大不列颠（预充式注射器包装1线和2线共用，主动型安全装置）说明书20230508-01

580 mm

210 mm

Package leaflet: Information for the user

Inhixa 2,000 IU (20 mg)/0.2 mL solution for injection
Inhixa 4,000 IU (40 mg)/0.4 mL solution for injection
Inhixa 6,000 IU (60 mg)/0.6 mL solution for injection
Inhixa 8,000 IU (80 mg)/0.8 mL solution for injection
Inhixa 10,000 IU (100 mg)/1 mL solution for injection

enoxaparin sodium

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Inhixa is and what it is used for

Inhixa contains the active substance called enoxaparin sodium that is a low molecular weight heparin (LMWH).

Inhixa works in two ways:
1) Stopping existing blood clots from getting bigger. This helps your body to break them down and stop them causing you harm.
2) Stopping blood clots forming in your blood.

Inhixa can be used to:
- Treat blood clots that are in your blood
- Stop blood clots from forming in your blood in the following situations:
  - Before and after an operation
  - When you have an acute illness and face period of limited mobility
  - If you have experienced a blood clot due to cancer to prevent further clots from forming.
  - When you have unstable angina (a condition when not enough blood gets to your heart)
  - After a heart attack
- Stop blood clots forming in the tubes of your dialysis machine (used for people with severe kidney problems).

2. What you need to know before you use Inhixa

Do not use Inhixa
- If you are allergic to enoxaparin sodium or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are allergic to heparin or other low molecular weight heparins such as nadroparin, tinzaparin or dalteparin.
- If you have had a reaction to heparin that caused a severe drop in the number of your clotting cells (platelets) - this reaction is called heparin-induced thrombocytopenia - within the last 100 days or if you have antibodies against enoxaparin in your blood.
- If you are bleeding heavily or have a condition with a high risk of bleeding (such as stomach ulcer, recent surgery of the brain or eyes), including recent bleeding stroke.
- If you are using Inhixa to treat blood clots in your body and going to receive spinal or epidural anaesthesia or lumbar puncture within 24 hours.

Warnings and precautions
Inhixa **should not be used interchangeably** with other medicines belonging to the group of low molecular weight heparins. This is because they are not exactly the same and do not have the same activity and instructions for use.

Talk to your doctor or pharmacist before using Inhixa if:
- you have ever had a reaction to heparin that caused a severe drop in the number of your platelets
- you are going to receive spinal or epidural anesthesia or lumbar puncture (see Operations and Anaesthetics): a delay should be respected between Inhixa use and this procedure.
- you have had a heart valve fitted
- you have endocarditis (an infection of the inner lining of the heart)
- you have history of gastric ulcer
- you have had a recent stroke
- you have high blood pressure
- you have diabetes or problems with blood vessels in the eye caused by diabetes (called diabetic retinopathy)
- you have had an operation recently on your eyes or brain
- you are elderly (over 65 years old) and especially if you are over 75 years old
- you have kidney problems
- you have liver problems
- you are underweight or overweight
- you have high level of potassium in your blood (this may be checked with a blood test)
- you are currently using medicines which affect bleeding (see section below – Other medicines and Inhixa).

You may have a **blood test** before you start using this medicine and at intervals while you are using it; this is to check the level of the clotting cells (platelets) and potassium in your blood.

Children and adolescents
The safety and efficacy of Inhixa has not been evaluated in children or adolescents.

Other medicines and Inhixa
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.
- Warfarin – another anticoagulant medicine used for thinning the blood
- Acetylsalicylic acid (also known as aspirin or ASA), clopidogrel or other medicines used to stop blood clots from forming (see also in section 3, "Changing anticoagulant medicine")
- Dextran injection – used as a blood replacer
- Ibuprofen, diclofenac, ketorolac or other medicines known as non-steroidal anti-inflammatory agents which are used to treat pain and swelling in arthritis and other conditions
- Prednisolone, dexamethasone or other medicines used to treat asthma, rheumatoid arthritis and other conditions
- Medicines which increase potassium level in your blood such as potassium salts, water pills, some medicines for heart problems.

