

Package leaflet: Information for the user

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection histamine dihydrochloride

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is and what it is used for
2. What you need to know before you use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection
3. How to use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection
4. Possible side effects
5. How to store Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection
6. Contents of the pack and other information

1. What Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is and what is used for

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection belongs to a group of medicines called immunomodulatory medicines. These medicines help the body's immune system fight diseases like cancer by improving the immune system's natural role in fighting disease. The active substance in Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is histamine dihydrochloride; it is identical to a naturally occurring substance in the body. It is used together with low doses of interleukin-2 (IL-2), another medicine which helps the immune system to fight diseases like cancer.

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is used in adult patients, together with IL-2, to treat a particular type of leukaemia called acute myeloid leukaemia (AML) which is a cancer of blood forming cells in the bone marrow. It is used to maintain the remission (the period during which the disease is less severe or not detectable). Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection with IL-2 will help your immune system attack any remaining cancer cells after a previous cancer treatment.

During your treatment, you will always use IL-2 AND Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection. Ask your doctor if you have any questions about Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection or IL-2.

2. What you need to know before you use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

Do not use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

- If you are allergic (hypersensitive) to histamine or any of the other ingredients of this medicine (listed in section 6).
- If you have severe heart problems.

- If you are receiving one of the following medicines:
 - Steroids such as prednisone and dexamethasone. They are used to inhibit activity of the immune system (immunosuppressant) and to reduce inflammation.
 - Clonidine, a medicine used to reduce high blood pressure.
 - H₂ blockers such as cimetidine, ranitidine, famotidine or nizatidine which are used to treat stomach ulcers, indigestion (dyspepsia) or heartburn.
- If you have received a stem cell transplant (a kind of bone marrow transplant) from a donor.
- If you are pregnant.
- If you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection.

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2 are not to be injected at the same time. IL-2 has to be injected first. Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection must be injected 1 to 3 minutes later.

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection must be injected slowly in the layer of tissue just under the skin (subcutaneously), over a period of approximately 5 to 15 minutes. Rapid injection can cause a drop in your blood pressure and make you feel faint or even pass out.

You will start your treatment with Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection in the clinic under supervision of a doctor. You must be monitored to check how you respond to treatment. Your doctor will check your blood pressure, pulse rate and lung function. Your doctor will also carry out some blood tests during treatment.

If you have had one of the following conditions you will be monitored in the hospital during the next treatment days or the next cycles of treatment:

- bleeding ulcers,
- stroke,
- narrowing of the arteries (systemic peripheral arterial disease),
- heart disease (for severe heart problems see above “Do not use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection”),
- a history of auto-immune disease (a disease where the immune system attacks the body’s own cells or tissues, such as systemic lupus, rheumatoid arthritis, inflammatory bowel disease or psoriasis).

If you are taking any other medicines mentioned under “Other medicines and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection” or if you are to have an operation or special X-ray investigation requiring an injection, talk to your doctor.

If you have an infection, your doctor will closely monitor you. If you have had an infection within 14 days of starting this treatment which required you to take medicines to treat infections (antibiotics, antifungals or antivirals), your doctor will closely monitor you.

If you have kidney problems, talk to your doctor before using this medicine. A decrease of blood pressure may occur.

If you have liver problems, talk to your doctor before using this medicine. Your doctor may change your dose.

Children and adolescents

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection use is not recommended in children and adolescents, as there is no information available about using this medicine in this age group.

