

# THE FREEDOM OF ONCE WEEKLY



**SKYTROFA®**

## **MORE INJECTION-FREE DAYS**

with once-weekly dosing compared  
with daily therapies

## **CONVENIENT STORAGE WITHOUT PRESERVATIVES**

and with no required refrigeration for up to 6 months\*

## **HIGHER GROWTH RATE†**

after 1 year in a clinical trial compared  
with a daily somatropin therapy‡

## **DELIVERS SOMATROPIN,**

which is used in daily growth  
hormone injections

\*Store SKYTROFA in the original package to protect from light. Do not freeze. SKYTROFA can be stored at room temperature (not to exceed 86°F [30°C]) for up to 6 months. Alternatively, SKYTROFA can be stored under refrigeration at 36°F to 46°F (2°C to 8°C) until the expiration date. If refrigerated, keep at room temperature for 15 minutes before use. Do not use SKYTROFA beyond the expiration date or 6 months after the date it was first removed from refrigeration (whichever is earlier).

†In a clinical trial that compared once-weekly SKYTROFA with a daily somatropin in 161 children with pediatric growth hormone deficiency (GHD) who previously had not been on treatment. The primary endpoint from the clinical trial was measuring annualized height velocity (AHV) at 52 weeks.

‡11.2 cm/year for SKYTROFA versus 10.3 cm/year for a daily somatropin.

### **— What is SKYTROFA® used for?**

SKYTROFA is a prescription medication for the replacement of growth hormone in children 1 year old or older who weigh at least 26 pounds (11.5 kilograms) with growth hormone deficiency (GHD).

### **— What Warnings should I know about SKYTROFA?**

There have been reports of death when using treatments like SKYTROFA in patients with critical illness due to complications following certain surgeries, severe injury, or in people with respiratory failure.

**Please see Important Safety Information throughout  
and accompanying full Prescribing Information.**

Once-weekly  
**Skytrofa®**  
lonapegsomatropin-tcqd

# Understanding pediatric GHD

If your child has been diagnosed with pediatric GHD, it means:



Their pituitary gland does not produce enough growth hormone to stimulate their body to grow



You may notice your child is  
**FALLING OFF  
THE CURVE**  
on their growth chart  
because they are

growing at a slower rate

## — What Warnings should I know about SKYTROFA? (continued)

Severe hypersensitivity reactions including anaphylactic reactions and swelling underneath the skin, have been reported during use with treatments like SKYTROFA. Seek medical help right away if the following happen after administering SKYTROFA: hives, trouble breathing, and swelling of the face, eyes, lips, or mouth. Do not use if there is any history of hypersensitivity reactions to any ingredients in SKYTROFA.

Childhood cancer survivors treated with brain/head radiation are at increased risk of secondary cancers and, as a precaution, need to be monitored for recurrence. Changes in behavior, new headaches, vision disturbances or changes in skin color or changes in birthmarks or moles should be discussed with the healthcare provider.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

**In addition to short stature, pediatric GHD may impact your child in other ways**



They may look younger when compared with friends of the same age and gender



Puberty may be delayed or absent



Normal metabolism, bone strength, and muscle development may also be affected as growth hormone is important for these

**These are some of the important reasons for treating pediatric GHD.**

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# Why start with SKYTROFA®?

SKYTROFA is the first FDA-approved once-weekly treatment of pediatric GHD delivering somatropin, which is used in daily growth hormone therapies.

## Higher growth rate at 52 weeks in a clinical trial

Whether your child is just starting treatment or has been treated with daily somatropin, once-weekly SKYTROFA is proven to help increase height.

Learn more  
about clinical  
trial results



SKYTROFA provides a higher average growth rate versus daily somatropin at 52 weeks\*



Clinical trials showed that SKYTROFA supports growth in children new to treatment and children switching from daily somatropin†

## — What Warnings should I know about SKYTROFA? (continued)

Children with certain rare genetic causes of short stature have an increased risk of developing cancer. Talk with the healthcare provider about risks and benefits of starting SKYTROFA.

Patients may develop impaired glucose tolerance or Type 2 diabetes or have a worsening of diabetes when using SKYTROFA. Dosage of diabetes medicines may need to be adjusted during growth hormone treatment.

Please see Important Safety Information throughout and accompanying full Prescribing Information.



## More injection-free days

Children switching from daily injections can enjoy up to **313 injection-free days per year**, which means up to **86% fewer injection days** than daily somatropin.



## Convenient storage, with no refrigeration

SKYTROFA cartridges **do not need to be refrigerated** for up to 6 months, allowing more flexibility for storage.‡



## No preservatives

Each single-dose cartridge contains **only** lonapegsomatropin-tcqd, diluent, and sterile water.



## Established safety profile

Once-weekly SKYTROFA is FDA approved, with an **established safety profile**.