Operations and anaesthetics
If you are going to have a spinal puncture or an operation where an epidural or spinal anaesthetic is used, tell your doctor that you are using Inhixa. See "Do not use Inhixa". Also, tell your doctor if you have any problem with your spine or if you ever had spinal surgery.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
If you are pregnant and have a mechanical heart valve, you may be at an increased risk of developing blood clots. Your doctor should discuss this with you.

If you are breast-feeding or plan to breast-feed, you should ask your doctor for advice before taking this medicine.

Driving and using machines
Inhixa does not affect the ability to drive and operate machinery.

Traceability
It is important to keep a record of the batch number of your Inhixa. So, every time you get a new package of Inhixa, note down the date and the batch number (which is on the packaging after Lot) and keep this information in a safe place.

Inhixa contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Inhixa

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Having this medicine
- Your doctor or nurse will normally give you Inhixa. This is because it needs to be given as an injection.
- When you go home, you may need to continue to use Inhixa and give it yourself (see instructions below on how to do this).
- Inhixa is usually given by injection underneath the skin (subcutaneous).
- Inhixa can be given by injection into your vein (intravenous) after certain types of heart attack or operation.
- Inhixa can be added to the tube leaving the body (arterial line) at the start of the dialysis session.

Do not inject Inhixa into a muscle.

How much will be given to you
- Your doctor will decide how much Inhixa to give you. The dose will depend on the reason it is being used.
- If you have problems with your kidneys you may be given a smaller amount of Inhixa.

1. Treating blood clots that are in your blood
   - The usual dose is 150 IU (1.5 mg) for every kilogram of your weight once daily or 100 IU (1 mg) for every kilogram of your weight twice a day.
   - Your doctor will decide how long you should receive Inhixa.

2. Stopping blood clots forming in your blood in the following situations:
   - ❖ *Operation or periods of limited mobility due to an illness*
     - The dose will depend on how likely you are to develop a clot. You will be given 2,000 IU (20 mg) or 4,000 IU (40 mg) of Inhixa each day.
     - If you are going to have an operation your first injection will be usually given 2 hours or 12 hours before your operation.
     - If you have restricted mobility due to illness, you will normally be given 4,000 IU (40 mg) of Inhixa each day.
     - Your doctor will decide how long you should receive Inhixa.

❖ *After you have had a heart attack*
Inhixa can be used for two different types of heart attack called STEMI (ST segment elevation myocardial infarction) or non-STEMI (NSTEMI). The amount of Inhixa given to you will depend on your age and the kind of heart attack you have had.

NSTEMI type of heart attack:
- The usual dose is 100 IU (1 mg) for every kilogram of weight every 12 hours.
- Your doctor will normally ask you to take acetylsalicylic acid (aspirin) as well.
- Your doctor will decide how long you should receive Inhixa.

STEMI type of heart attack if you are under 75 years old:
- An initial dose of 3,000 IU (30 mg) of Inhixa will be given as injection into your vein.
- At the same time you will also be given Inhixa as an injection underneath your skin (subcutaneous injection). The usual dose is 100 IU (1 mg) for every kilogram of your weight, every 12 hours.
- Your doctor will normally ask you to take acetylsalicylic acid (aspirin) as well.
- Your doctor will decide how long you should receive Inhixa.

STEMI type of heart attack if you are 75 years old or older:
- The usual dose is 75 IU (0.75 mg) for every kilogram of your weight, every 12 hours.
- The maximum amount of Inhixa given for the first two injections is 7,500 IU (75 mg).
- Your doctor will decide how long you should receive Inhixa.

For patients having a procedure called percutaneous coronary intervention (PCI):
Depending on when you were last given Inhixa, your doctor may decide to give an additional dose of Inhixa before the PCI procedure. This is by injection into your vein.