Other medicines and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

If you are taking any of the following medicines, please be sure to discuss this with your doctor or pharmacist before using Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection. Some of them must not be taken during treatment with Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection or may need special precautions:

- **Steroids** such as prednisone and dexamethasone. They are used to inhibit activity of the immune system (immunosuppressant) and to reduce inflammation (see above “Do not use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection”).
- **H₂ blockers** such as cimetidine, ranitidine, famotidine or nizatidine. They are used to treat stomach ulcers, indigestion (dyspepsia) or heartburn (see above “Do not use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection”).
- **Antihistamines** used to treat allergy.
- Certain **anti-psychotics** such as chlorpromazine, flupenthixol, thioridazine, clozapine and risperidone. They are used to treat mental conditions.
- **Tricyclic antidepressant medicines** such as amitriptyline, imipramine, or **monoamine oxidase inhibitors**, such as phenelzine, isocarboxazide, tranylcypromine or moclobemide. They are used to treat depression.
- **Anti-malarial or medicines used to treat infections responsible for sleeping sickness.**
- **Beta-blockers**, such as propranolol, metoprolol, atenolol. They are used for angina and heart beat disorders.
- Any treatment for **high blood pressure** (for example thiazide diuretics [bendrofluazide], ACE inhibitors [captopril], calcium antagonists [nifedipine] and alpha-blockers [prazosin]).

Also, if you are to have an **operation** or special **X-ray investigation** requiring an injection, first make sure that your doctor knows that you are receiving Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection. Certain medicines used for an operation (for example neuromuscular blocking medicines and narcotic pain-killers) or dyes used for certain X-rays may interfere with this medicine.

Pregnancy and breast-feeding

There is no information about the use of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection in pregnant women. Therefore, the treatment with Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2 must not be used during pregnancy.

For both men and women using this treatment, an effective method of contraception must be used as it is important not to conceive a child while being treated with Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2.

It is not known whether Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection appears in breast milk. Therefore Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2 must not be used during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines within one hour after receiving a Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection injection as it may reduce blood pressure causing dizziness, light-headedness and blurred vision. This can affect your ability to drive and operate machines.

3. How to take Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

Always use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection exactly as your doctor has instructed. You should check with your doctor, pharmacist or nurse if you are not sure about this.

This treatment must be prescribed and supervised by a physician with knowledge of acute myeloid leukaemia.

Recommended dose

Since you will be using both IL-2 and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection in a combined treatment, information about both dosages is provided:

Interleukin-2 (IL-2)

IL-2 is injected twice daily as a subcutaneous injection (in the layer of tissue just under the skin) 1 to 3 minutes before the injection of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection. Each dose is calculated from your body weight. Your doctor will let you know how much it is and how to inject it.

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

The usual dose of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is 0.5 mL of solution twice a day given as a slow subcutaneous injection (in the layer of tissue just under the skin).

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection must be injected 1 to 3 minutes after IL-2.

The two medicines, IL-2 and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection, are both injected twice a day, with a minimum of 6 hours between injections.

Treatment periods and treatment breaks

The treatment with IL-2 and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection lasts for 81 weeks and is cyclic.

- For the first 18 weeks: you will use IL-2 and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection daily for 3 weeks, followed by a 3 week break (no treatment at all).
- For the following 63 weeks: you will use IL-2 and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection daily for 3 weeks, followed by a 6 week break (no treatment at all).

Injecting Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection yourself

Your doctor may decide that it would be more convenient for you to inject IL-2 and Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection yourself. Your doctor or nurse will show you how to inject yourself. Do not try to inject yourself unless a qualified professional has trained you.

It is recommended that you always have someone with you when injecting this medicine, such as an adult family member, friend or other care provider who could help you if you feel light-headed or faint.

For further instructions on how to inject this medicine yourself, please read the section “INSTRUCTIONS FOR SELF-INJECTION OF HISTAMINE DIHYDROCHLORIDE 0.5 MG/0.5 ML SOLUTION FOR INJECTION” at the end of this leaflet.

Your doctor may advise you that it is appropriate to use a syringe pump to regulate the injection of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection. If you are using a syringe pump you must refer to the instructions provided by the pump manufacturer and the training provided by your doctor or nurse.

If you use more Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection than you should
You must use this medicine exactly as it has been prescribed for you. If you accidentally inject more than you were told to, contact your doctor or pharmacist immediately.

