Overview of Long-acting Growth Hormone (LAGH) Administration Devices

Once-weekly Skytrofa® lonapegsomatropin-tcgd

This is an overview of select features of devices used to administer once-weekly growth hormone therapies for pediatric growth hormone deficiency. This is not intended to be a comparison of safety or efficacy and is not based on any head-to-head data.

The chart on the following pages does not provide a comprehensive list of device attributes or storage information for the products. Please refer to each product's Prescribing Information for full details.

INDICATION

SKYTROFA® is a human growth hormone (GH) indicated for the treatment of pediatric patients aged ≥ 1 years weighing ≥ 11.5 kg with growth failure due to inadequate secretion of endogenous GH.

IMPORTANT SAFETY INFORMATION

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 risk of increased mortality with use of pharmacologic doses of somatropin
- **Hypersensitivity** to somatropin or any of the excipients in SKYTROFA. Systemic hypersensitivity reactions have been reported with post-marketing use of somatropin products
- **Closed epiphyses**
- **Active malignancy**
- Active proliferative/severe non-proliferative **diabetic retinopathy**
- **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

WARNINGS AND PRECAUTIONS

- 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. The safety of continuing SKYTROFA treatment in patients receiving replacement doses for approved indications who concurrently develop these illnesses has not been established

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

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Select features	 **SKYTROFA®** (lonapegsomatropin-tcgd)[1,2]	 **SOGROYA®** (somapacitan-beco)[3,4]	 **NGENLA®** (somatrogon)[5]
Device for dose delivery	**Auto-Injector for use with single-dose cartridges**	**Prefilled pens**	**Prefilled pens**
Disposable device	**No** Auto-Injector is reusable with rechargeable battery that can be used for approximately 4 years	**Yes** Discard once the prefilled drug runs out	**Yes** Discard once the prefilled drug runs out
Medication reconstitution	**Yes** (automated)	**No** (prefilled)	**No** (prefilled)
Color coding	**Dose cartridges**	**Pen strengths**	**Pen strengths**
Dose dialing	**No** Single-dose cartridges	**Yes** Manual dial	**Yes** Manual dial
Dosage adjustment	**20% increments using the same Auto-Injector** (9 dose cartridge strengths)	**0.025- to 0.1-mg increments across 3 pens** (160 increments)	**0.2- to 0.5-mg increments across 2 pens** (108 increments)
Weight limit for single injection	**60.4 kg** Second cartridge/injection needed to complete the dose in patients weighing > 60.4 kg	**50 kg** Second injection needed to complete the dose in patients weighing > 50 kg	**45.5 kg** Second injection needed to complete the dose in patients weighing > 45.5 kg
Leftover medication	**No** Delivers entire content of the cartridge	**Yes** If leftover amount of medication is insufficient for the dose, either discard and start a new pen or split the dose between current and new pen	**Yes** If leftover amount of medication is insufficient for the dose, either discard and start a new pen or split the dose between current and new pen
Integrated needle guard	**Yes**	**No**	**No**
Needles included in the carton	**Yes**	**No**	**No**
Needle size	**31G, 4 mm**	**Up to 8 mm**	**31G to 32G, up to 8 mm**
Contains preservative	**No**	**Yes** (phenol)	**Yes** (metacresol)
Room temperature storage	**6 months**	**72 hours**	**No**

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Serious systemic hypersensitivity reactions including anaphylaxis 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. Do not use SKYTROFA in patients with known hypersensitivity to SKYTROFA or any of its excipients
- Patients with active malignancy have an increased risk of progression with somatropin treatment. Any preexisting malignancy should be inactive and treatment complete before instituting therapy with SKYTROFA. In childhood cancer survivors treated with radiation to the brain/head for their first neoplasm who developed subsequent GHD treated with somatropin, an increased risk for a second neoplasm has been reported. Monitor patients with a history of GHD secondary to an intracranial neoplasm routinely for progression/recurrence of the tumor. Monitor patients carefully for development of neoplasms and/or increased growth/potential malignant changes of preexisting nevi

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Treatment with somatropin may decrease insulin sensitivity, and new onset type 2 diabetes mellitus has been reported. Previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked. Patients with type 1 and 2 diabetes mellitus or impaired glucose tolerance should be monitored closely, and antihyperglycemic drugs may require adjustment
- 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 resolved rapidly after cessation of therapy/reduction of the dose. Perform fundoscopic examination routinely before initiating treatment with SKYTROFA to exclude preexisting papilledema, and periodically thereafter. If papilledema is observed, stop the treatment. If somatropin-induced IH is diagnosed, restart treatment at a lower dose after IH-associated signs and symptoms have resolved

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

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Fluid retention during somatropin therapy may occur. Clinical manifestations of fluid retention (eg, edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paresthesia) are usually transient and dose dependent
- Patients receiving somatropin therapy may be at risk for reduced serum cortisol levels and/or unmasking of central hypoadrenalism. Patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance/stress doses following initiation of SKYTROFA therapy. Monitor patients with known hypoadrenalism for reduced serum cortisol levels and/or need for glucocorticoid dose increases
- Undiagnosed or untreated hypothyroidism may prevent response to SKYTROFA. Central hypothyroidism may first become evident or worsen with treatment. Perform periodic thyroid function tests and initiate/properly adjust thyroid hormone replacement therapy when indicated
- 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
- Monitor patients for progression of preexisting scoliosis
- Cases of pancreatitis have been reported in pediatric patients receiving somatropin. Consider pancreatitis in patients with persistent severe abdominal pain
- Lipoatrophy may result when somatropin is administered at the same site over a long period of time. Rotate injection sites to reduce this risk
- 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
- Serum levels of inorganic phosphorus, alkaline phosphatase, and parathyroid hormone may increase after somatropin treatment. Monitor abnormal laboratory tests as appropriate

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ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) in patients treated with SKYTROFA were: viral infection (15%), pyrexia (15%), cough (11%), nausea and vomiting (11%), hemorrhage (7%), diarrhea (6%), abdominal pain (6%), and arthralgia and arthritis (6%).

DRUG INTERACTIONS

- **Glucocorticoids:** SKYTROFA may reduce serum cortisol concentrations, which may require an increase in the dose of glucocorticoids
- **Cytochrome P450-metabolized drugs:** Somatropin may increase cytochrome P450 (CYP450)-mediated antipyrine clearance. Carefully monitor patients using drugs metabolized by CYP450 liver enzymes in combination with SKYTROFA
- **Oral estrogen:** May reduce the response to SKYTROFA. Higher doses of SKYTROFA may be required
- **Insulin and/or other hypoglycemic agents:** SKYTROFA may decrease insulin sensitivity. Patients with diabetes mellitus may require adjustment of insulin or hypoglycemic agents

You are encouraged to report side effects to FDA at (800) FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Ascendis Pharma at 1-844-442-7236.

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

References: 1. SKYTROFA. Prescribing information. Ascendis Pharma, Inc.; 2022. **2.** SKYTROFA. Instructions for use. Ascendis Pharma, Inc.; 2021. **3.** SOGROYA. Prescribing information. Novo Nordisk Inc.; 2023. **4.** Novo Nordisk Inc. Get to know the Sogroya® pen. Accessed February 9, 2024. https://www.sogroya.com/how-to-use/sogroya-pen.html **5.** NGENLA. Prescribing information. Pfizer Inc.; 2023.

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