SKYTROFA- lonapegsomatropin-tcgd injection, powder, lyophilized, for solution
Ascendis Pharma, Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SKYTROFA™ safely and effectively. See full prescribing information for SKYTROFA™.

SKYTROFA™ (lonapegsomatropin-tcgd) for injection, for subcutaneous use

Initial U.S. Approval: 2021

INDICATIONS AND USAGE

SKYTROFA is a human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH) (1).

DOSAGE AND ADMINISTRATION

SKYTROFA should be administered subcutaneously into the abdomen, buttock, or thigh with regular rotation of the injection sites (2.5).
The recommended dose is 0.24 mg/kg body weight once-weekly.
See Full Prescribing Information for instructions on preparation and administration of drug (2.4, 2.5).

DOSAGE FORMS AND STRENGTHS

SKYTROFA is a lyophilized powder available in single-dose, dual-chamber, prefilled cartridges containing lonapegsomatropin-tcgd and diluent, Water for Injection, as follows:
For injection: 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg and 13.3 mg (3).

CONTRAINDICATIONS

- Acute critical illness (4)
- Hypersensitivity to somatropin or any of the excipients in SKYTROFA (4)
- Children with closed epiphyses (4)
- Active malignancy (4)
- Active proliferative or severe non-proliferative diabetic retinopathy (4)
- Children with Prader-Willi syndrome who are severely obese or have severe respiratory impairment due to risk of sudden death (4)

WARNINGS AND PRECAUTIONS

- Severe Hypersensitivity: Serious hypersensitivity reactions may occur. In the event of an allergic reaction, seek prompt medical attention (5.2).
- Increased Risk of Neoplasms: Monitor patients with preexisting tumors for progressions or recurrence. Increased risk of a second neoplasm in childhood cancer survivors treated with somatropin – in particular meningiomas in patients treated with radiation to the head for their first neoplasm (5.3).
- Glucose Intolerance and Diabetes Mellitus: May be unmasked. Periodically monitor glucose levels in all patients. Doses of concurrent antihyperglycemic drugs in diabetics may require adjustment (5.4).
- Intracranial Hypertension: Exclude preexisting papilledema. May develop and is usually reversible after discontinuation or dose reduction (5.5).
- Fluid Retention (i.e., edema, arthralgia, carpal tunnel syndrome): May occur. Reduce dose as necessary (5.6).
- Hypoadrenalism: Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in those with known hypoadrenalism (5.7).
- Hypothyroidism: May first become evident or worsen (5.8).
- Slipped Capital Femoral Epiphysis: May develop. Evaluate children with the onset of a limp or persistent hip/knee pain (5.9).
- Progression of Preexisting Scoliosis: May develop (5.10).
- Pancreatitis: Consider pancreatitis in patients with persistent severe abdominal pain (5.11).

ADVERSE REACTIONS

Most common adverse reactions (≥5%) in pediatric patients include: viral infection, pyrexia, cough, nausea and vomiting, hemorrhage, diarrhea, abdominal pain, and arthralgia and arthritis (6).

To report SUSPECTED ADVERSE REACTIONS, contact Ascendis Pharma, Inc., at 1-844-442-7236 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Replacement Glucocorticoid Treatment: Patients treated with glucocorticoid for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SKYTROFA (7).
- Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment: Adjust glucocorticoid replacement dosing in pediatric patients receiving glucocorticoid treatment to avoid both hypoadrenalism and an inhibitory effect on growth (7).
- Cytochrome P450-Metabolized Drugs: SKYTROFA may alter the clearance. Monitor carefully if used with SKYTROFA (7).
- Oral Estrogen: Larger doses of SKYTROFA may be required (7).
- Insulin and/or Other Antihyperglycemic Agents: Dose adjustment of insulin or antihyperglycemic agent may be required (7).

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 8/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
2.1 General Dosing Information
2.2 Dosage Recommendations
2.3 Missed Doses
2.4 Administration Instructions
2.5 Preparation and Administration
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Increased Mortality in Patients with Acute Critical Illness
5.2 Severe Hypersensitivity
5.3 Increased Risk of Neoplasms
5.4 Glucose Intolerance and Diabetes Mellitus
5.5 Intracranial Hypertension
5.6 Fluid Retention
5.7 Hypoadrenalism
5.8 Hypothyroidism
5.9 Slipped Capital Femoral Epiphysis
5.10 Progression of Preexisting Scoliosis
5.11 Pancreatitis
5.12 Lipoatrophy
5.13 Sudden Death in Pediatric Patients with Prader-Willi Syndrome
5.14 Laboratory Tests
6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
6.2 Immunogenicity
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.2 Lactation

8.4 Pediatric Use
9 DRUG ABUSE AND DEPENDENCE
9.1 Controlled Substance
9.2 Abuse
9.3 Dependence
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenicity, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
14.1 Treatment-Naïve Pediatric Patients with Growth Hormone Deficiency (NCT02781727)
16 HOW SUPPLIED/STORAGE AND HANDLING
16.1 How Supplied
16.2 Storage and Handling
17 PATIENT COUNSELING INFORMATION
* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

SKYTROFA (lonapegsomatropin-tcgd) is a human growth hormone indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

- For subcutaneous injection, once-weekly.
- Therapy with SKYTROFA should be supervised by a physician who is experienced in the diagnosis and management of pediatric patients with growth failure due to growth hormone deficiency (GHD).
- To exclude preexisting papilledema, perform fundoscopic examination before initiating treatment with SKYTROFA and reassess periodically thereafter *[see Warnings and Precautions (5.5)]*.

2.2 Dosage Recommendations

- The recommended dose of SKYTROFA for treatment-naïve patients and patients switching from daily somatropin therapy is 0.24 mg/kg body weight, given once-weekly.

- Individualize and titrate the dosage of SKYTROFA based on response.
- When changing from daily somatropin therapy to once-weekly SKYTROFA, wait at least 8 hours between the final dose of daily somatropin and the first dose of once-weekly SKYTROFA.
- Assess compliance and evaluate other causes of poor growth such as hypothyroidism, under-nutrition, advanced bone age and antibodies to recombinant human growth hormone if patients experience failure to increase height velocity, particularly during the first year of treatment.
- Discontinue SKYTROFA once epiphyseal fusion has occurred.