If you forget to take Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

Do not take any additional dose to make up for the forgotten doses. Continue with the treatment as prescribed. If you have missed one of your doses in a day, contact your doctor or pharmacist.

If you stop taking Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

If you want to stop taking Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection you should try to consult your doctor in advance. Please inform your doctor immediately if you have stopped taking Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection by your own decision.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Side effects observed when Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is used as described in this package leaflet:

Hypotension (low blood pressure) may occur very commonly and may lead to light-headedness and fainting. If you notice a severe drop in blood pressure after use of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection, please contact your physician immediately or at least prior to administration of further Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection injections.

Very common side effects (may affect more than 1 in 10 people)

- Infections of the upper breathing (respiratory) tract
- Increase in the number of a certain type of white blood cells in the blood (eosinophilia) and decrease in the number of blood platelets (thrombocytopenia)
- Headache and dizziness
- Altered taste (dysgeusia)
- Rapid heart beat (tachycardia)
- Flushing
- Cough, difficulty in breathing (dyspnoea)
- Nausea, indigestion (dyspepsia) and diarrhoea
- Rash
- Joint and muscle pain (arthralgia and myalgia)
- Inflamed granulated skin at the injection site, fatigue, fever (pyrexia), injection site redness, feeling hot, injection site reaction, itching at the injection site, flu-like symptoms, shivering (chills), injection site inflammation and pain.

Common side effects (may affect up to 1 in 10 people)

- Decrease in the number of white blood cells (leucopenia)
- Decrease in the number of a certain type of white blood cells (neutropenia)
- Inflammation of the lung (pneumonia)
- Loss of appetite (anorexia)
- Difficulty in sleeping (insomnia)
- Feeling your own heart beat (palpitations)
- Nasal congestion
- Vomiting, pain in the upper belly (abdominal pain) and dry mouth
- Inflammation of the stomach (gastritis)
- Bloating of the belly (abdominal distension)
- Abnormal redness of the skin (erythema), increased sweating (hyperhidrosis), night sweats and itching (pruritus)
- Pain in limbs and back pain
- Hives, bruising, rash and swelling at the injection site, weakness (asthenia) and chest pain

Additional side effects observed when Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection was used in other types of treatment:

Very common side effects (may affect more than 1 in 10 people)

- Dry skin

- Anxiety
- Feeling of general discomfort or unease
- Accumulation of fluid in the body especially in the legs (oedema)
- Loss of weight

Common side effects (may affect up to 1 in 10 people)

- Sensation of spinning (vertigo)
- Your body does not make enough thyroxine, a body chemical called a hormone (hypothyroidism)
- Decrease in the number of red blood cells (anaemia)
- Drying-out of the body (dehydration)
- Depression
- Tingling, prickling or numbness of the skin (paraesthesia)
- Hot flushes
- Wheezing
- Constipation, swollen stomach, inflamed mouth
- Pain and formation of extra tissue in the skin around the injection site

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: 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 Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection

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

Do not use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection after the expiry date which is stated on the carton and vial label. The expiry date refers to the last day of that month.

Do not freeze.

The solution should be visually inspected for particulate matter and discolouration prior to administration. The solution must be clear and colourless.

Medicines must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection contains

- The active substance is histamine dihydrochloride. One vial contains 0.5 mg histamine dihydrochloride in 0.5 mL solution.
- The other ingredients are water for injections and sodium chloride, and it may also contain sodium hydroxide and/or hydrochloric acid for pH adjustment.

What Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection looks like and contents of the pack

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is a clear, colourless liquid. It is provided in a glass vial with a grey rubber stopper and a blue peel flip off aluminium tamper evident over seal.

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection is available in pack sizes of 14 vials.

Marketing Authorisation Holder

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Church House, 48 Church Street
Reigate, Surrey
RH2 0SN, United Kingdom

Manufacturer

Labiana Pharmaceuticals, S.L.U.
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For information in large print, Braille or on CD, telephone 0800 198 5000.

