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2. Tinzaparin

Tinzaparin (Subcutaneous)

Generic name: tinzaparin [tin-za-PAR-in]

Brand name: Innohep Drug class: Heparins

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Uses Before taking Dosage Warnings Side effects Brand names

Subcutaneous route(Solution)

Epidural or spinal hematomas, which may result in long-term or permanent paralysis, may occur in patients who are anticoagulated with low molecular weight heparins or heparinoids and are receiving neuraxial anesthesia or undergoing spinal puncture. Factors that can increase the risk of developing these hematomas include: use of indwelling epidural catheters, concomitant use of drugs affecting hemostasis such as NSAIDs, platelet inhibitors, or other anticoagulants, or history of traumatic or repeated epidural or spinal puncture, spinal deformity, or spinal surgery. Monitor patients frequently for neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider risks/benefits before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

Uses for tinzaparin

Tinzaparin is used for the treatment of deep venous thrombosis, a condition in which harmful blood clots form in the blood vessels of the legs. These blood clots can travel to the lungs and can become lodged in the blood vessels of the lungs, causing a condition called pulmonary embolism. Tinzaparin is used for several days after surgery, while you are unable to walk. It is during this time that blood clots are most likely to form. Tinzaparin also may be used for other conditions as determined by your doctor.

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

Before using tinzaparin

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 have not been performed on the relationship of age to the effects of tinzaparin in the pediatric population. Safety and efficacy have not been established.

Geriatric

Appropriate studies performed to date have not demonstrated geriatric-specific problems that would limit the usefulness of tinzaparin in the elderly. However, elderly patients are more likely to have age-related kidney problems, which may require an adjustment in the dose for patients receiving tinzaparin.

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. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.

Defibrotide

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

- Abciximab
- Aceclofenac
- Acemetacin
- Acenocoumarol
- Alipogene Tiparvovec
- Alteplase, Recombinant
- Amtolmetin Guacil
- Anagrelide
- Anistreplase
- · Antithrombin, Recombinant
- Apixaban
- Argatroban

• Aspirin
Bemiparin
Betrixaban
Bivalirudin
Bromfenac
Bufexamac
Caplacizumab-yhdp
Celecoxib
Choline Salicylate
Citalopram
Clonixin
Clopidogrel
Collagenase, Clostridium histolyticum
Curcumin
Dabigatran Etexilate
Dalteparin
Danaparoid
Desvenlafaxine
Dexibuprofen
Dexketoprofen
• Dextran
Diclofenac
Diflunisal
Dipyridamole
• Dipyrone
Drotrecogin Alfa
Droxicam
Edoxaban
Enoxaparin
Eptifibatide
Escitalopram
Etodolac
Etofenamate

• Etoricoxib

- FelbinacFenoprofenFepradinol
- Feprazone
- roprazono
- Floctafenine
- Flufenamic Acid
- Fluoxetine
- Flurbiprofen
- Fluvoxamine
- Ibrutinib
- Ibuprofen
- Ibuprofen Lysine
- Iloprost
- Indomethacin
- Inotersen
- Ketoprofen
- Ketorolac
- Lepirudin
- Levomilnacipran
- Lornoxicam
- Loxoprofen
- Lumiracoxib
- Meclofenamate
- Mefenamic Acid
- Meloxicam
- Milnacipran
- Morniflumate
- Nabumetone
- Nadroparin
- Naproxen
- Nepafenac
- Niflumic Acid
- Nimesulide

- Nimesulide Beta Cyclodextrin
 Nintedanib
 Omadacycline
 Orlistat
 Oxaprozin
 Oxyphenbutazone
 - Parecoxib
 - Paroxetine
 - Pentosan Polysulfate Sodium
 - Phenindione
 - Phenprocoumon
 - Phenylbutazone
 - Piketoprofen
 - Piracetam
 - Piroxicam
 - Prasugrel
 - Proglumetacin
 - Propionic Acid
 - Propyphenazone
 - Proquazone
 - Reteplase, Recombinant
 - Rivaroxaban
 - Rofecoxib
 - Salicylic Acid
 - Salsalate
 - Sarecycline
 - Sertraline
 - Sodium Salicylate
 - Streptokinase
 - Sulfinpyrazone
 - Sulindac
 - Tenecteplase
 - Tenoxicam
 - Tiaprofenic Acid

- Ticlopidine
- Tirofiban
- Tolfenamic Acid
- Tolmetin
- Trazodone
- Treprostinil
- Turmeric
- Urokinase
- Valdecoxib
- Venlafaxine
- Vilazodone
- Vorapaxar
- Vortioxetine
- Warfarin

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. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

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:

- · Major bleeding, active or
- Thrombocytopenia, heparin-induced (or history of)—Should not be used in patients with these conditions.
- Blood disease or bleeding problems or
- · Catheter insertion in your spine or
- Eye problems caused by diabetes or high blood pressure or
- · Heart infection or
- · Hypertension (high blood pressure), severe and uncontrolled or
- · Liver disease or
- · Stomach or intestinal ulcer, active or history of or
- Stroke, recent or
- Surgery (e.g., surgery of the eye, brain, or spine), recent or history of or
- Thrombocytopenia—Use with caution. The risk of bleeding may be increased.

- Kidney disease—Effects of tinzaparin may be increased because of slower removal of the medicine from the body.
- Prosthetic heart valve—Tinzaparin may not protect these patients from developing a blood clot.

Proper use of tinzaparin

A nurse or other trained health professional will give you this medicine. This medicine is given as a shot under your skin, usually in the abdomen.

If you are using tinzaparin at home, your doctor will teach you how to inject yourself with the medicine. Be sure to follow the directions carefully. Check with your doctor if you have any problems using the medicine.

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.

If the medicine in the vial (glass container) has changed color, or if you see particles in it, do not use it.

Put used syringes in a puncture-resistant, disposable container, or dispose of them as directed by your doctor.

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 prevention of deep venous thrombosis (leg clots) due to surgery:
 - Adults
 - General surgery—3500 International Units (IU) given 2 hours before surgery then 3500 IU once a day for 7 to 10 days.
 - Hip surgery—50 International Units (IU) per kilogram (kg) of body weight given 2 hours before surgery then 50 IU per kg of body weight once a day for 7 to 10 days, or 75 IU per kg of body weight given after surgery once a day for 7 to 10 days.
 - Knee surgery—75 International Units (IU) per kilogram (kg) of body weight given after surgery once a day for 7 to 10 days.
 - Children—Use and dose must be determined by your doctor.
 - For treatment of deep venous thrombosis (leg clots) with or without pulmonary embolism (lung clots):
 - Adults—Dose is based on body weight and must be determined by your doctor. The dose is usually 175
 International Units (IU) per kilogram (kg) of body weight injected under the skin once a day for 6 to 7 days.
 - Children—Use and dose must be determined by your doctor.

Missed Dose

Call your doctor or pharmacist for instructions.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

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.

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

1 Detailed Tinzaparin dosage information

Precautions while using tinzaparin

It is very important that your doctor check your progress at regular visits to make sure this medicine is working properly. Blood tests will be needed to check for unwanted effects. Be sure to keep all appointments.

This medicine may cause a serious type of allergic reaction called anaphylaxis. Anaphylaxis can be life-threatening and requires immediate medical attention. Tell your doctor right away if you have a rash; itching; swelling of the face, tongue, and throat; trouble breathing; or chest pain after you receive this medicine.

Make sure your doctor knows if you have had an allergic reaction to heparin, sulfites, benzyl alcohol, or pork products.

Tinzaparin may increase your chance of bleeding or bruising. This risk is higher if you have a catheter in your back for pain medicine or anesthesia (sometimes called an "epidural"), or if you have kidney problems. The risk of bleeding increases as the severity of your kidney problems increases. Check with your doctor right away if you notice any unusual bleeding or bruising; black, tarry stools; bleeding gums; blood in the urine or stools; or pinpoint red spots on your skin.

