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2. Tev-Tropin

Tev-Tropin (Subcutaneous, Injection)

Generic name: somatropin, e-coli derived [soe-ma-TROE-pin, E-KOH-lye-dee-rived]

Brand names: Accretropin, Genotropin, Genotropin Miniquick, Humatrope, Norditropin, ... show all 12 brands

Drug class: Growth hormones

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Uses Before taking Dosage Warnings Side effects Brand names



The Tev-Tropin brand name has been **discontinued** in the U.S. If generic versions of this product have been approved by the FDA, there may be generic equivalents available.

Uses for Tev-Tropin

Somatropin is a man-made version of the human growth hormone. Growth hormone is naturally produced by the pituitary gland and is necessary to stimulate growth in children. Man-made growth hormone may be used in adults or children who have certain conditions that prevent normal growth. These conditions include growth hormone deficiency (inability to produce enough growth hormone), chronic kidney disease, idiopathic short stature (unexplained shortness), Noonan syndrome, Turner syndrome, Prader-Willi syndrome (PWS), short stature homeobox-containing gene (SHOX) deficiency, and short stature born small for gestational age (SGA) with no catch-up growth by age 2 to 4 years of age.

This medicine is available only with your doctor's prescription.

Before using Tev-Tropin

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric

Appropriate studies performed to date have not demonstrated pediatric-specific problems that would limit the usefulness of somatropin in children.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of somatropin in the elderly. However, elderly patients are more sensitive to the effects of somatropin and are more likely to have unwanted effects, which may require an adjustment in the dose for patients receiving somatropin.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your healthcare professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine.

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- · Allergy to benzyl alcohol or
- · Allergy to metacresol or
- · Brain tumor or
- · Cancer, active or
- · Closed epiphyses (normal bone growth stopped) in children or
- Diabetic retinopathy (eye condition) or
- Prader-Willi syndrome (a genetic disorder), if severely overweight or have severe breathing problems or
- Severe illness after surgery or major medical emergency (eg, open heart surgery, abdominal surgery, accidental trauma, or respiratory failure)—Should not be used in patients with these conditions.
- · Cancer, history of or
- · Hypopituitarism (pituitary gland produces low hormone levels) or
- Hypothyroidism (underactive thyroid gland) or
- Otitis media (ear infection) in children, history of or
- Scoliosis (abnormally curved spine)—Use with caution. May make these conditions worse.
- Diabetes, or a family history of—Use with caution. May prevent insulin or other drugs for diabetes from working

properly.

• Turner syndrome—Use with caution. May increase risk of having serious problems (eg, pancreas, thyroid, or heart and blood vessel problems, ear or hearing disorders, diabetes, increased pressure in the head, and bone problems such as dislocation in the hip bone or scoliosis).

Proper use of Tev-Tropin

This medicine is given as a shot under your skin. Somatropin may sometimes be given at home to patients who do not need to be in the hospital. If you are using this medicine at home, your doctor will teach you how to prepare and inject the medicine. Be sure that you understand exactly how the medicine is prepared and injected.

This medicine comes with a patient information insert. Read and follow the instructions carefully. Ask your doctor if you have any questions.

There are many different forms (eg, vial, cartridge, injection device) available for this medicine. Read all instructions carefully to be sure you know how to use your device.

Each time you get your medicine, check to be sure you have received the proper device. Talk to your pharmacist if you have questions about the device that you were given.

You will be shown the body areas where this shot can be given. *Use a different body area each time you give yourself a shot*. Keep track of where you give each shot to make sure you rotate body areas. This will help prevent skin problems from the injections.

Use a new needle, unopened vial, prefilled pen, or syringe each time you inject your medicine.

Check the liquid in the *Norditropin® prefilled pen*. It should be clear and colorless. Do not use the medicine if the liquid is cloudy, discolored, or has particles in it.

You might not use all of the medicine in each vial (glass container) or prefilled syringe. Use each vial or syringe only one time. Do not save an open vial or syringe. If the medicine in the vial or syringe has changed color, or if you see particles in it, do not use it.

Use only the brand of this medicine that your doctor prescribed. Different brands may not work the same way.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- · For injection dosage form:
 - For all indications:
 - Adults—Dose is usually based on body weight (depending on the brand of somatropin you are using) and must be determined by your doctor. Norditropin® may also be given without concern to weight. At first, you

may give Norditropin® 0.2 milligram (mg) per day. Your doctor will adjust your dose as needed.

 Children—Dose is based on body weight and must be determined by your doctor. Your doctor will adjust your child's dose as needed.

Missed Dose

This medicine needs to be given on a fixed schedule. If you miss a dose or forget to use your medicine, call your doctor or pharmacist for instructions.

Storage

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Ask your healthcare professional how you should dispose of any medicine you do not use.

Store this medicine in the refrigerator, away from direct light. Do not freeze or shake.

Store the *unopened Norditropin*® *FlexPro pen* in the refrigerator, away from direct light. Do not freeze. You may also keep the *opened Norditropin*® *FlexPro pen* in the refrigerator for up to 4 weeks or at room temperature for up to 3 weeks.

Throw away used needles in a hard, closed container where the needles cannot poke through. Keep this container away from children and pets.

Detailed Tev-Tropin dosage information

Precautions while using Tev-Tropin

If you will be taking this medicine for a long time, it is very important that your doctor check you and your child's progress at regular visits. Blood and urine tests may be needed to check for any problems or unwanted effects that may be caused by this medicine.

This medicine may cause serious allergic reactions, including anaphylaxis and angioedema, which are life-threatening and require immediate medical attention. Tell your doctor right away if you or your child have a rash, itching, swelling of the face, tongue, or throat, trouble breathing, or chest pain after receiving the medicine.

This medicine may cause a dislocation in the hip bone, especially in patients with growth hormone deficiency or Turner syndrome. Check with your doctor right away if you or your child has a limp or pain in the hip or knee.

This medicine may affect blood sugar levels. Check with your doctor if you notice a change in the results of your or your child's blood or urine sugar tests or if you have any questions.

This medicine may cause an increased pressure in the head. Check with your doctor immediately if headache, nausea, vomiting, blurred vision, or any other change in vision occurs during treatment. Your doctor may want you to have your or your child's eyes checked by an ophthalmologist (eye doctor).

This medicine may cause fluid retention (extra water in the body). Tell your doctor if you or your child have burning, numbness, pain, or tingling in all fingers except the smallest finger, swelling of the hands and feet, or pain, swelling, or stiffness of the muscles. Your doctor may adjust your dose to reduce these side effects.

Pancreatitis (inflammation of the pancreas) has occurred rarely in some patients receiving somatropin. Tell your doctor right away if you or your child have sudden and severe stomach pain, chills, constipation, nausea, vomiting, fever, or lightheadedness.

Check with your doctor right away if you have darkening of skin, diarrhea, dizziness, fainting, loss of appetite, mental depression, nausea, skin rash, unusual tiredness or weakness, or vomiting. These may be symptoms of an adrenal gland problem (hypoadrenalism).

Using this medicine may increase your or your child's risk of getting cancer. Talk to your doctor if you have concerns about this risk.

Before you have any medical tests, tell the medical doctor in charge that you are using this certain brand of somatropin (*Humatrope*®, *Norditropin*®, or *Zomacton*®). The results of some tests may be affected by this medicine.

Do not take other medicines unless they have been discussed with your doctor. This includes prescription or nonprescription (over-the-counter [OTC]) medicines and herbal or vitamin supplements.

Side Effects of Tev-Tropin

Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

More common

- · Bleeding gums
- bloating or swelling of the face, arms, hands, ankles, lower legs, or feet
- · burning, numbness, pain, or tingling in all fingers except the smallest finger
- · coughing up blood
- · difficulty with breathing or swallowing
- difficulty with moving
- dizziness
- increased menstrual flow or vaginal bleeding
- muscle pain or stiffness
- nosebleeds
- not able to move
- pain, swelling, or redness in the joints
- prolonged bleeding from cuts
- · rapid weight gain
- · red or black, tarry stools
- · red or dark brown urine
- · tingling of the hands or feet