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The reference medicinal product has been authorised under ‘exceptional circumstances’. This means that due to the rarity of the disease it has not been possible to obtain complete information on this medicine. The MHRA will review any new information on this medicine every year and this package leaflet will be updated as necessary.

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency (MHRA) website: <http://www.mhra.gov.uk>.

INSTRUCTIONS FOR SELF-INJECTION OF HISTAMINE DIHYDROCHLORIDE 0.5 MG/0.5 ML SOLUTION FOR INJECTION

This section contains information on how to give yourself an injection of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection.

For general information about the dosage and how to use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2, please see section 3, “How to use Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection”.

Read the following instructions carefully. It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse. If you are not sure about how to give yourself the injection or you have any questions, please ask your doctor or nurse for help.

If you feel faint or dizzy during or after the injections, tell your doctor before injecting your next dose. Your doctor may want to increase the time you take to complete your injection, or change your dose.

You will have to inject Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2 twice a day by subcutaneous injection (in the layer of tissue just under the skin), according to the directions provided by your doctor.

Always inject IL-2 first. Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection must be injected **1 to 3 minutes later**.

Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection must not be mixed with any other products and must not be diluted.

Your doctor will explain to you how to prepare and inject IL-2.

It is recommended that you always have **someone with you when injecting Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection**, such as an adult family member, friend, or other care provider to help you if you feel light-headed or faint.

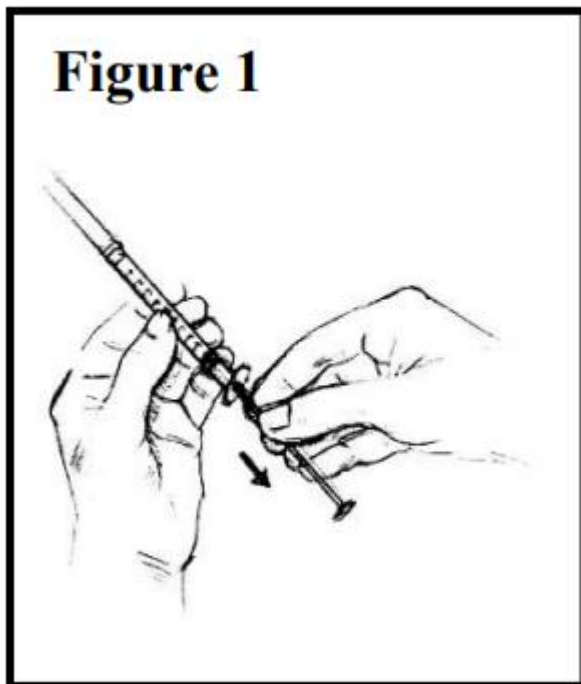
PREPARATION FOR INJECTION OF HISTAMINE DIHYDROCHLORIDE 0.5 MG/0.5 ML SOLUTION FOR INJECTION

To prepare a dose of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection you will need the following:

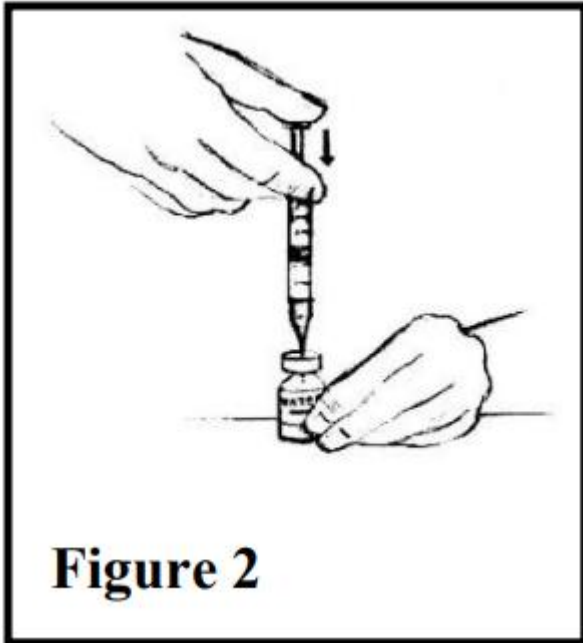
- 1 vial of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection solution (0.5 mL)
- 1 sterile graduated syringe with needle
- 1 alcohol wipe

