

PATIENT MEDICATION INFORMATION
(100 mg/mL pre-filled syringes)

**READ THIS FOR SAFE AND EFFECTIVE USE OF
YOUR MEDICINE**

REDESCA®
Enoxaparin sodium injection
Pre-filled syringe

Read this carefully before you start taking **REDESCA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **REDESCA**.

REDESCA is a biosimilar biologic drug (biosimilar) to the reference biologic drug Lovenox®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is REDESCA used for?

- to prevent the formation of deep vein thrombosis (blood clots), which can occur as a complication of orthopedic surgery such as hip or knee surgery or of intra-abdominal (inside the body cavity below diaphragm which contains stomach, intestines, liver, and other organs) surgeries;
- to prevent the formation of deep vein thrombosis in medical patients who are at risk of thromboembolic (blockage of blood vessel by a blood clot) complications due to severely restricted mobility during acute illnesses (cardiac insufficiency [reduced ability of heart to pump blood], respiratory failure or severe chest infections);
- to treat deep vein thrombosis with or without pulmonary embolism (blockage of blood vessel in the lungs);
- to treat unstable angina and non-Q-wave myocardial infarction (death of a part of the heart muscle that does not involve full thickness of the heart wall), concurrently with acetylsalicylic acid (ASA);
- to treat acute ST-segment Elevation Myocardial Infarction (STEMI), a particular form of heart attack. This indication includes patients to be managed medically or those with subsequent Percutaneous Coronary Intervention (PCI), a procedure that opens up a coronary artery (blood vessel that brings blood and oxygen to the heart muscle) and restores blood flow;
- to prevent clotting in the extra-corporeal circulation during hemodialysis.

How does REDESCA work?

REDESCA is an anti-thrombotic drug. This means that **REDESCA** helps to prevent blood clots from forming in patients who have either undergone surgery or are suffering from a medical condition that limits their mobility. It can also treat existing blood clots in deep veins or in unstable coronary artery disease (Unstable Angina or non Q-wave Myocardial Infarction).

What are the ingredients in REDESCA?

Medicinal ingredients: enoxaparin sodium (a low molecular-weight heparin)

Non-medicinal ingredients: water for injection

REDESCA comes in the following dosage forms:

REDESCA 100 mg/mL is available in pre-filled syringes offered with a system that shields the needle after injection:

- Single dose 30 mg/0.3 mL pre-filled syringes with protective shield
- Single dose 40 mg/0.4 mL pre-filled syringes with protective shield
- Single dose 60 mg/0.6 mL pre-filled syringes with protective shield
- Single dose 80 mg/0.8 mL pre-filled syringes with protective shield

- Single dose 100 mg/mL pre-filled syringes with protective shield.

Do not use REDESCA if:

- you have a known allergy to **REDESCA** or any of its constituents, including benzyl alcohol (when using multidose vials);
- you have a known allergy to any other low molecular weight heparins and/or heparin;
- you have thrombocytopenia (a severe decrease in the number of platelets in the blood); History (within the past 100 days) of heparin-induced thrombocytopenia (HIT) (a blood clotting disorder caused by heparin);
- you have bacterial endocarditis (bacterial infection inside of the heart);
- you have active bleeding;
- you have a major clotting disorder;
- you have gastric or duodenal ulcer (defect of the internal walls of the stomach or small intestine);
- you have cerebrovascular accident (except if there are systemic emboli);
- you have severe uncontrolled hypertension (high blood pressure);
- you have eye problems due to diabetes (diabetic retinopathy) or hemorrhage (bleeding);
- you have a tendency to bleeding regardless of the reason;
- you have injury or surgery on the brain, spinal cord, eyes and ears;
- you have kidney problems;
- you have liver problems;
- you have spinal/epidural anesthesia contraindicated where repeated treatment doses of **REDESCA** (1 mg/kg every 12 hours or 1.5 mg/kg once daily) are required, due to an increased risk of bleeding;
- you have other conditions or diseases involving an increased risk of bleeding;

Because of the content of benzyl alcohol, **REDESCA**, when using multiple dose vials, must not be given to newborns or premature neonates.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take REDESCA. Talk about any health conditions or problems you may have, including if you:

- have prosthetic (artificial) heart valve,
- have stroke (cerebrovascular accident),
- have a known allergy to **REDESCA** or any of its constituents, or to other low molecular weight heparins and/or heparin,
- have thrombocytopenia (a severe decrease in the number of platelets in the blood), a history of heparin-induced thrombocytopenia (HIT) (a blood clotting disorder caused by heparin),
- have bacterial endocarditis (bacterial infection inside of the heart),
- have a major clotting disorder,
- have gastric or duodenal ulcer (defect of the internal walls of the stomach or small intestine),
- have hypertension (high blood pressure),
- have a tendency to bleeding regardless of the reason;
- have an injury or surgery (spinal surgery with spinal/epidural anesthesia) involving the central nervous system, eyes or ears;
- have spinal defect (or deformity),
- have kidney problems,
- have liver problems,
- have eye problems due to diabetes or hemorrhage (bleeding).