- In a clinical trial, some children taking once-weekly SKYTROFA had mild injection-site reactions
- Side effects occurring more frequently than with daily somatropin included viral infection, fever, cough, nausea and vomiting, bleeding, diarrhea, stomach area pain, and joint pain and arthritis

\*In a clinical trial that compared once-weekly SKYTROFA with a daily somatropin in 161 children with pediatric GHD who previously had not been on treatment. The primary endpoint from the clinical trial was measuring AHV at 52 weeks. AHV at 52 weeks was 11.2 cm/year for SKYTROFA versus 10.3 cm/year for a daily somatropin.

†SKYTROFA was studied in a 26-week clinical trial investigating the safety, tolerability, and efficacy of SKYTROFA administered once weekly in children with pediatric GHD. The trial included 3 children who previously had not been on treatment and 143 children previously treated with daily growth hormone therapies for ≤ 130 weeks. Safety and tolerability were the primary endpoints.

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# SKYTROFA® Auto-Injector— innovation in your hands

SKYTROFA is the first FDA-approved once-weekly pediatric injection that delivers somatropin, which is used in daily growth hormone therapies. The innovative SKYTROFA Auto-Injector provides clear direction at every step of the process with precise mixing and automated injection.

## Needle guard

Starts injection when pressed against skin

## Progress bar

Shows progress of mixing and injection with visual and auditory cues

## Needle

## Cartridge

Contains medicine and water for injection

Watch  
video



## Button

To turn on Auto-Injector or  
reject mixed medicine

## Battery icon

## — What Warnings should I know about SKYTROFA? (continued)

Increased pressure in the brain has been reported in a small number of patients taking treatments like SKYTROFA, which can cause changes in vision, headache, nausea or vomiting. Treatment may be reduced or stopped if any of these conditions occur.

SKYTROFA can cause the body to retain fluid which may cause swelling, joint pain, or muscle pain, and usually goes away after treatment is stopped or dose is reduced.

Patients taking SKYTROFA who have or are at risk for pituitary hormone deficiencies may be at risk for reduced serum cortisol levels and/or unmasking of central hypoadrenalism. Patients should be checked regularly for low serum cortisol levels and/or the need to increase the dose of the glucocorticoids they are taking.

Please see Important Safety Information throughout  
and accompanying full Prescribing Information.



## No need to dial the dose

SKYTROFA comes in **ready-to-use, color-coded cartridges** for the prescribed dose. During administration, the Auto-Injector delivers the entire dose without wasting medicine.

- All cartridges work in the SKYTROFA Auto-Injector
- SKYTROFA has a range of dosage strengths. Your doctor can easily adjust your child's prescribed dose as they grow



## No refrigeration, no preservatives

SKYTROFA cartridges **do not need to be refrigerated** for up to 6 months.\* SKYTROFA is **preservative free**. Each single-dose cartridge contains only lonapegsomatropin-tcgd, diluent, and sterile water.



## Small needle size selected with your child's comfort in mind

Uses a **thin, 31-gauge needle** provided to patients with every SKYTROFA cartridge delivery.

- The SKYTROFA Auto-Injector has a needle guard that covers the needle during injections



## Unplug, inject, and go

The Auto-Injector is **reusable and rechargeable**. It reduces the waste of disposable injector pens and batteries. A full charge lasts for 4 weeks, with 1 injection per week. The Auto-Injector is designed to last for approximately 4 years or 210 injections, whichever comes first.



## Get a text when it's time to inject

The **Ascendis Signature Access Program® (A-S-A-P) Messaging Service** is designed to help you stay on track when taking SKYTROFA. Because SKYTROFA has fewer injection days than daily therapies, weekly reminders may be helpful when getting started. Sign up for injection reminders sent directly to your phone at Skytrofa.com.

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A·S·A·P  
ASCENDIS SIGNATURE  
ACCESS PROGRAM®



Visit [Skytrofa.com](https://www.skytrofa.com) to learn more about personalized patient support with A-S-A-P



## A-S-A-P is powered by nurses, who support you at every step of the way

At enrollment, you and your child are connected with a dedicated **Nurse Advocate** and can access SKYTROFA® Auto-Injector training throughout treatment. This also includes personalized help with navigating coverage issues, financial assistance, and reimbursement education.

### — What Warnings should I know about SKYTROFA? (continued)

Thyroid function should be monitored as low thyroid levels can cause SKYTROFA to not work. Low thyroid hormone levels may become apparent or worsen during SKYTROFA treatment.

In children experiencing rapid growth, limping or hip or knee pain may occur. If a child being treated with SKYTROFA starts to limp or gets hip or knee pain, the child's doctor should be notified and the child should be examined. Children and caregivers should be aware that decreased blood flow to bones may occur with human growth hormone products.