Method

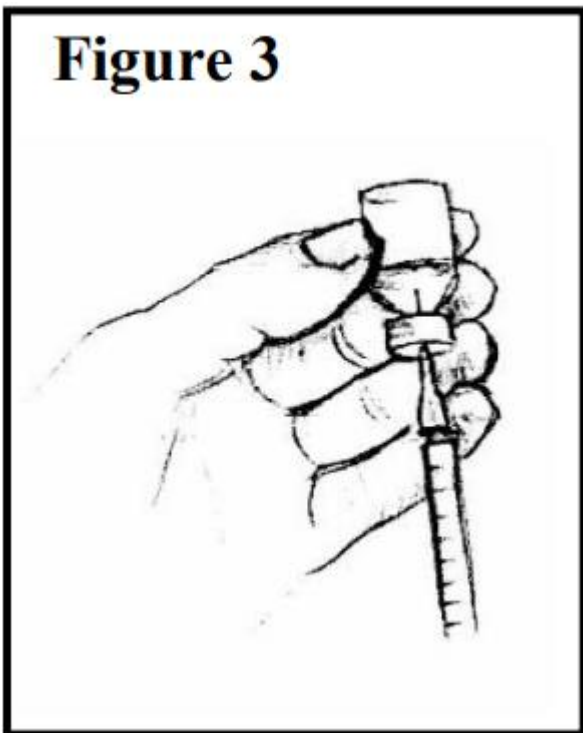
1. Take 1 vial out of the carton. Check the expiry date (EXP) on the vial label.
2. Do not use if the date has passed the last day of the month shown.
3. Wash your hands thoroughly with soap and water.
4. Double check the vial label to make sure you are using the correct medicine. The solution must be clear and colourless. If not, use another vial and inform your doctor or pharmacist.
5. Remove the plastic cap from the vial, exposing the stopper with the inner rubber circle.
6. Use an alcohol wipe to clean the rubber part of the stopper. Do not touch the stopper with your hands.
7. Pick up the sterile syringe. Notice the numbered marks on it. Each mark (0.1, 0.2, 0.3, etc.) represents one-tenth of a millilitre (0.1 mL). With the needle cover on, pull back the plunger and draw air into the syringe to the level (number of millilitres) instructed by your doctor. See **Figure 1**.



8. Pull the needle cover straight off. With the vial standing on a flat surface, insert the needle straight through the rubber stopper into the vial.
9. Push the plunger of the syringe down to inject air into the vial. See **Figure 2**.



10. Holding both the vial and the syringe, turn the vial upside down. Adjust the syringe so that the tip of the needle is slightly above the rubber stopper but still within the solution. See **Figure 3**.



11. Slowly pull back the plunger to draw the solution into the syringe, filling it to the level (number of millilitres) instructed by your doctor. If bubbles appear in the syringe, push the solution slowly back into the vial and withdraw the solution again.
12. Take the needle out of the vial. Do not lay the syringe down or let the needle touch anything.
13. Replace the cover on the needle. Place the syringe on a clean flat surface.
14. There may be a small amount of solution left in the vial. This is to be returned to the pharmacist for disposal. NOTE: The vial of Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection contains an overfill to facilitate the dose extraction of a single 0.5 mL dose.
15. Double check the syringe to make sure that you have withdrawn the correct amount.
16. Take the syringe and follow the “INSTRUCTIONS FOR INJECTION” information below.

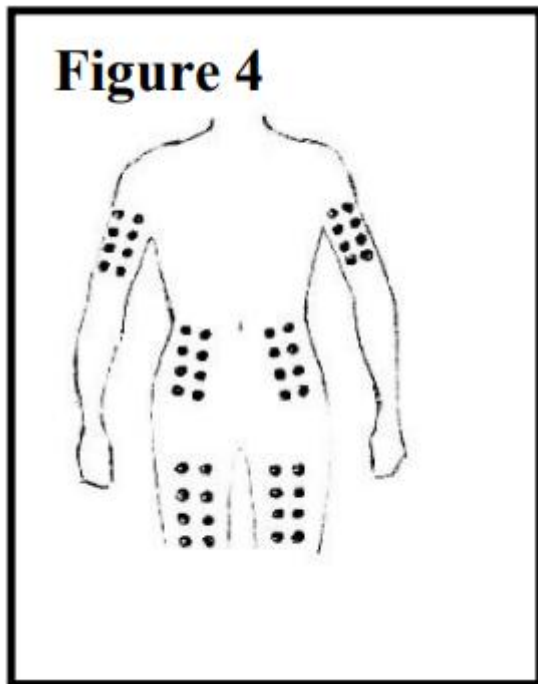
INSTRUCTIONS FOR INJECTION

You will usually inject two doses of 0.5 mL in a day, unless your doctor has prescribed a lower dose for you. For the injection you will need the following:

- 1 prepared syringe for your IL-2 injection (refer to the IL-2 package leaflet and your doctor's dose instructions).
- 1 prepared syringe containing Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection.
- Alcohol wipe(s).
- A timer, clock or watch with a second hand.
- A puncture-proof container so you can dispose of used syringes safely.

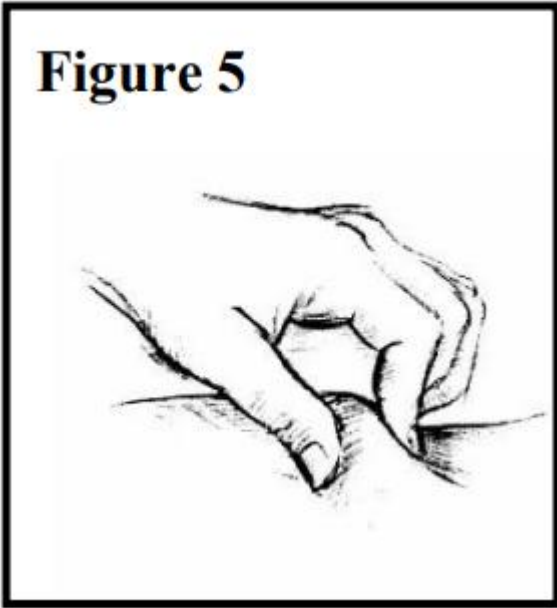
Method

1. Find a comfortable, well-lit place to sit and where you can lie back. Place the pre-prepared syringes containing IL-2, Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and an opened alcohol wipe where you can reach them. For your safety it is very important that you are sitting where you can lean back or lie flat when you perform the injections.
2. Inject IL-2 as you have been instructed.
3. Wait 1 to 3 minutes.
4. Decide where you will inject Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection. You may choose the inner or outer thighs, arms or stomach. **Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection and IL-2 must not be injected into the same region.** For example, if you inject IL-2 in the left arm, you could inject Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection into the left or right thigh, the stomach, or the right arm. Always vary the site that you inject. For possible injection sites, see **Figure 4**.