You should also inform your doctor at once if you are pregnant or if you are breast-feeding, so he can evaluate the possible risks to you and the infant.

Certain medications may intensify the anticoagulant effect (increase the anti-clotting effect) of REDESCA.

Therefore, it is important for you to advise your doctor of all drugs that you are presently taking. It is necessary that you follow the instructions of your doctor or nurse carefully. Only give yourself the

injections prescribed and do so the entire time period specified by your doctor.

Do not take any drugs other than those prescribed by your doctor while you are taking REDESCA.

If you need to consult with another doctor or see your dentist, be absolutely sure to tell them that you are being treated with REDESCA.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with REDESCA:

- Acetylsalicylic acid (ASA), salicylates, and nonsteroidal anti-inflammatories (e.g. diclofenac, ibuprofen, ketorolac);
- Prednisolone;
- Dextran, vitamin K antagonists, clopidogrel, ticlopidine and dipyridamole.

How to take REDESCA:

REDESCA is a prescription drug and must be used as directed. Usually it is administered as a subcutaneous injection, which means the injection is made just under the surface of the skin. For some conditions, **REDESCA** may be administered as an intravenous (IV) injection. **REDESCA** must NOT be administered by the intramuscular route.

Detailed instructions on how to inject REDESCA are provided in "Instructions for Use".

Usual dose:

Hip or Knee Replacement Surgery: While you are in the hospital, your doctor or a nurse will give your first injection within 24 hours after your operation, so as to prevent blood clots from forming. After that, your doctor or a nurse will give you 2 subcutaneous injections every day (one injection every 12 hours) while you are in hospital.

In case of hip replacement surgery, after completing the treatment with 2 subcutaneous injections per day, your doctor may ask you to take 1 subcutaneous injection every day for the following days at home or in hospital for an additional 3 weeks.

Abdominal or Colorectal Surgery: While you are in the hospital, your doctor or a nurse will give your first injection 2 hours prior to surgery. After that, your doctor or a nurse will give you 1 subcutaneous injection once a day while you are in hospital, your doctor may ask you to continue to take 1 subcutaneous injection every day for up to 4 weeks.

Medical Patients: While you are in the hospital, your doctor or a nurse will give you 1 subcutaneous injection once a day. The usual duration of administration is 6 to 11 days.

Treatment of Deep Vein Thrombosis, with or without Embolism: while you are in the hospital, your doctor or a nurse will give you 1 subcutaneous injection once or twice daily for about 10 days.

Treatment of Unstable Angina or Non-Q-Wave Myocardial Infarction: while you are in the hospital, your doctor or a nurse will give you 2 subcutaneous injections every day (one injection every 12 hours) along with oral ASA (100 to 325 mg once daily) for a minimum of 2 days.

Treatment of acute ST-segment Elevation Myocardial Infarction (STEMI): while you are in the hospital, your doctor or a nurse will give you a single intravenous (IV) injection followed by 2 subcutaneous injections every day (one injection every 12 hours) along with oral ASA (75 to 325 mg once daily) for a minimum of 8 days, unless contraindicated.

It is possible that after you go home, you may need to continue your injections of **REDESCA** for a few days. **Prevention of thrombus formation in the extracorporeal circulation during hemodialysis:** while you are in the hospital, your doctor or a nurse will inject **REDESCA** into the arterial line of the circuit at the beginning of the

dialysis session. The effect of this dose is usually sufficient for a 4-hour session.

Overdose:

Accidental overdosage may result in hemorrhaging, which cannot be treated at home. Therefore, if you suspect that you have used too much REDESCA, call your doctor immediately even if you do not yet observe any unusual symptoms. Your doctor can then make arrangements to bring you to hospital for observation and/or treatment.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of this medication by a few hours, take it as soon as you remember. However if you are close to the time of the next dose, skip the missed dose and proceed with the regular dosing schedule. Do not double dose. If you are unsure about how to proceed contact your doctor or your pharmacist.