2.3 Missed Doses

- Administer a missed dose as soon as possible and not more than 2 days after the missed dose.
- To avoid missed doses, SKYTROFA can be taken 2 days before or 2 days after the scheduled dosing day. Resume once-weekly dosing for the next dose at the previously scheduled dosing day.
- If more than 2 days have passed from the scheduled day, skip the dose and administer the next dose on the regularly scheduled day.
- At least 5 days should elapse between doses.

2.4 Administration Instructions

SKYTROFA is available in 9 cartridges (dosage strengths in somatropin equivalents). Selection of the appropriate cartridge is based on the prescribed dose (mg/kg) and the patient's body weight (kg).

- If prescribing a dose of 0.24 mg/kg/week and the patient's weight is 11.5 to 100 kg, follow the recommended dosing in Table 1.
- If prescribing a dose other than 0.24 mg/kg/week, calculate the total weekly dose (in mg) and select the appropriate cartridge as follows:
  - Total weekly dose (mg) = prescribed weekly dose (mg/kg) × patient's body weight (kg).
  - Round the total weekly dose (mg) to the closest cartridge dose while also considering treatment goals and clinical response.

Table 1: Recommended Dosing for Patients Prescribed Doses of 0.24 mg/kg/week

Weight (kg)	Dose (mg)
11.5 – 13.9	3
14 – 16.4	3.6
16.5 – 19.9	4.3
20 – 23.9	5.2
24 – 28.9	6.3
29 – 34.9	7.6
35 – 41.9	9.1
42 – 50.9	11
51 – 60.4	13.3
60.5 – 69.9	15.2 (using two cartridges of 7.6 mg each)

70 – 84.9	18.2 (using two cartridges of 9.1 mg each)
85 – 100	22 (using two cartridges of 11 mg each)

2.5 Preparation and Administration

- The SKYTROFA cartridge has been designed for use only with the SKYTROFA Auto-Injector.
- If refrigerated, the SKYTROFA cartridge must be kept at room temperature for 15 minutes before use.
- The SKYTROFA Auto-Injector provides a fully automated reconstitution of the lyophilized drug product which is followed by a manual mixing step controlled by the device. When the injection needle is inserted into the skin, the device automatically delivers the drug product. The built-in electronics and software assist the user during the entire preparation and injection sequence and provide confirmation that the full dose has been delivered.
- The mixed solution should be clear and colorless to opalescent and may occasionally contain air bubbles. DO NOT inject if the solution is cloudy or contains particulate matter.
- Use SKYTROFA cartridges within 4 hours after reconstitution. Discard reconstituted SKYTROFA cartridges after 4 hours when stored at room temperature up to 86°F (30°C).
- Inject SKYTROFA subcutaneously into the abdomen, buttock, or thigh. Rotate injection sites between and within regions to reduce the risk of lipoatrophy.
- Refer to the Instructions for Use for complete administration instructions with illustrations. The instructions can also be found on www.Skytrofa.com/IFU.

3 DOSAGE FORMS AND STRENGTHS

SKYTROFA is a white to off-white lyophilized powder available in a single-dose, dual-chamber, prefilled cartridge containing lonapegsomatropin-tcgd in one chamber and diluent, Water for Injection, in the other chamber and is available in the following strengths:

For injection: 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 7.6 mg, 9.1 mg, 11 mg and 13.3 mg.

4 CONTRAINDICATIONS

SKYTROFA is contraindicated in patients with:

- Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin *[see Warnings and Precautions (5.1)]*.
- Hypersensitivity to somatropin or any of the excipients in SKYTROFA. Systemic hypersensitivity reactions have been reported with post-marketing use of somatropin products *[see Warnings and Precautions (5.2)].*
- Closed epiphyses.
- Active malignancy due to the risk of malignancy progression *[see Warnings and Precautions (5.3)].*

- Active proliferative or severe non-proliferative diabetic retinopathy because treatment with somatropin may worsen this condition.
- Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea or have severe respiratory impairment due to the risk of sudden death *[see Warnings and Precautions (5.13)].*

5 WARNINGS AND PRECAUTIONS

5.1 Increased Mortality in Patients with Acute Critical Illness

Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic doses of somatropin *[see Contraindications (4)].* The safety of continuing SKYTROFA treatment in patients receiving replacement doses for the approved indication who concurrently develop these illnesses has not been established.

5.2 Severe Hypersensitivity

Serious systemic hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with post-marketing use of somatropin products. Inform patients and caregivers that such reactions are possible, and that prompt medical attention should be sought if an allergic reaction occurs *[see Contraindications (4)]*. Do not use SKYTROFA in patients with known hypersensitivity to somatropin or any of the excipients in SKYTROFA.

5.3 Increased Risk of Neoplasms

Active Malignancy

There is an increased risk of malignancy progression with somatropin treatment in patients with active malignancy *[see Contraindications (4)].* Any preexisting malignancy should be inactive, and its treatment should be completed prior to instituting therapy with SKYTROFA. Discontinue SKYTROFA if there is evidence of recurrent malignancy.

Risk of Second Neoplasm in Pediatric Patients

In childhood cancer survivors who were treated with radiation to the brain/head for their first neoplasm and who developed subsequent growth hormone deficiency (GHD) and were treated with somatropin, an increased risk of a second neoplasm has been reported. Intracranial tumors, in particular meningiomas, were the most common of these second neoplasms. Monitor all patients with a history of GHD secondary to an intracranial neoplasm while on somatropin therapy for progression or recurrence of the tumor.

New Malignancy During Treatment

Because children with certain rare genetic causes of short stature have an increased risk of developing malignancies, thoroughly consider the risks and benefits of starting somatropin in these patients. If treatment with somatropin is initiated, carefully monitor these patients for development of neoplasms.

Monitor patients on somatropin therapy carefully for increased growth or potential

malignant changes of preexisting nevi. Advise patients/caregivers to report marked changes in behavior, onset of headaches, vision disturbances and/or changes in skin pigmentation or changes in the appearance of preexisting nevi.

