

Brightside Specialty Pharmacy

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Patient Education for FONDAPARINUX 10 MG/0.8 ML SYR



If available, dispense patient package insert and explain to pt Physician must know patient's complete medical history Lab tests may be ordered to monitor therapy Follow instructions on aseptic technique preparing/administering Report excessive bleeding to your doctor immediately Complications may occur if current therapy is not disclosed. Low dose aspirin prophylaxis ok. Avoid other aspirin & NSAIDs. For subcutaneous or intravenous administration. Not for IM dosing.

If available, read the patient package insert Tell doctor your complete medical history Lab tests may be ordered to monitor therapy Prepare carefully as you have been shown Call MD NOW if persistent or severe bleeding occurs Tell doctor/surgeon on drug prior to any surgery Low dose daily aspirin ok Ask MD about other NSAIDs Inject under skin or into vein, but not into muscle

Education Section

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

FONDAPARINUX - INJECTION

(FON-da-PAR-in-ux)

COMMON BRAND NAME(S):

Arixtra

WARNING:

People using this medication may bleed near the spinal

cord after certain spinal procedures. Bleeding in this area can cause paralysis that lasts a long time or could become permanent. Talk with your doctor about the benefits and risks before any spinal procedure. Your doctor may direct you to stop this medication for a certain amount of time before and after the procedure. Carefully follow your doctor's directions.

The risk of bleeding may be higher if you have a deformed spine, or have had spinal procedures/surgery before (such as epidural catheter placement, difficult epidural/spinal puncture), or are taking other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, "blood thinners" such as warfarin/rivaroxaban, nonsteroidal anti-inflammatory drugs-NSAIDs such as ibuprofen). Tell your doctor right away if you notice symptoms such as back pain, leg numbness/tingling/weakness, loss of control of the bowels or bladder (incontinence).

USES:

Fondaparinux is used to treat serious blood clots in the

legs and/or lungs. It is usually used with another "blood thinner" medication (warfarin). If untreated, blood clots can travel to the lungs, heart, or brain, causing serious (possibly

fatal) breathing problems, heart attack, or stroke. This drug may also be used to prevent blood clots after certain surgeries with an increased risk of blood clots (such as hip fracture, abdominal, knee/hip replacement).

Fondaparinux is known as a "blood thinner" (anticoagulant). It is a drug similar to heparin that works by blocking certain natural substances in the blood that cause clotting.

OTHER USES:

This section contains uses of this drug that are not

listed in the approved professional labeling for the drug but that may be prescribed by your health care professional. Use this drug for a condition that is listed in this section only if it has been so prescribed by your health care professional.

This drug may also be used for certain types of heart attack or a specific type of chest pain called unstable angina.

HOW TO USE:

Read the Patient Information Leaflet if available

from your pharmacist before you start using fondaparinux and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

This medication is given by injection under the skin of the stomach/abdomen as directed by your doctor, usually once daily. Do not inject into a muscle. The dosage and length of treatment are based on your medical condition and response to treatment. The dosage may also be based on your weight. Use this medication regularly to get the most benefit from it. To help you remember, use it at the same time each day.

If you are using this medication at home, learn all preparation and usage instructions from your health care professional and the product package. Before using, check this product visually for particles or discoloration. If either is present, do not use the liquid. Do not mix any other medication in the same injection. Before injecting each dose, clean the injection site with rubbing alcohol. Change the injection site each time to lessen injury under the skin. To minimize bruising, do not rub the injection site after a shot. Learn how to store and discard medical supplies safely.

When treating a blood clot, another "blood thinner" (warfarin)

is usually started within 3 days after you start using fondaparinux. Your doctor will direct you to use both of these medications until the warfarin is working well. Do not stop either of these medications until your doctor directs you to stop.

To prevent blood clots due to surgery, your doctor may direct you to start using this medication after surgery (such as 6 to 8 hours after knee/hip replacement surgery) and continue for several days. Follow your doctor's directions closely. Starting this medication too soon after surgery may increase the risk of serious bleeding.

This medication may also be given by injection into a vein by a health care professional, as directed by your doctor.

SIDE EFFECTS:

Pain, bruising, redness, and swelling at the

injection site may occur. Headache, nausea, vomiting, swelling of the hands/feet, or fever may also occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: easy bleeding/bruising, dark urine, yellow eyes/skin.

This medication may rarely cause serious bleeding. (See also Warning section.) Tell your doctor right away if you have any signs of serious bleeding, including: shortness of breath, coughing up blood, chest pain, cold/blue fingers or toes, unusual dizziness, fainting, fast/irregular heartbeat, joint/muscle pain, mental/mood changes (such as confusion), numbness/tingling, severe stomach/abdominal pain, bloody/black/tarry stools, red/pinkish urine, vomit that looks like coffee grounds.

Get medical help right away if you have any very serious side effects, including: headache that is severe or doesn't go away, vision problems, weakness on one side of the body, trouble speaking, seizures, difficulty moving.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before using fondaparinux, tell your doctor or pharmacist if

you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients (such as dry natural rubber/latex in the needle cover on the prefilled syringe), which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using fondaparinux, tell your doctor or pharmacist your medical history, especially of: infection in the heart (bacterial endocarditis), current serious bleeding (such as bleeding ulcer), low platelet count because of antiplatelet antibody, bleeding/blood problems (such as low blood count/platelets), a past blood-clotting problem because of heparin (heparin-induced thrombocytopenia), a certain eye problem (diabetic retinopathy), high blood pressure, kidney disease, seizures, stomach/intestinal problems (such as recent ulcers, colitis), stroke, recent spinal procedures or puncture, spine problems (such as spinal deformity), recent surgery (especially on the eye, brain, or spine), low body weight (less than 50 kilograms/110 pounds).

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Limit alcohol while taking this drug because it may increase the risk of stomach bleeding.

To lower the chance of getting cut, bruised, or injured, use caution with sharp objects like razors and nail cutters, and avoid activities such as contact sports.

Older adults may be more sensitive to the side effects of this drug, especially bleeding.

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. If you become pregnant or think you may be pregnant, tell your doctor right away.

It is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also Warning section.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: mifepristone, other drugs that can cause bleeding/bruising (including antiplatelet drugs such as clopidogrel, NSAIDs such as ketorolac, "blood thinners" such as rivaroxaban).

Check all prescription and nonprescription medicine labels carefully since many medications contain pain relievers/fever reducers (NSAIDs such as ibuprofen, naproxen, aspirin) which can increase the risk of bleeding when used with fondaparinux. However, if your doctor has directed you to take low-dose aspirin for heart attack or stroke prevention (usually 81-162 milligrams a day), you should continue taking it unless your doctor instructs you otherwise. Ask your doctor or pharmacist for more details.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: excessive bleeding and bruising.

NOTES:

Do not share this medication with others.

Laboratory and/or medical tests (such as complete blood count, kidney function tests, tests to check for blood in the stool) should be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

MISSED DOSE:

If you miss a dose, use it as soon as you remember.

If it is near the time of the next dose, skip the missed dose. Use your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Each prefilled syringe can be used only once; discard any unused portion.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

MEDICAL ALERT:

Your condition can cause complications in a

medical emergency. For information about enrolling in MedicAlert, call 1-888-633-4298 (US) or 1-800-668-1507 (Canada).

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