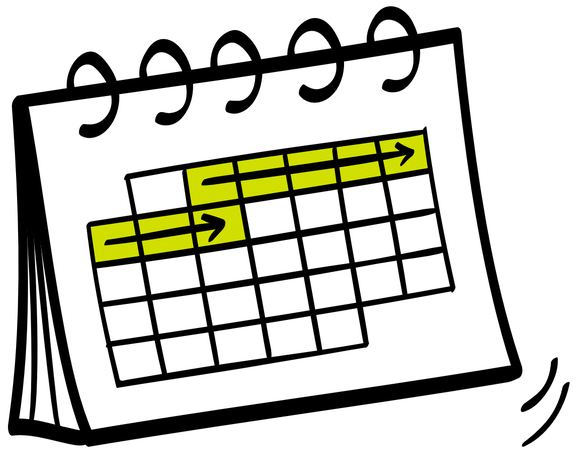

CI, confidence interval; GH, growth hormone; pGHD, paediatric growth hormone deficiency.

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Who can benefit from 313 injection-free days?

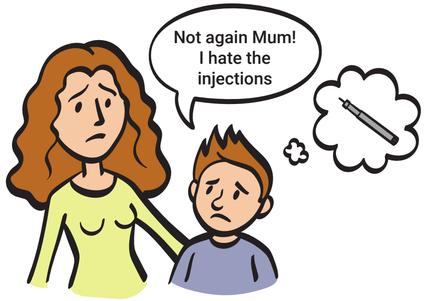
KIDS WHO JUST WANT TO BE KIDS

NGENLA offers an effective treatment with less frequent injections, **giving kids more time to be kids!**

ADOLESCENTS BECOMING MORE INDEPENDENT

Evidence suggests **adherence to treatment is reduced among adolescents.** Less frequent injections could **improve persistence and potentially growth outcome.**[22]

CAREGIVERS



Caregivers may find it difficult to manage daily injections due to:

- Having a **large family**[25]
- Child having **multiple caregivers**[26]
- Frequent passive **forgetting**[25]
- Feeling **guilty** or **stressed**[25]

PATIENTS WITH A FEAR OF NEEDLES[25]

Taking fewer injections may be a suitable option for patients with a fear of needles, as evidence suggests:

- **Lower concordance** is associated with a **longer duration of therapy**[27]
- Having **multiple conditions** may also heighten the treatment burden[26]

Have you considered switching your eligible patients with pGHD taking daily GH to once-weekly NGENLA?
NGENLA is indicated for pGHD in patients aged 3 years and over.[1]

NGENLA delivers similar efficacy and safety to daily GH, with a significantly reduced treatment burden.[1,11]

HOW TO SWITCH

GH, growth hormone; pGHD, paediatric growth hormone deficiency.

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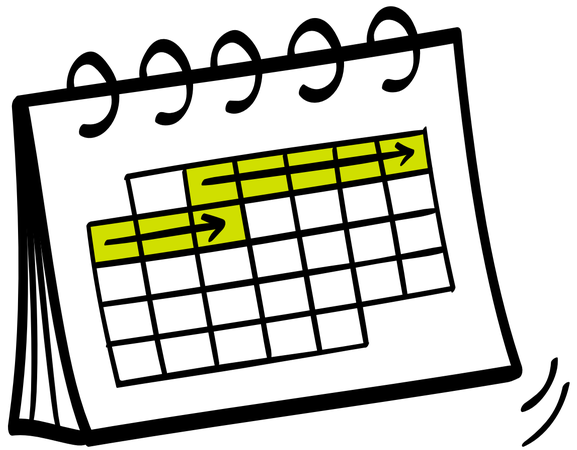

NGENLA delivers similar efficacy and safety to daily GH, with a significantly reduced treatment burden.[1,2]

GH, growth hormone; pGHD, paediatric growth hormone deficiency.

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Tailored support and resources for your NGENLA and Genotropin patients and their families

NGENLA and Genotropin are about more than just treatment. At Pfizer, we put your patients first, providing them with a variety of different platforms and services they can utilise for support and resources in addition to their treatment plans

- **Standard Homecare Services**
- **GroSupport** For Genotropin patients
- **Dedicated Patient Helpline**
- **Homecare Plus**
- **NGENLA Starter Kits**
- **Genotropin Starter Kits**

Image is an actor portrayal

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Genotropin indications – giving you flexibility to prescribe across multiple paediatric indications[2,3]

- ✓ **GHD in children**
- ✓ **Growth disturbance in Turner syndrome**
- ✓ **Growth disturbance due to chronic renal insufficiency**
- ✓ **Growth disturbance**
  (current height SDS <-2.5 and parental adjusted height SDS <-1) in short children born SGA, with a birth weight and/or length below -2 SD, who failed to show catch-up growth (height velocity SDS <0 during the last year) by 4 years of age or later
- ✓ **Prader-Willi syndrome, for improvement of growth and body composition in children**

Image is an actor portrayal

GHD, growth hormone deficiency; SD, standard deviation; SDS, standard deviation score; SGA, small for gestational age.