5.4 Glucose Intolerance and Diabetes Mellitus

Treatment with somatropin may decrease insulin sensitivity, particularly at higher doses. Previously undiagnosed impaired glucose tolerance and overt type 2 diabetes mellitus may be unmasked. Monitor glucose levels in all patients receiving SKYTROFA, especially in those with risk factors for type 2 diabetes mellitus, such as obesity or a family history of type 2 diabetes mellitus. When initiating SKYTROFA, monitor closely patients with preexisting type 1 or type 2 diabetes mellitus or impaired glucose tolerance and adjust the doses of antihyperglycemic drugs as needed.

5.5 Intracranial Hypertension

Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in a small number of patients treated with somatropin. Symptoms usually occurred within 8 weeks after the initiation of somatropin. In all reported cases, IH-associated signs and symptoms resolved rapidly after cessation of therapy or a reduction of the somatropin dose. To exclude preexisting papilledema, perform fundoscopic examination before initiating treatment with SKYTROFA, and reassess periodically thereafter. If papilledema is observed by fundoscopy, stop somatropin treatment. If somatropin-induced IH is confirmed, restart treatment with SKYTROFA at a lower dose after IH-associated signs and symptoms have resolved.

5.6 Fluid Retention

Fluid retention during somatropin therapy may occur. Clinical manifestations of fluid retention (e.g., edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paresthesia) are usually transient and dose-dependent.

5.7 Hypoadrenalism

Patients receiving somatropin therapy who have or are at risk for pituitary hormone deficiency(s) may be at risk for reduced serum cortisol levels and/or unmasking of central (secondary) hypoadrenalism. In addition, patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SKYTROFA therapy. Monitor patients for reduced serum cortisol levels and/or need for glucocorticoid dose increases in patients with known hypoadrenalism *[see Drug Interactions (7)]*.

5.8 Hypothyroidism

Undiagnosed or untreated hypothyroidism may prevent optimal response to SKYTROFA. In patients with GHD, central (secondary) hypothyroidism may first become evident or worsen during SKYTROFA treatment. Therefore, perform periodic thyroid function tests in patients and initiate or appropriately adjust thyroid hormone replacement therapy when indicated.

5.9 Slipped Capital Femoral Epiphysis

Slipped capital femoral epiphysis may occur more frequently in patients undergoing rapid growth. Evaluate pediatric patients with the onset of a limp or complaints of persistent hip or knee pain.

5.10 Progression of Preexisting Scoliosis

Somatropin increases growth rate, and progression of existing scoliosis can occur in patients who experience rapid growth. Somatropin has not been shown to increase the occurrence of scoliosis. Monitor patients with a history of scoliosis for disease progression.

5.11 Pancreatitis

Pancreatitis has been reported in pediatric patients receiving somatropin. The risk may be greater in pediatric patients than adults. Consider pancreatitis in patients who develop persistent severe abdominal pain.

5.12 Lipoatrophy

When SKYTROFA is administered subcutaneously at the same site over a long period of time, lipoatrophy may result. Rotate injection sites when administering SKYTROFA to reduce this risk *[see Preparation and Administration (2.5)]*.

5.13 Sudden Death in Pediatric Patients with Prader-Willi Syndrome

There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. SKYTROFA is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome.

5.14 Laboratory Tests

Serum levels of phosphate, alkaline phosphatase, and parathyroid hormone may increase after somatropin treatment. If a patient is found to have abnormal laboratory tests, monitor as appropriate.

6 ADVERSE REACTIONS

The following important adverse reactions are described elsewhere in the labeling:

- Increased mortality in patients with acute critical illness *[see Warnings and Precautions (5.1)]*
- Severe hypersensitivity *[see Warnings and Precautions (5.2)]*
- Increased risk of neoplasms *[see Warnings and Precautions (5.3)]*
- Glucose intolerance and diabetes mellitus *[see Warnings and Precautions (5.4)]*
- Intracranial hypertension *[see Warnings and Precautions (5.5)]*
- Fluid retention *[see Warnings and Precautions (5.6)]*
- Hypoadrenalism *[see Warnings and Precautions (5.7)]*
- Hypothyroidism *[see Warnings and Precautions (5.8)]*
- Slipped capital femoral epiphysis in pediatric patients *[see Warnings and Precautions (5.9)]*

- Progression of preexisting scoliosis in pediatric patients *[see Warnings and Precautions (5.10)]*
- Pancreatitis *[see Warnings and Precautions (5.11)]*
- Lipoatrophy *[see Warnings and Precautions (5.12)]*
- Sudden death in pediatric patients with Prader-Willi syndrome *[see Warnings and Precautions (5.13)]*

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in clinical practice.

SKYTROFA was studied in a 52-week, open-label, active-controlled trial in 161 treatment-naïve, prepubertal pediatric patients with growth hormone deficiency (GHD) *[see Clinical Studies (14.1)]*. The subjects ranged in age from 3.2 to 13.1 years with a mean of 8.5 years. One hundred thirty-two (82%) of the subjects were male and 29 (18%) were female. One subject was Asian, 3 were Black or African American, 152 were Caucasian, and 5 were categorized as "other."

Table 2 shows common adverse reactions that occurred in ≥5% of patients treated with SKYTROFA in this trial.

Table 2: Adverse Reactions Occurring in ≥5% SKYTROFA-Treated Pediatric Patients and More Frequently than in Daily Somatropin-Treated Pediatric Patients (52 Weeks of Treatment)

Adverse Reactions	**Daily Somatropin (N = 56) n (%)**	**SKYTROFA (N = 105) n (%)**
Infection, viral	6 (11%)	16 (15%)
Pyrexia	5 (9%)	16 (15%)
Cough	4 (7%)	11 (11%)
Nausea and vomiting	4 (7%)	11 (11%)
Hemorrhage*	1 (2%)	7 (7%)
Diarrhea	3 (5%)	6 (6%)
Abdominal pain	2 (4%)	6 (6%)
Arthralgia and arthritis†	1 (2%)	6 (6%)

Adverse reactions that are medically related were grouped to a single preferred term.

* Hemorrhage in the SKYTROFA treatment group included epistaxis (3), contusion (2), petechiae (1) and eye hemorrhage (1).

† Arthralgia and arthritis in the SKYTROFA treatment group included arthralgia (5) and reactive arthritis (1).