3. Stopping blood clots from forming in the tubes of your dialysis machine
   - The usual dose is 100 IU (1 mg) for every kilogram of your weight.
   - Inhixa is added to the tube leaving the body (arterial line) at the start of the dialysis session. This amount is usually enough for a 4-hour session. However, your doctor may give you a further dose of 50 IU to 100 IU (0.5 to 1 mg) for every kilogram of your weight, if necessary.

<u>How to give yourself an injection of Inhixa with a pre-filled syringe with needle guard</u>
Your pre-filled syringe has a needle guard attached to it in order to protect you from needle stick injury.
If you are able to give this medicine to yourself, your doctor or nurse will show you how to do this. Do not try to inject yourself if you have not been trained to do so. If you are not sure what to do, talk to your doctor or nurse immediately.

Before injecting yourself with Inhixa
- Check the expiry date on the medicine. Do not use if the date has passed.
- Check if the syringe is not damaged and the liquid inside is clear. If not, use another syringe.
- Do not use this medicine if you notice any change in its appearance.
- Make sure you know how much you are going to inject.
- Check if the last injection caused any redness, change in skin colour, swelling, oozing or is still painful. If so, talk to your doctor or nurse.
- Decide where you are going to inject the medicine. Change the place where you inject each time from the right to the left side of your abdomen (belly). This medicine should be injected just under the skin on your abdomen, but not too near the belly button or any scar tissue (at least 5 cm away from these).
- The pre-filled syringe is intended for single use only.

Instructions on injecting yourself with Inhixa
1) Wash your hands and the area that you will inject with soap and water. Dry them.
2) Sit or lie in a comfortable position so you are relaxed. Make sure you can see the place you are going to inject. In a lounge chair, recliner, or propped up in bed with pillows is ideal.
3) Choose an area on the right or left side of your stomach. This should be at least 5 cm away from your belly button and out towards your sides.

Remember: Do not inject yourself within 5 cm of your belly button or around existing scars or bruises. Change the place where you inject between the left and right sides of your stomach, depending on the area you were last injected.

4) Remove the plastic blister containing the pre-filled syringe from the box. Open the blister and remove the pre-filled syringe.

5) Carefully pull off the needle cap from the syringe. Throw away the cap. The syringe is pre-filled and ready to use.

Do not press on the plunger before injecting yourself. Once you have removed the cap, do not allow the needle to touch anything. This is to make sure the needle stays clean (sterile).

6) 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.

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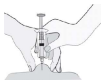
Make sure you **hold the skin fold throughout the injection.**

7) 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.

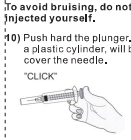


8) Press down on the plunger with your thumb. This will inject the medicine into the fatty tissue of the abdomen. Make sure you hold the skin fold throughout the injection.

9) 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.

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



11) Drop the used syringe into the sharps container. Close the container lid tightly and place the container out of reach of children.

When the container is full, dispose of it as your doctor or pharmacist has instructed. Do not put it in the household rubbish.

Changing anticoagulant treatment

- *Changing from Inhixa to blood thinners called vitamin-K antagonists (e.g. warfarin)*
  Your doctor will ask you to have performed blood tests called INR and tell you when to stop Inhixa accordingly.
- *Changing from blood thinners called vitamin-K antagonists (e.g. warfarin) to Inhixa*
  Stop taking the vitamin-K antagonist. Your doctor will ask you to have performed blood tests called INR and tell you when to start Inhixa accordingly.
- *Changing from Inhixa to treatment with direct oral anticoagulant (e.g apixaban, dabigatran, edoxaban, rivaroxaban)*
  Stop taking Inhixa. Start taking the direct oral anticoagulant 0-2 hours before the time you would have had the next Inhixa injection, then continue as normal.
- *Changing from treatment with direct oral anticoagulant to Inhixa*
  Stop taking direct oral anticoagulant. Do not start treatment with Inhixa until 12 hours after the final dose of direct oral anticoagulant.

If you use more Inhixa than you should
If you think that you have used too much or too little Inhixa, tell your doctor, nurse or pharmacist immediately, even if you have no signs of a problem. If a child accidentally injects or swallows Inhixa, take the child to a hospital casualty department straight away.