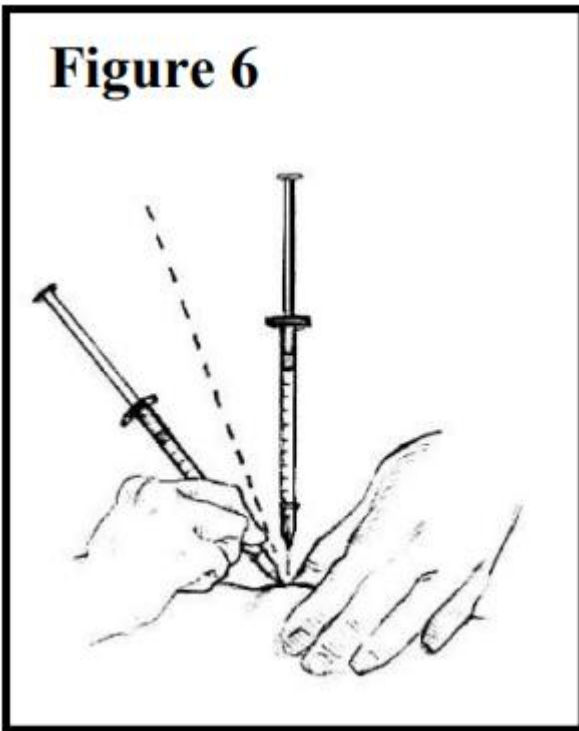
5. Make sure that the area of the skin you select is exposed. Use an alcohol wipe to clean it. Allow the area to dry for 10 seconds.
6. Pinch up a section of the cleaned skin between your thumb and forefinger, without squeezing it. See **Figure 5**.

Figure 5



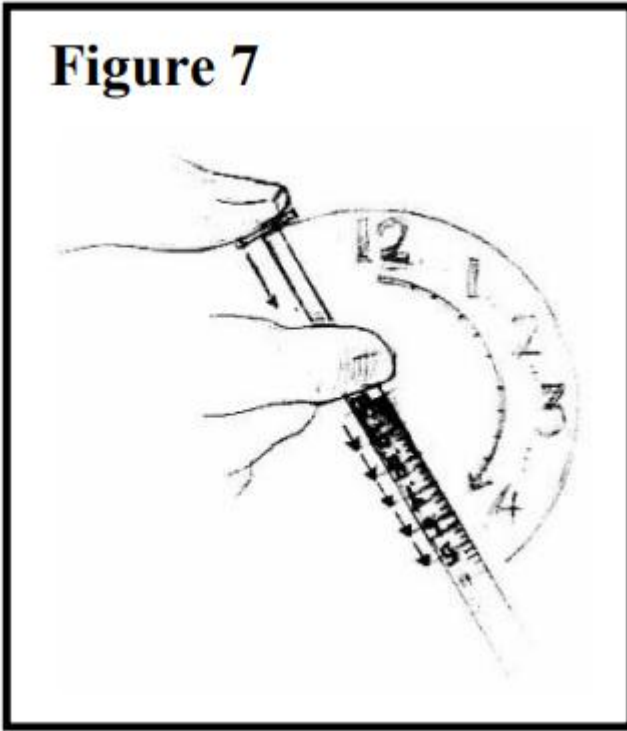
7. Hold the needle either vertically (90°) or at a 45° angle to the skin and insert it under the skin as far as it will go in one quick motion. The needle must be inserted under the skin, but not into any blood vessels below the skin. See **Figure 6**.

Figure 6



8. Slightly pull back the plunger. **If blood appears, do not inject Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection because the needle has entered a blood vessel.** Withdraw and discard the syringe as instructed. Obtain new supplies and start the procedure over again, even if 3 minutes have passed after injection of IL-2.
9. Notice the numbered marks on each syringe. Each mark (0.1, 0.2, 0.3, etc.) represents one-tenth of a millilitre (0.1 mL).
10. Push down the syringe plunger and inject one-tenth of a millilitre (0.1 mL) every minute, or more slowly if instructed to do so by your doctor. See **Figure 7**.

Figure 7



11. Never inject Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection any faster or all at once.
12. When the syringe is empty, remove the needle from your skin.
13. Apply gentle pressure with the alcohol wipe over the injection site without rubbing it.
14. **Remain seated or lying down for 20 minutes** after injecting Histamine dihydrochloride 0.5 mg/0.5 mL solution for injection.
15. Dispose of the syringe in the puncture-proof container as instructed.