Laboratory Tests

More SKYTROFA-treated patients shifted from normal baseline levels to elevated phosphate and alkaline phosphatase levels at the end of the trial compared to the daily

somatropin group (44.2% vs. 30.2% and 19.2% vs. 9.4%, respectively); these laboratory changes occurred intermittently *[see Warnings and Precautions (5.14)]*.

6.2 Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to SKYTROFA with the incidence of antibodies to other products may be misleading.

Anti-lonapegsomatropin-tcgd antibodies were evaluated in samples collected every 3 months in phase 3 trials in pediatric patients with GHD receiving lonapegsomatropin-tcgd. Mean duration of exposure to SKYTROFA was 70.2 weeks. Of the 304 patients with post-baseline assessments, 19 (6.3%) showed detectable binding antibodies to lonapegsomatropin-tcgd at any time. No apparent correlation of anti-lonapegsomatropin-tcgd antibodies to adverse events or loss of efficacy was observed. No neutralizing antibodies to SKYTROFA were detected.

7 DRUG INTERACTIONS

Table 3 includes a list of drugs with clinically important drug interactions when administered concomitantly with SKYTROFA and instructions for preventing or managing them.

Table 3: Clinically Important Drug Interactions with SKYTROFA

Replacement Glucocorticoid Treatment	
Clinical Impact:	Microsomal enzyme 11β-hydroxysteroid dehydrogenase type 1 (11βHSD-1) is required for conversion of cortisone to its active metabolite, cortisol, in hepatic and adipose tissue. Somatropin inhibits 11βHSD-1. Consequently, individuals with untreated growth hormone deficiency (GHD) have relative increases in 11βHSD-1 and serum cortisol. Initiation of SKYTROFA may result in inhibition of 11βHSD-1 and reduced serum cortisol concentrations.
Intervention:	Patients treated with glucocorticoid replacement for hypoadrenalism may require an increase in their maintenance or stress doses following initiation of SKYTROFA *[see Warnings and Precautions (5.7)]*
Examples	Cortisone acetate and prednisone may be affected more than others because conversion of these drugs to their biologically active metabolites is dependent on the activity of 11βHSD-1.
Pharmacologic Glucocorticoid Therapy and Supraphysiologic Glucocorticoid Treatment	

Clinical Impact:	Pharmacologic glucocorticoid therapy and supraphysiologic glucocorticoid treatment may attenuate the growth-promoting effects of SKYTROFA in pediatric patients.
Intervention:	Carefully adjust glucocorticoid replacement dosing in pediatric patients receiving glucocorticoid treatments to avoid both hypoadrenalism and an inhibitory effect on growth.
Cytochrome P450-Metabolized Drugs	
Clinical Impact:	Limited published data indicate that somatropin treatment increases cytochrome P450 (CYP450)-mediated antipyrine clearance. SKYTROFA may alter the clearance of compounds known to be metabolized by CYP450 liver enzymes.
Intervention:	Careful monitoring is advisable when SKYTROFA is administered in combination with drugs metabolized by CYP450 liver enzymes.
Oral Estrogen	
Clinical Impact:	Oral estrogens may reduce the serum insulin-like growth factor-1 (IGF-1) response to SKYTROFA.
Intervention:	Patients receiving oral estrogen replacement may require higher SKYTROFA dosages.
Insulin and/or Other Antihyperglycemic Agents	
Clinical Impact:	Treatment with SKYTROFA may decrease insulin sensitivity, particularly at higher doses.
Intervention:	Patients with diabetes mellitus may require adjustment of their doses of insulin and/or other antihyperglycemic agents *[see Warnings and Precautions (5.4)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on lonapegsomatropin-tcgd use in pregnant patients to evaluate a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Available published data over several decades for somatropin, the active component of lonapegsomatropin-tcgd, have not identified a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies, there was no evidence of embryo-fetal or neonatal harm when pregnant rats were administered subcutaneous lonapegsomatropin-tcgd at doses up to 13-fold the clinical dose of 0.24 mg/kg/week *(see Data)*.

The estimated background risk of birth defects and miscarriages for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriages in clinically recognized pregnancies is 2% to 4%

and 15% to 20%, respectively.

Data

Animal Data

No embryonic or fetal development toxicities occurred in rats administered subcutaneous lonapegsomatropin-tcgd at doses up to 13-fold the clinical dose of 0.24 mg/kg/week.

In a peri- and post-natal developmental study in rats, there were no adverse effects on the pregnant/lactating female or on development of the conceptus and the offspring following exposure of the female from implantation through weaning to doses of a structurally related pegylated somatropin prodrug up to 13-fold the clinical dose of 0.24 mg/kg/week.

8.2 Lactation

Risk Summary

There are no data on the presence of lonapegsomatropin-tcgd in human milk, effects on the breastfed infant, or effects on milk production. High molecular weight therapeutic proteins, including lonapegsomatropin-tcgd, are expected to have low passage into human milk and limited systemic exposure in the breastfed infant. Additionally, published data indicate that exogenous somatropin does not increase normal human milk concentrations of growth hormone. No adverse effects on the breastfed infant have been reported with somatropin. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SKYTROFA and any potential adverse effects on the breastfed infant from SKYTROFA or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of SKYTROFA have been established in pediatric patients 1 year and older and who weigh at least 11.5 kg. Pediatric use was established in a controlled study of 161 treatment-naïve pediatric patients ages 3 to 13 years and by supportive data in pediatric patients 1 year and older *[see Adverse Reactions (6) and Clinical Studies (14)]*.

The safety and effectiveness of SKYTROFA in children less than 1 year of age have not been established.

Use of somatropin in pediatric patients with Prader-Willi syndrome has been associated with reports of sudden death. SKYTROFA is not indicated for the treatment of pediatric patients with growth failure due to genetically confirmed Prader-Willi syndrome *[see Warnings and Precautions (5.13)]*.

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

SKYTROFA is a prodrug of somatropin. Somatropin is not a controlled substance.

9.2 Abuse

Inappropriate use of somatropin may result in significant negative health consequences.

9.3 Dependence

Somatropin is not associated with drug related withdrawal adverse reactions.

10 OVERDOSAGE

Acute overdosage may lead initially to hypoglycemia and subsequently to hyperglycemia. Overdose with somatropin may cause fluid retention. Long-term overdosage may result in signs and symptoms of gigantism consistent with the known effects of excess growth hormone.