You may bleed and bruise more easily while you are using this medicine. Stay away from rough sports or other situations where you could be bruised, cut, or injured. Be careful when using sharp objects, including razors and fingernail clippers. Avoid nose picking and forceful nose blowing.

Be careful when using a regular toothbrush, dental floss, or toothpick. Your medical doctor, dentist, or nurse may recommend other ways to clean your teeth and gums. Check with your medical doctor before having any dental work done.

Make sure any doctor or dentist who treats you knows that you are using this medicine. You may need to stop using tinzaparin several days before having surgery or medical tests.

This medicine contains benzyl alcohol which may cause serious reactions to newborn or premature infants. Discuss this with your doctor if you are concerned.

Do not take or discontinue 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 tinzaparin

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

· Deep, dark purple bruise, pain, or swelling at the place of injection

Less common

- Bladder pain
- · bleeding gums
- blood in the urine
- bloody or cloudy urine
- · blurred vision
- chest pain
- · chest tightness
- chills
- confusion
- cough
- · coughing up blood
- difficulty with breathing or swallowing
- dizziness, faintness, or lightheadedness when getting up suddenly from a lying or sitting position
- fast, slow, or irregular heartbeat
- fever
- · frequent urge to urinate
- headache
- increased menstrual flow or vaginal bleeding
- · lower back or side pain
- nosebleeds
- · pain or burning while urinating
- painful or difficult urination
- · pale skin
- palpitations

- paralysis
- · pounding in the ears
- · prolonged bleeding from cuts
- red or black, tarry stools
- · red or dark brown urine
- · severe or continuing dull nervousness
- shortness of breath
- skin rash
- sore throat
- sores, ulcers, or white spots on the lips or in the mouth
- sweating
- swollen glands
- · troubled breathing, exertional
- unexplained pain, swelling, or discomfort, especially in the chest, abdomen or stomach, joints, or muscles
- unusual bleeding or bruising
- · unusual tiredness or weakness
- · vomiting of blood or material like coffee grounds

Rare

- Blue-green to black skin discoloration
- bowel or bladder dysfunction
- hives
- itching
- leg weakness
- numbness
- · pain, redness, or sloughing of the skin at the place of injection
- · puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue
- wheezing

Incidence not known

- Abdominal or stomach pain
- · accumulation of pus
- break in the skin, especially associated with blue-black discoloration, swelling, or drainage of fluid
- change in vision
- clay-colored stools

- · collection of blood under the skin
- diarrhea
- · excessive thirst
- · general feeling of discomfort or illness
- hoarseness
- large, flat, blue or purplish patches in the skin
- large, hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs
- loss of appetite
- · muscle cramps
- · numbness and tingling of the face, fingers, or toes
- pain in the arms, legs, or lower back, especially pain in the calves or heels upon exertion
- · pain, redness, or swelling
- painful knees and ankles
- pale, bluish-colored, or cold hands or feet
- problems with vision or hearing
- raised, red swellings on the skin, buttocks, legs or ankles
- · red or irritated eyes
- redness, tenderness, burning, blistering, or peeling of the skin (usually on the backs of arms and the fronts of legs, mouth, eyes, hands, or feet)
- · seeing floating spots before the eyes
- swollen, red, or tender area of infection
- · unpleasant breath odor
- · weak or absent pulses in the legs
- · yellow eyes or skin

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:

Less common or rare

- Constipation
- · nausea and vomiting
- prolonged, painful, or inappropriate erection of the penis
- trouble with sleeping

Incidence not known

- · Hives or welts
- · redness of the skin

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.

i <u>Tinzaparin side effects</u> (more detail)

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In the U.S.

Innohep

Pharmacologic Class: Low Molecular Weight Heparin

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Patient resources

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Innohep

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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

Approval History

Drug history at FDA

User Reviews & Ratings

3 Reviews

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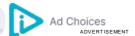


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