In children experiencing rapid growth, curvature of the spine may worsen, known as scoliosis. Patients with scoliosis should be checked regularly to make sure their scoliosis does not get worse during treatment with SKYTROFA.

Please see Important Safety Information throughout and accompanying full Prescribing Information.



### Your dedicated Nurse Advocate:

- Offers insurance support and/or help with seeking financial assistance to pay for your SKYTROFA
- Connects you with an A-S-A-P Clinical Educator to teach you and your child how to use the SKYTROFA Auto-Injector during an in-person or virtual training session
- Answers any questions you may have



### The Nurse Advocate helps you navigate insurance barriers, including:

- Benefits verification, prior authorization (PA) approvals, and appeals
- Assisting with reimbursement education
- Helping you enroll in the Co-Pay Program for SKYTROFA, if eligible
- Coordinating enrollment in the FastStart Program to start you on SKYTROFA as you go through the insurance reimbursement process
- Ensuring there is no gap in treatment caused by job changes or PA expirations through the SKYTROFA Bridge Program
- Accessing support for uninsured families



### SKYTROFA is delivered to your doorstep with help from the Nurse Advocate who:

- Ensures the SKYTROFA Auto-Injector and Starter Kit are shipped right to your door
- Coordinates delivery of your SKYTROFA medicine from the Specialty Pharmacy
- Provides overall case management

**How to enroll in A-S-A-P:** Your doctor will initiate A-S-A-P enrollment after prescribing SKYTROFA.

[illegible]

— **What Warnings should I know about SKYTROFA? (continued)**

SKYTROFA can cause inflammation of the pancreas which may cause pain in the area of the stomach.

SKYTROFA can cause loss of fat tissue around the injection site with continued use. Injection sites should be different each time SKYTROFA is administered to prevent this risk.

SKYTROFA should not be used in patients with Prader-Willi syndrome who are very overweight or who have severe breathing problems due to risk of death. SKYTROFA is not indicated for treatment of Prader-Willi syndrome.

**Please see Important Safety Information throughout and accompanying full Prescribing Information.**



## Helpful questions to ask your doctor

Use our discussion guide at your next visit to talk with your doctor about once-weekly SKYTROFA®.

Scan the QR code to download the discussion guide.



### Information and resources at Skytrofa.com

Scan the QR code to visit [Skytrofa.com](https://www.skytrofa.com) for more information about once-weekly SKYTROFA, including a video on how to use the SKYTROFA Auto-Injector.

— You should not use SKYTROFA if you have:

- Critical illness immediately after open heart surgery, abdominal surgery, or accidental trauma, or those with severe breathing problems known as respiratory failure;
- Had a reaction to SKYTROFA or any of its ingredients;
- Bones that have stopped growing;
- Cancer;
- Eye vision problems due to diabetes;
- A condition known as Prader-Willi syndrome and are overweight; have a history of upper airway breathing problems, have sleep apnea, or have severe breathing problems, due to the risk of sudden death

— What are the side effects of SKYTROFA?

The most common side effects include viral infection, fever, cough, nausea and vomiting, bleeding, diarrhea, stomach area pain, and joint pain and arthritis.

# THE FREEDOM OF ONCE WEEKLY



**More injection-free days**  
with once-weekly dosing  
compared with daily therapies



**Convenient storage without  
preservatives** and with no  
required refrigeration for up  
to 6 months\*



**Higher growth rate<sup>†</sup>** after  
1 year in a clinical trial compared  
with a daily somatotropin therapy<sup>‡</sup>



**Delivers somatotropin**, which is  
used in daily growth hormone  
injections



**People on your team** with  
personalized support from a  
Nurse Advocate

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<sup>†</sup> In a clinical trial that compared once-weekly SKYTROFA with a daily somatotropin in 161 children with pediatric GHD who previously had not been on treatment. The primary endpoint from the clinical trial was measuring least squares (LS) mean AHV at 52 weeks.

<sup>‡</sup> 11.2 cm/year for SKYTROFA versus 10.3 cm/year for a daily somatotropin; treatment difference in AHV of 0.9 cm/year (LS mean by analysis of covariance).



**Visit [Skytrofa.com](https://www.skytrofa.com) for more information about  
once-weekly SKYTROFA, including a video on  
how to use the SKYTROFA Auto-Injector.  
Questions? Please call 1-844-442-7236**

## — What other medication might interact with SKYTROFA?

Make certain to tell your healthcare provider about all medicines you take including corticosteroids, estrogen containing products, including certain birth control medications, or medicine for diabetes. These are not all of the drugs that may interact with SKYTROFA.

These are not all of the possible side effects of SKYTROFA. Call your doctor for medical advice about side effects. **You are encouraged to report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](https://www.fda.gov/medwatch). You may also report side effects to Ascendis Pharma at 1-844-442-7236.**

**Please see accompanying full Prescribing Information for SKYTROFA.**

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