11 DESCRIPTION

Lonapegsomatropin-tcgd is a long-acting prodrug of a human growth hormone (somatropin) produced by recombinant DNA technology using *E. coli*. Lonapegsomatropin-tcgd consists of a parent drug, somatropin, that is conjugated to a methoxypolyethylene glycol carrier (4 × 10 kDa mPEG) via a proprietary TransCon Linker and has a molecular weight of 63 kDa (released somatropin is 22 kDa). *In vitro* assay confirms the minimum potency of released somatropin is NLT 2.5 IU/mg.

SKYTROFA (lonapegsomatropin-tcgd) for injection is a sterile, preservative-free, white to off-white lyophilized powder available in a single-dose, dual-chamber, prefilled cartridge containing lonapegsomatropin-tcgd in one chamber and the diluent, Water for Injection, in the other chamber. SKYTROFA prefilled cartridge must be used with SKYTROFA Auto-Injector to provide an automatic mixing step for reconstitution prior to subcutaneous use.

After reconstitution, each prefilled cartridge delivers:

- 0.273 mL containing 3 mg lonapegsomatropin-tcgd, succinic acid (0.32 mg), trehalose dihydrate (22.7 mg), and tromethamine for pH adjustment to 5.
- 0.327 mL containing 3.6 mg lonapegsomatropin-tcgd, succinic acid (0.39 mg), trehalose dihydrate (27.1 mg), and tromethamine for pH adjustment to 5.
- 0.391 mL containing 4.3 mg lonapegsomatropin-tcgd, succinic acid (0.46 mg) and trehalose dihydrate (32.5 mg) and tromethamine for pH adjustment to 5.
- 0.473 mL containing 5.2 mg lonapegsomatropin-tcgd, succinic acid (0.56 mg) and trehalose dihydrate (39.3 mg) and tromethamine for pH adjustment to 5.
- 0.286 mL containing 6.3 mg lonapegsomatropin-tcgd, succinic acid (0.34 mg) and trehalose dihydrate (21.2 mg) and tromethamine for pH adjustment to 5.
- 0.345 mL containing 7.6 mg lonapegsomatropin-tcgd, succinic acid (0.41 mg) and trehalose dihydrate (25.5 mg) and tromethamine for pH adjustment to 5.
- 0.414 mL containing 9.1 mg lonapegsomatropin-tcgd, succinic acid (0.49 mg) and trehalose dihydrate (30.6 mg) and tromethamine for pH adjustment to 5.
- 0.5 mL containing 11 mg lonapegsomatropin-tcgd, succinic acid (0.59 mg) and trehalose dihydrate (37 mg) and tromethamine for pH adjustment to 5.
- 0.605 mL containing 13.3 mg lonapegsomatropin-tcgd, succinic acid (0.71 mg) and trehalose dihydrate (44.8 mg) and tromethamine for pH adjustment to 5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

SKYTROFA is a pegylated human growth hormone (somatropin) for once-weekly subcutaneous injection *[see Pharmacokinetics (12.3)]*.

Somatropin binds to the growth hormone (GH) receptor in the cell membrane of target cells resulting in intracellular signal transduction and a host of pharmacodynamic effects. Somatropin has direct tissue and metabolic effects, and indirect effects mediated by insulin-like growth factor-1 (IGF-1), including stimulation of chondrocyte differentiation and proliferation, stimulation of hepatic glucose output, protein synthesis and lipolysis. Somatropin stimulates skeletal growth in pediatric patients with growth hormone deficiency (GHD) as a result of effects on the growth plates (epiphyses) of long bones.

12.2 Pharmacodynamics

Somatropin released from SKYTROFA produces a dose linear IGF-1 response, with a change of 0.02 mg/kg on average resulting in a change in IGF-1 standard deviation score (SDS) of 0.17.

At steady-state, IGF-1 levels peak approximately 2 days post-dose, with the average weekly IGF-1 occurring approximately 4.5 days post-dose. IGF-1 levels are in the normal range for GHD patients for the majority of the week, similar to daily somatropin.

12.3 Pharmacokinetics

Absorption

Following subcutaneous dose administration, SKYTROFA releases fully active somatropin via autocleavage of the TransCon linker that follows first-order kinetics.

In pediatric patients with GHD, following subcutaneous dose administration of 0.24 mg/kg/week SKYTROFA, the observed mean (CV%) steady state peak serum concentration (C_{max}) of lonapegsomatropin-tcgd was 1230 (86.3) ng hGH/mL, and the median time to reach maximum concentrations (T_{max}) was 25 hours. For released somatropin, C_{max} was 15.2 (83.4) ng/mL with a median T_{max} of 12 hours. The mean (CV%) somatropin exposure over the one-week dose interval (area under the curve) was 500 (83.8) h*ng/mL. No significant accumulation of lonapegsomatropin-tcgd and somatropin following repeat dose administration was observed.

C_{max} of the methoxypolyethylene glycol carrier was 13.1 (28.1) µg /mL with a median T_{max} of 36 hours.

In healthy adults, following single subcutaneous dose administration in the range of 0.24 to 0.42 mg/kg of SKYTROFA, exposure of released somatropin increased greater than proportional to dose.

Distribution

In pediatric patients with GHD, the mean (CV%) steady state apparent volume of distribution of lonapegsomatropin-tcgd after subcutaneous administration of 0.24 mg/kg/week SKYTROFA was 0.13 (109) L/kg. A similar distribution pattern as observed for daily somatropin is expected once somatropin is released from lonapegsomatropin-tcgd.

Elimination

Metabolism

The metabolism of somatropin involves protein catabolism in both the liver and kidneys. The methoxypolyethylene glycol carrier is cleared by the kidneys.

Excretion

In pediatric patients with GHD, the mean (CV%) lonapegsomatropin-tcgd apparent clearance at steady state was 3.2 (67) mL/h/kg following subcutaneous administration of 0.24 mg/kg/week SKYTROFA with a mean (±SD) observed half-life of 30.7 (±12.7) hours. The apparent half-life of somatropin released from lonapegsomatropin-tcgd was approximately 25 hours.