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Genotropin dosage recommendations[2,3]

Indication	mg/kg body weight dose per day	mg/m² body surface area dose per day
GHD in children	0.025–0.035	0.7–1.0
Prader-Willi syndrome in children	0.035	1.0
Turner syndrome	0.045–0.050	1.4
Chronic renal insufficiency	0.045–0.050	1.4
Children born small for gestational age	0.035	1.0

GHD, growth hormone deficience.

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GIVING YOUR PATIENTS THE BROADEST RANGE OF DEVICES TO SUIT THEIR NEEDS

Pen®

GoQuick™

MiniQuick®

Offering the only daily somatropin formulation that doesn't need to be stored in the fridge prior to mixing[28–32]

Out of fridge storage ≤25°C. After mixing, Genotropin should be used immediately or protected from light and stored in the fridge (2–8°C) and used within 24 hours (MiniQuick)[3] or 1 month (Pen refill cartridges or GoQuick prefilled pens).[2] Price doesn't vary with device type. Price is calculated per milligram of Genotropin.

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Genotropin is backed by over 35 years of real-world evidence[2–4]

Tabulated list of adverse reactions. For full details regarding adverse events, please refer to the Summary of Product Characteristics						
System Organ Class (somatropin)	**Very Common (≥1/10)**	**Common (≥1/100 to <1/10)**	**Uncommon (≥1/1,000 to <1/100)**	**Rare (≥1/10,000 to <1/1,000)**	**Very Rare (<1/10,000)**	**Not Known (cannot be estimated from available data)**
Neoplasms benign, malignant and unspecified (including cysts and polyps)			Leukaemia‡			
Metabolism and nutrition disorders						Type 2 diabetes mellitus
Nervous system disorders			Benign intracranial hypertension Paraesthesia*			Headache
Skin and subcutaneous tissue disorders			Rash§ pruritus§ urticaria§			
Musculoskeletal and connective tissue disorders		Arthralgia*	Myalgia*			Musculoskeletal stiffness*
Reproductive system and breast disorders			Gynaecomastia			
General disorders and administration site conditions		Injection site reaction†	Oedema peripheral*			Face oedema*
Investigations						Blood cortisol decreased¶

*In general, these adverse effects are mild to moderate, arise within the first months of treatment, and subside spontaneously or with dose reduction. The incidence of these adverse effects is related to the administered dose, the age of the patients, and possibly inversely related to the age of the patients at the onset of growth hormone deficiency. †Transient injection site reactions in children have been reported. ‡Reported in growth hormone-deficient children treated with somatropin, but the incidence appears to be similar to that in children without growth hormone deficiency. §Adverse drug reactions identified post-marketing. ¶Clinical significance is unknown.
ADR, adverse drug reaction.

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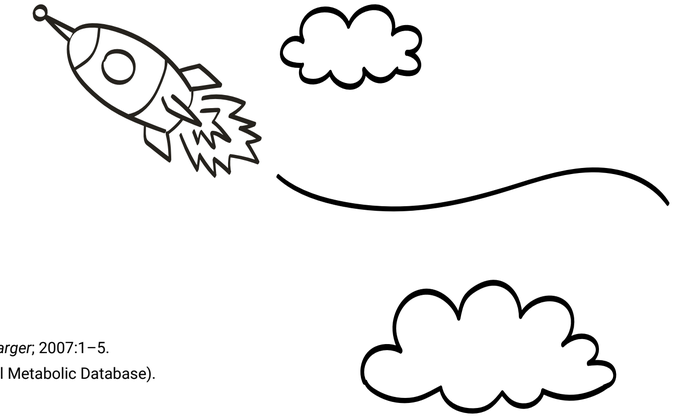
Genotropin® somatropin(rbe)

IN CONCLUSION

- Indicated for **a range of paediatric growth disorders**[2,3]
- **Over 35 years** of clinical backing[4]
- **Broad device range** to suit your patients' needs



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32. Omnitrope (somatropin) Summary of Product Characteristics.

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