If you forget to use Inhixa
If you forget to give yourself a dose, have it as soon as you remember. Do not give yourself a double dose on the same day to make up for a forgotten dose. Keeping a diary will help to make sure you do not miss a dose.

If you stop using Inhixa
If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.
It is important for you to keep having Inhixa injections until your doctor decides to stop them. If you stop, you could get a blood clot which can be very dangerous.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Like other anticoagulant medicines (medicines to reduce blood clotting), Inhixa may cause bleeding which may potentially be life-threatening. In some cases the bleeding may not be obvious.

If you experience any bleeding that does not stop by itself or if you experience signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling), consult your doctor immediately. Your doctor may decide to keep you under closer observation or change your medicine.

Stop using Inhixa and talk to a doctor or nurse at once if you get any signs of a severe allergic reaction (such as difficulty breathing, swelling of the lips, mouth, throat or eyes).

Stop using Inhixa and seek medical attention immediately if you notice any of the following symptoms:
A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).

You should tell your doctor straight away
- If you have any sign of blockage of a blood vessel by a blood clot such as:
  - cramping pain, redness, warmth, or swelling in one of your legs – these are symptoms of deep vein thrombosis
  - breathlessness, chest pain, fainting or coughing up blood – these are symptoms of a pulmonary embolism
- If you have a painful rash of dark red spots under the skin which do not go away when you put pressure on them.

Your doctor may ask you to have performed a blood test to check your platelet count.

Overall list of possible side effects:
Very common (may affect more than 1 in 10 people)
- Bleeding.
- Increases in liver enzymes.

Common (may affect up to 1 in 10 people)
- You bruise more easily than usual. This could be because of a blood problem with low platelet counts.
- Pink patches on your skin. These are more likely to appear in the area you have been injected with Inhixa.
- Skin rash (hives, urticaria).
- Itchy red skin.
- Bruising or pain at the injection site.
- Decreased red blood cell count.
- High platelet counts in the blood.
- Headache.

Uncommon (may affect up to 1 in 100 people)
- Sudden severe headache. This could be a sign of bleeding in the brain.
- A feeling of tenderness and swelling in your stomach. You may have bleeding in your stomach.
- Large red irregularly shaped skin marks with or without blisters.
- Skin irritation (local irritation).
- Yellowing of your skin or eyes and your urine becoming darker. These may be signs of a liver problem.

Rare (may affect up to 1 in 1,000 people)
- Severe allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- Increased potassium in your blood. This is more likely to happen in people with kidney problems or diabetes. Your doctor will be able to check this by carrying out a blood test.
- An increase in the number of white blood cells called eosinophils in your blood. Your doctor will be able to check this by carrying out a blood test.
- Hair loss.
- Osteoporosis (a condition where your bones are more likely to break) after long-term use.
- Tingling, numbness and muscular weakness (particularly in the lower part of your body) when you have had a spinal puncture or a spinal anaesthetic.
- Loss of control over your bladder or bowel (so you cannot control when you go to the toilet).
- Hard mass or lump at the injection site.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Inhixa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
Store below 25 °C. Do not freeze.
After dilution the solution should be used within 8 hours.
Do not use this medicine if you notice any visible change in the appearance of the solution.
The Inhixa pre-filled syringes are for single dose use only. Discard any unused medicine.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Inhixa contains
- The active substance is enoxaparin sodium.
  Each mL contains 10,000 IU (100 mg) enoxaparin sodium.
  Each pre-filled syringe of 0,2 mL contains 2,000 IU (20 mg) of enoxaparin sodium.
  Each pre-filled syringe of 0,4 mL contains 4,000 IU (40 mg) of enoxaparin sodium.
  Each pre-filled syringe of 0,6 mL contains 6,000 IU (60 mg) of enoxaparin sodium.
  Each pre-filled syringe of 0,8 mL contains 8,000 IU (80 mg) of enoxaparin sodium.
  Each pre-filled syringe of 1 mL contains 10,000 IU (100 mg) of enoxaparin sodium.
- The other ingredient is water for injections.