Specific Populations

Based on a population pharmacokinetic analysis, age, sex, race, and body weight do not have clinically meaningful effects on pharmacokinetics.

Male and Female Patients — No sex-specific pharmacokinetic studies have been performed with SKYTROFA. The available literature indicates that the pharmacokinetics of somatropin are similar in men and women.

Patients with Renal or Hepatic Impairment — No specific studies have been performed with SKYTROFA.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenicity, Mutagenesis, Impairment of Fertility

Carcinogenicity studies have not been conducted with lonapegsomatropin-tcgd.

Lonapegsomatropin-tcgd was not mutagenic in the Ames test, in the human chromosomal aberration assay or in the rat bone marrow micronucleus test.

In an animal fertility study, lonapegsomatropin-tcgd was administered via subcutaneous injection to male and female rats before cohabitation, through mating to implantation.

Lonapegsomatropin-tcgd did not affect fertility or early embryo-fetal development at doses up to 20-fold the clinical dose of 0.24 mg/kg/week.

14 CLINICAL STUDIES

14.1 Treatment-Naïve Pediatric Patients with Growth Hormone Deficiency (NCT02781727)

A multi-center randomized, open-label, active-controlled, parallel-group phase 3 study was conducted in 161 treatment-naïve, prepubertal pediatric subjects with growth hormone deficiency (GHD); 105 subjects received once-weekly SKYTROFA, and 56 received daily somatropin. The dose in both arms was 0.24 mg/kg/week. The primary efficacy endpoint was annualized height velocity at Week 52.

The subjects ranged in age from 3.2 to 13.1 years with a mean of 8.5 years. One hundred thirty-two (82%) subjects were male and 29 (18%) were female. One subject

was Asian, three were Black or African American, 152 were Caucasian, and five were categorized as "other." The subjects had a mean baseline height SDS (standard deviation score) of -2.9.

Treatment with once-weekly SKYTROFA for 52 weeks resulted in an annualized height velocity of 11.2 cm/year. Subjects treated with daily somatropin achieved an annualized height velocity of 10.3 cm/year after 52 weeks of treatment. Refer to Table 4.

Table 4: Annualized Height Velocity at Week 52 in Pediatric Treatment-Naïve Subjects with Growth Hormone Deficiency

	Once-Weekly SKYTROFA (N=105)	**Daily Somatropin (N=56)**	**Estimate of Treatment Difference (95% CI) (SKYTROFA minus Daily Somatropin)**
Annualized Height Velocity (cm/year)*	11.2	10.3	0.9 (0.2-1.5)

* The estimates of least square (LS) means and 95% confidence interval (CI) are from an ANCOVA model that included baseline age, peak GH levels (log transformed) at stimulation test, baseline height SDS – average SDS of parental height as covariates, and treatment and sex as factors. Missing data were imputed with multiple imputation method.

Height SDS (change from baseline) was 1.1 in the SKYTROFA arm and 0.96 in the daily somatropin arm at Week 52. Refer to Table 5.

Table 5: Height SDS over 52 Weeks in Pediatric Treatment-Naïve Subjects with Growth Hormone Deficiency

	Once-Weekly SKYTROFA (N=105)	**Daily Somatropin (N=56)**
Height SDS, baseline	-2.9	-3.0
Height SDS, change from baseline*	1.1	0.96

Abbreviations: SDS: Standard deviation score.

* Height SDS, change from baseline: The estimates of LS means are from an ANCOVA model that included baseline age, peak GH levels (log transformed) at stimulation test and baseline height SDS as covariates, and treatment and sex as factors.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

SKYTROFA (lonapegsomatropin-tcgd) for injection is a sterile, preservative-free, white to off-white lyophilized powder available in a single-dose, dual-chamber, prefilled cartridge containing lonapegsomatropin-tcgd in one chamber and the diluent, Water for Injection, in the second chamber. The dual-chamber glass cartridge is available in 9 strengths (in somatropin equivalents) as described in Table 6.

Table 6: SKYTROFA Presentations

SKYTROFA	NDC
3 mg	73362-003-01
3.6 mg	73362-004-01
4.3 mg	73362-005-01
5.2 mg	73362-006-01
6.3 mg	73362-007-01
7.6 mg	73362-008-01
9.1 mg	73362-009-01
11 mg	73362-010-01
13.3 mg	73362-011-01

Each carton contains 4 single-dose prefilled cartridges and 6 sterile, single-use, disposable 0.25 mm × 4 mm (31-gauge × 5/32 inch) needles. The cartridges are for use only with the SKYTROFA Auto-Injector, packaged in a separate carton. The SKYTROFA Auto-Injector is not supplied with SKYTROFA cartridges but is available for patients with a prescription for SKYTROFA through the Ascendis Pharma Customer Support by calling the toll-free number at 1-844-442-7236 (1-844-44ASCENDIS).

16.2 Storage and Handling

- For patients: Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in the outer carton to protect from light until the expiration date. Do not freeze. Alternatively, SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months. Write the date first removed from the refrigerator in the space provided on the outer carton. Do not use SKYTROFA beyond the expiration date or 6 months after the date it was first removed from refrigeration (whichever is earlier).
- For pharmacy long-term storage: Store SKYTROFA cartridges refrigerated at 36°F to 46°F (2°C to 8°C) in the outer carton to protect from light until the expiration date. Do not freeze.

17 PATIENT COUNSELING INFORMATION

- Provide appropriate instructions for injection to the patient/caregiver, by providing the SKYTROFA Auto-Injector Instructions for Use (available at www.Skytrofa.com/IFU). Patients/caregivers and healthcare providers may also call the Ascendis Pharma Customer Support toll-free number at 1-844-442-7236 (1-844-44ASCENDIS) for assistance or additional training, if needed.
- Advise patients/caregivers to refer to the Instructions for Use that accompanies the SKYTROFA Auto-Injector for complete mixing and administration instructions with

illustrations *[see Preparation and Administration (2.5)]*. Instruct patients/caregivers of proper needle disposal and caution against any reuse of needles. An appropriate container for the disposal of used cartridge and needle should be used.