• unusual weight gain or loss

Rare

- Bleeding, blistering, burning, coldness, discoloration of the skin, feeling of pressure, hives, infection, inflammation, itching, lumps, numbness, pain, rash, redness, scarring, soreness, stinging, swelling, tenderness, tingling, ulceration, or warmth at the injection site
- blurred vision
- bone pain
- · change in personality
- change in the ability to see colors, especially blue or yellow
- · changes in vision
- chills
- confusion
- constipation
- · curved spine
- · darkened urine
- dry mouth
- fast heartbeat
- fever
- · flushed, dry skin
- fracture
- · fruit-like breath odor
- headache
- · increased hunger
- · increased thirst
- · increased urination
- indigestion
- limp pain in the hip or knee
- · loss of appetite
- loss of consciousness
- nausea
- · pains in the stomach, side, or abdomen, possibly radiating to the back
- problems with walking or talking
- seizures

- stomachache
- sweating
- tumor
- · unusual tiredness or weakness
- vomiting
- · yellow eyes or skin

Incidence not known

- Cough
- · hives, itching, skin rash
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or genitals
- puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- · skin lesions
- · tightness in the chest
- · unexplained weight loss

Get emergency help immediately if any of the following symptoms of overdose occur:

Symptoms of overdose

- Backache
- · excessive sweating
- · extreme weakness
- · increase in hand and foot size
- · increased volume of pale, diluted urine
- · pain in the arms or legs
- stop in menstruation

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- · Large, flat, blue, or purplish patches in the skin
- unusually warm skin

Rare

· Swelling of the breasts or breast soreness in both females and males

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

1 Tev-Tropin side effects (more detail)

Related/similar drugs

Egrifta

Egrifta (tesamorelin) is used to reduce excess fat around the stomach that is caused by taking ...

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6.5 / 10

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Humatrope injection (somatropin) is a human growth hormone used to treat growth failure in children ...

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Ngenla is a long-acting human growth hormone used to treat children aged 3 and older who are not ...

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Norditropin

Norditropin is used to treat growth hormone deficiency (GHD) in adults and children and other ...

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Commonly used brand name(s)

In the U.S.

- Accretropin
- Genotropin
- Genotropin Miniquick
- Humatrope
- Norditropin
- Norditropin Flexpro
- Nutropin
- Nutropin AQ NuSpin 10
- Nutropin AQ NuSpin 5
- Nutropin AQ Pen
- Omnitrope
- Tev-Tropin

In Canada

• Nutropin Aq

Saizen

Available Dosage Forms:

- Solution
- Powder for Solution

Therapeutic Class: Endocrine-Metabolic Agent

Zomacton (somatropin) - Ferring Pharmaceuticals Inc.

Pharmacologic Class: Somatropin

Tev-tropin Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There are 11 for Tev-Tropin.

Accretropin (somatropin) - Emergent Biosolutions Canada Inc.		
Formulation type	Strength	
Multi-Dose Vial	5 mg/mL Discontinued , Voluntarily Revoked	
View Accretropin information in d	etail.	
Genotropin (somatropin) - Pharmacia & Upjohn Company LLC		
Humatrope (somatropin) - Eli Lilly and Company		~
Norditropin (somatropin) - Novo Nordisk Inc.		~
Nutropin (somatropin) - Genentech, Inc.		
Nutropin AQ (somatropin) - Genentech, Inc.		
Omnitrope (somatropin) - Sandoz Inc.		
Saizen (somatropin) - EMD Seroi	no, Inc.	~
Serostim (somatropin) - EMD Serono, Inc.		
Zanastan (annatan'a) - Fanisa Bhannan diadaha		

More about Tev-Tropin (somatropin)

- · Check interactions
- · Compare alternatives
- Reviews (3)
- · Side effects
- Dosage information
- During pregnancy
- Drug class: growth hormones
- Breastfeeding

Patient resources

Other brands

Genotropin, Norditropin, Omnitrope, Humatrope, ... +8 more

Professional resources

· Somatropin monograph

Other brands

Genotropin, Norditropin, Omnitrope, Humatrope, ... +6 more

Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Medical Disclaimer

DRUG STATUS

Availability

O Discontinued

Pregnancy & Lactation

ം Risk data available

CSA Schedule*

N/A Not a controlled drug



3 Reviews

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