What are possible side effects from using REDESCA?

These are not all the possible side effects you may feel when taking REDESCA. If you experience any side effects not listed here, tell your healthcare professional. Administration of REDESCA may result in bleeding which can have serious or life-threatening consequences. Hemorrhagic strokes (bleeding inside of the brain) and serious intra-abdominal bleeding (bleeding into the body cavity below diaphragm which contains stomach, intestines, liver, and other organs) have been reported. REDESCA is generally well tolerated when used according to directions of use, nevertheless e.g. hair loss could occur. Long term use of REDESCA (greater than 3 months) may increase the risk of bone thinning (osteoporosis).

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Bleeding (e.g. at site injection, nosebleeds, blood in urine, bloody stools, bleeding gums)			✓
Changes in the results of blood tests done to check your liver		✓	
COMMON Headache	✓		
Purplish or reddish discolouration or pain around the injection site	✓		
Spontaneous bruising (a bruise not caused by a blow or any apparent reason)		✓	
UNCOMMON Abdominal pain		✓	
Signs of liver problems such as loss of appetite, dark urine, light-colored stools, yellowing of the skin or eyes (jaundice)		✓	
RARE Allergic reaction skin rash, angioedema (swelling of lips, face, throat and tongue, breathing difficulties) and anaphylactic/anaphylactoid reactions including shock			✓
Problems in controlling your bowels and/or bladder		✓	
Tingling, numbness and muscular weakness (particularly in the lower part of your body) when you			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
have had a spinal puncture or a spinal anaesthetic			
UNKNOWN Chest pain or shortness of breath			✓
Confusion		✓	
Dizziness		✓	
Pain or swelling in any part of your leg, foot or hip		✓	
Rapid or unusual heart beat			✓
Skin discolouration as caused by ruptured blood vessels		✓	
Vomiting		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by: Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store below 25 C. Do NOT freeze. Keep out of the reach and sight of children.

If you want more information about REDESCA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.valeopharma.com, or by calling 1-855-694-0151.

Instructions for Use:

Instructions for self-injection of REDESCA. Your doctor may want you to continue your REDESCA injections at home for a few days. **If so, he or a nurse will show you how to administer your REDESCA injections before you are released from hospital. It is essential that you follow these instructions exactly. If you have questions, be sure you ask your doctor or nurse to provide the explanations you require.**

Proper subcutaneous (under the skin) injection of REDESCA is essential to prevent pain and bruising at the injection site.

When at home, there is nothing for you to prepare. The syringe is pre-filled with the exact amount of drug required. Do not press on the plunger prior to injection.

REDESCA solution should be inspected visually for clarity, particulate matter, precipitation, discolouration, and leakage prior to administration. Do not use if solution shows haziness, particulate matter, discolouration or leakage.

The recommended site for injection is into the fat of the lower abdomen. This should be at least 5 centimeters away from your belly button and out towards your sides.

Prior to injection, wash your hands and cleanse (do not rub) the selected site for injection with an alcohol swab. Select a different site of the lower abdomen for each injection.

Carefully pull off the needle cap from the syringe.

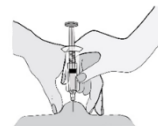
Throw away the cap. The syringe is pre-filled and ready to use.



NOTE: To avoid the loss of drug when using the 30 and 40 mg pre-filled syringes, do not expel the air bubble from the syringe before the injection.

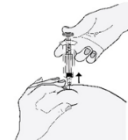
Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).

- Sit or lie down in a comfortable position and gather a fold of skin with your thumb and forefinger.
- Hold the syringe in the hand you write with (like a pencil) and with your other hand, gently pinch the cleaned area of your abdomen between your forefinger and thumb to make a fold in the skin.
- Make sure you hold the skin fold throughout the injection.
- Hold the syringe so that the needle is pointing downwards (vertically at a 90° angle). Insert the full length of the needle into the skin fold.



Press down on the plunger with your finger. This will send the medicine into the fatty tissue of the stomach. Make sure you hold the skin fold throughout the injection.

- Remove the needle by pulling it straight out. Do not release the pressure on the plunger.



To avoid bruising, do not rub the injection site after you have injected yourself.

Push hard on the plunger. The protective sleeve, which is in the form of a plastic cylinder, will be activated automatically and it will completely cover the needle.



You should then safely dispose of the syringe and needle with its protective sleeve, so they remain out of reach of children.

This Patient Medication Information was prepared for Valeo Pharma Inc. (Importer/Distributor of REDESCA® in Canada)

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