- Advise patients/caregivers to administer SKYTROFA once weekly, at any time of day. Advise patients/caregivers that doses can be taken 2 days before or 2 days after the scheduled dosing day. Advise patients/caregivers to resume once-weekly dosing for the next dose. If more than 2 days have passed from the schedule dosing day, advise patients/caregivers to skip the missed dose and take the next dose on the regularly scheduled day. If subsequently changing the regular dosing day to a different day of the week, advise patients/caregivers to ensure that at least 5 days will elapse between the last dose and the newly-established regular dosing day.
- Neoplasms – Advise childhood cancer survivors/caregivers that individuals treated with brain/head radiation are at increased risk of secondary neoplasms and, as a precaution, need to be monitored for recurrence. Advise patients/caregivers to report marked changes in behavior, onset of headaches, vision disturbances and/or changes in skin pigmentation or changes in the appearance of preexisting nevi.
- Glucose Intolerance/Diabetes Mellitus – Advise patients/caregivers that new onset impaired glucose intolerance/type 2 diabetes mellitus or exacerbation of preexisting diabetes mellitus can occur and monitoring of blood glucose during treatment with SKYTROFA may be needed.
- Intracranial Hypertension – Advise patients/caregivers to report to their healthcare provider any visual changes, headache, and nausea and/or vomiting.
- Fluid Retention – Advise patients/caregivers that fluid retention during SKYTROFA replacement therapy may occur. Inform patients/caregivers of the clinical manifestations of fluid retention (e.g., edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paresthesia) and to report to their healthcare provider if any of these signs or symptoms occur during treatment with SKYTROFA.
- Hypoadrenalism – Advise patients/caregivers that patients who have or who are at risk for pituitary hormone deficiency(s) that hypoadrenalism may develop and to report to their healthcare provider if they experience hyperpigmentation, extreme fatigue, dizziness, weakness, or weight loss.
- Hypothyroidism – Advise patients/caregivers that undiagnosed/untreated hypothyroidism may prevent an optimal response to SKYTROFA. Advise patients/caregivers that patients may require periodic thyroid function tests.
- Pancreatitis – Advise patients/caregivers that pancreatitis may develop and to report to their healthcare provider any new onset abdominal pain.
- Hypersensitivity Reactions – Advise patients/caregivers that serious systemic hypersensitivity reactions (anaphylaxis and angioedema) are possible, and to seek prompt medical attention should an allergic reaction occur.
- Administration: Counsel patients/caregivers that they should never share the SKYTROFA Auto-Injector with another person, even if the needle is changed. Sharing of the Auto-Injector between patients may pose a risk of transmission of infection.

© 2021 Ascendis Pharma. All rights reserved. *SKYTROFA™, Ascendis®, TransCon®, the Ascendis Pharma logo and the company logo are trademarks owned by the Ascendis Pharma Group.*

PATENT INFORMATION: www.ascendispharma.us/products/patents

Manufactured by:

Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12 Hellerup Denmark DK-2900

U.S. License Number 2165

For information about SKYTROFA contact:
Ascendis Pharma, Inc.
500 Emerson Street
Palo Alto, CA 94301, USA
1-844-442-7236 (1-844-44ASCENDIS)
www.Skytrofa.com

PRINCIPAL DISPLAY PANEL - 3 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

126353

NDC 73362-003-01

GTIN: 00373362003010

Skytrofa.
(lonapegsomatropin-tcgd)
for injection

3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

126353

NDC 73362-003-01

3 73362 00301 0

GTIN: 00373362003010

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____
Discard after 6 months.

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

3 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

ascendis pharma

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

3 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark
US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.273 mL containing 3 mg of lonapegsomatropin-tcgd, succinic acid (0.32 mg), trehalose dihydrate (22.7 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

PRINCIPAL DISPLAY PANEL - 3.6 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

3.6 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122295

NDC 73362-004-01

GTIN: 00373362004017

Skytrofa
(lonapegsomatropin-tcgd)
for injection

3.6 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122295

NDC 73362-004-01

3 73362 00401 7

GTIN: 00373362004017

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____ / ____ / ____
Discard after 6 months.

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

3.6 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

ascendis pharma

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

3.6 mg

Content:
4 single-dose cartridges,
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark

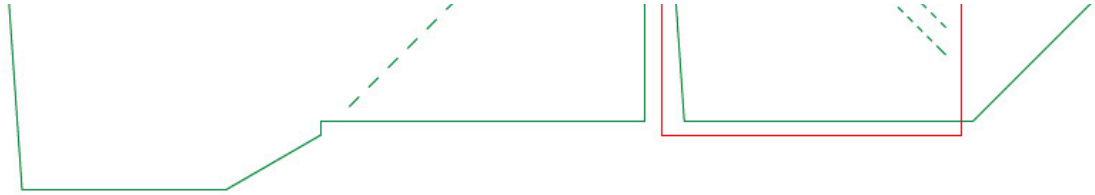
US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.327 mL containing 3.6 mg of lonapegsomatropin-tcgd, succinic acid (0.39 mg), trehalose dihydrate (27.1 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

122295



PRINCIPAL DISPLAY PANEL - 4.3 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

4.3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122296

NDC 73362-005-01

GTIN: 00373362005014

Skytrofa
(lonapegsomatropin-tcgd)
for injection

4.3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122296

NDC 73362-005-01

3 73362 00501 4

GTIN: 00373362005014

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____.
Discard after 6 months.

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

4.3 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

ascendis pharma

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

4.3 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark

US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.391 mL containing 4.3 mg of lonapegsomatropin-tcgd, succinic acid (0.46 mg), trehalose dihydrate (32.5 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

1146000

PRINCIPAL DISPLAY PANEL - 5.2 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

5.2 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

123431

NDC 73362-006-01

GTIN: 00373362006011

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

5.2 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

123431

NDC 73362-006-01

3 73362 00601 1

GTIN: 00373362006011

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____ / ____ / ____.
Discard after 6 months.

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

ascendis pharma

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

5.2 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

5.2 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark

US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.473 mL containing 5.2 mg of lonapegsomatropin-tcgd, succinic acid (0.56 mg), trehalose dihydrate (39.3 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

T-16001

PRINCIPAL DISPLAY PANEL - 6.3 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

6.3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122298

NDC 73362-007-01

GTIN: 00373362007018

Skytrofa.
(lonapegsomatropin-tcgd)
for injection

6.3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122298

NDC 73362-007-01

3 73362 00701 8

GTIN: 00373362007018

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____
Discard after 6 months.

Rx Only

OPEN HERE

ascendis pharma

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

6.3 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

6.3 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark
US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.286 mL containing 6.3 mg of lonapegsomatropin-tcgd, succinic acid (0.34 mg), trehalose dihydrate (21.2 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

PRINCIPAL DISPLAY PANEL - 7.6 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

7.6 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122299

NDC 73362-008-01

GTIN: 00373362008015

Skytrofa.
(lonapegsomatropin-tcgd)
for injection

7.6 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122299

NDC 73362-008-01

3 73362 00801 5

GTIN: 00373362008015

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature [up to 86°F (30°C)] for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____
Discard after 6 months.

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

7.6 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

ascendis pharma

1149675

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

7.6 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark

US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.345 mL containing 7.6 mg of lonapegsomatropin-tcgd, succinic acid (0.41 mg), trehalose dihydrate (25.5 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

PRINCIPAL DISPLAY PANEL - 9.1 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

9.1 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122300

NDC 73362-009-01

GTIN: 007373362009012

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

9.1 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122300

NDC 73362-009-01

3 73362 00901 2

GTIN: 00373362009012

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature (up to 86°F (30°C)) for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____.
Discard after 6 months.

ascendis pharma

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

9.1 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

1148002

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

9.1 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark

US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.414 mL containing 9.1 mg of lonapegsomatropin-tcgd, succinic acid (0.49 mg), trehalose dihydrate (30.6 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

PRINCIPAL DISPLAY PANEL - 11 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

11 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122301

NDC 73362-010-01

GTIN: 00373362010018

Skytrofa®
(lonapegsomatropin-tcgd)
for injection

11 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

122301

NDC 73362-010-01

3 73362 01001 8

GTIN: 00373362010018

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature (up to 86°F (30°C)) for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____.
Discard after 6 months.

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

11 mg

FOR SUBCUTANEOUS USE ONLY
SKYTROFA Cartridge and Needle kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

ascendis pharma

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

11 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark

US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.5 mL containing 11 mg of lonapegsomatropin-tcgd, succinic acid (0.59 mg), trehalose dihydrate (37 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

1149303

PRINCIPAL DISPLAY PANEL - 13.3 mg Cartridge Blister Pack Carton

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

13.3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

126350

NDC 73362-011-01

GTIN: 00373362011015

Skytrofa
(lonapegsomatropin-tcgd)
for injection

13.3 mg

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

126350

NDC 73362-011-01

3 73362 01101 5

GTIN: 00373362011015

Do Not use without training.

Refrigerate SKYTROFA cartridges at 36°F to 46°F (2°C to 8°C) in outer carton to protect from light until the expiration date.

Do Not Freeze.

SKYTROFA outer carton containing blistered cartridges may be stored at room temperature (up to 86°F (30°C)) for up to 6 months and can be returned to refrigeration within the 6 months.

After reconstitution, use within 4 hours or discard.

Keep out of the sight and reach of children. This product contains small parts and should only be used under the supervision by a caregiver.

Write the date first removed from the refrigerator:
Date first removed ____/____/____
Discard after 6 months.

Do not use the SKYTROFA cartridges for the first time until you receive training from a healthcare provider.

ascendis pharma

Skytrofa™
(lonapegsomatropin-tcgd)
for injection

13.3 mg

FOR SUBCUTANEOUS USE ONLY

SKYTROFA Cartridge and Needle Kit

The cartridges are designed for use with SKYTROFA Auto-Injector only

Box with:
4 single-dose cartridges and
6 sterile injection needles

OPEN HERE

Rx Only

SKYTROFA
(lonapegsomatropin-tcgd)
for injection

13.3 mg

Content:
4 single-dose cartridges.
6 sterile injection needles
0.25 mm x 4 mm (31G x 5/32").

4 SKYTROFA cartridges

6 needles (2 spare)

ascendis pharma

Distributed by:
Ascendis Pharma, Inc.
Palo Alto, CA 94301
USA

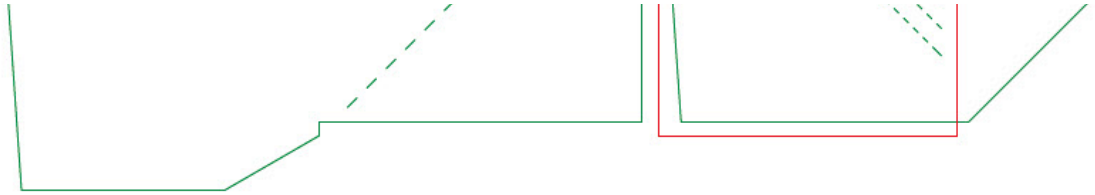
Manufactured by:
Ascendis Pharma Endocrinology Division A/S
Tuborg Boulevard 12, DK-2900 Hellerup
Denmark
US License No. 2165

After reconstitution, each prefilled cartridge delivers: 0.605mL containing 13.3 mg of lonapegsomatropin-tcgd, succinic acid (0.71 mg), trehalose dihydrate (44.8 mg), and tromethamine for pH adjustment to 5.

No Preservative.

Dosage: See Prescribing Information.

T-146504



SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-003
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	3 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-003-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-003-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-004
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	3.6 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-004-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-004-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-005
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	4.3 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-005-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-005-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-006
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	5.2 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-006-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-006-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-007
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	6.3 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-007-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-007-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-008
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	7.6 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-008-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-008-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-009
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	9.1 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-009-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-009-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-010
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	11 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-010-01	4 in 1 CARTON	08/25/2021	

1	NDC:73362-010-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

SKYTROFA

lonapegsomatropin-tcgd injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73362-011
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lonapegsomatropin (UNII: OP35X9610Y) (Somatropin - UNII:NQX9KB6PCL)	Somatropin	13.3 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73362-011-01	4 in 1 CARTON	08/25/2021	
1	NDC:73362-011-02	1 in 1 BLISTER PACK		
1		1 in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA761177	08/25/2021	

Labeler - Ascendis Pharma, Inc. (078828912)

Revised: 9/2021 Ascendis Pharma, Inc.