What Inhixa looks like and contents of the pack
Inhixa 2,000 IU (20 mg)/0,2 mL is 0,2 mL of solution in:
- a clear, colourless type I neutral glass syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a blue polypropylene plunger rod. The syringe can be additionally equipped with needle guard or manual needle guard; or
- a clear, colourless type I neutral glass syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a white polycarbonate plunger rod equipped with UltraSafe Passive needle guard.

Supplied in packs of:
- 1, 2, 6, 10 and 50 pre-filled syringe(s)
- 2, 6, 10, 20, 50 and 90 pre-filled syringes with needle guard
- 6 and 10 pre-filled syringes with manual needle guard
- 2 and 6 pre-filled syringes with UltraSafe Passive needle guard

Inhixa 4,000 IU (40 mg)/0,4 mL is 0,4 mL of solution in:
- a clear, colourless type I neutral glass syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a yellow polypropylene plunger rod. The syringe can be additionally equipped with needle guard or manual needle guard; or
- a clear, colourless type I neutral glass syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a white polycarbonate plunger rod equipped with UltraSafe Passive needle guard.

Supplied in packs of:
- 2, 5, 6, 10, 30 and 50 pre-filled syringes
- 2, 5, 6, 10, 20, 30, 50 and 90 pre-filled syringes with needle guard
- 6 and 10 pre-filled syringes with manual needle guard
- 2 and 6 pre-filled syringes with UltraSafe Passive needle guard

Inhixa 6,000 IU (60 mg)/0,6 mL is 0,6 mL of solution in:
- a clear, colourless type I neutral glass graduated syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and an orange polypropylene plunger rod. The syringe can be additionally equipped with needle guard or manual needle guard; or
- a clear, colourless type I neutral glass graduated syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a white polycarbonate plunger rod equipped with UltraSafe Passive needle guard.

Supplied in packs of:
- 2, 6, 10, 30 and 50 pre–filled syringes
- 2, 6, 10, 12, 20, 24 and 30 pre-filled syringes with needle guard
- 6 and 10 pre-filled syringes with manual needle guard
- 2 and 10 pre-filled syringes with UltraSafe Passive needle guard

Inhixa 8,000 IU (80 mg)/0,8 mL is 0,8 mL of solution in:
- a clear, colourless type I neutral glass graduated syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a red polypropylene plunger rod. The syringe can be additionally equipped with needle guard or manual needle guard; or
- a clear, colourless type I neutral glass graduated syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a white polycarbonate plunger rod equipped with UltraSafe Passive needle guard.

Supplied in packs of:
- 2, 6, 10, 30 and 50 pre–filled syringes
- 2, 6, 10, 12, 24 and 30 pre-filled syringes with needle guard
- 6 and 10 pre-filled syringes with manual needle guard
- 2 and 10 pre-filled syringes with UltraSafe Passive needle guard

Inhixa 10,000 IU (100 mg)/1 mL is 1 mL of solution in:
- a clear, colourless type I neutral glass graduated syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a black polypropylene plunger rod. The syringe can be additionally equipped with needle guard or manual needle guard; or
- a clear, colourless type I neutral glass graduated syringe barrel with fixed needle and needle shield closed by chlorobutyl rubber stopper and a white polycarbonate plunger rod equipped with UltraSafe Passive needle guard.

Supplied in packs of:
- 2, 6, 10, 30, 50 and 90 pre-filled syringes
- 2, 6, 10, 12, 24 and 30 pre-filled syringes with needle guard
- 6 and 10 pre-filled syringes with manual needle guard
- 2 and 10 pre-filled syringes with UltraSafe Passive needle guard

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Techdow Pharma Netherlands B.V.
Strawinskylaan 1143, Toren C-11
1077XX Amsterdam
Netherlands

Manufacturer

SciencePharma spółka z ograniczoną odpowiedzialnością
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00-725 Warsaw
Poland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
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Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency web site:
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency