

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Piasky 340 mg

170 mg/mL

Solution for injection/infusion

Composition:

crovalimab 170 mg/mL

Inactive ingredients and allergens in this medicine: See section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

In addition to the patient information leaflet, Piasky also has a patient safety information card and a patient guide. These documents contain important safety information that you need to know and that you should follow before starting and during treatment with Piasky. Carefully read these documents and the patient information leaflet before using this medicine. Keep the documents in case you need to read them again.

1. What is this medicine intended for?

Piasky as monotherapy is intended for the treatment of adult and pediatric patients 12 years of age and older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH):

- In patients with haemolysis (the breakdown of red blood cells) and clinical symptoms indicative of high disease activity.
- In patients who are clinically stable after having been treated with a C5 inhibitor for at least the past 6 months.

Therapeutic group:

Immunosuppressants, complement inhibitors.

How Piasky works?

PNH can cause the immune system to attack the red blood cells and as a result lead to haemolysis (the breakdown of red blood cells).

Piasky is also called "component 5 (C5) inhibitor of the complement system". The active ingredient in Piasky, crovalimab, attaches to the C5 protein, which is a part of the body's defence system called the "complement system". This action blocks activation of C5, which prevents the immune system from attacking and damaging red blood cells, thereby reducing the breakdown of red blood cells. This helps to reduce the symptoms of PNH and the number of blood transfusions required.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient crovalimab or to any of the other ingredients in this medicine (see section 6 – ‘Additional information’).
- You have a meningococcal infection (a serious infection caused by *Neisseria meningitidis* bacteria that can affect the lining of the brain and spinal cord and spread throughout the blood).
- You have not been vaccinated against meningococcal infection, unless you will receive preventive treatment with antibiotics until 2 weeks after you have received this vaccination. See the section below: ‘Serious meningococcal infections’ and section 3 – ‘Vaccines given before you use Piasky’.

Special warnings about using this medicine

Talk to your doctor before and while using Piasky.

Serious meningococcal infections

Piasky can increase your risk of meningococcal infections caused by *Neisseria meningitidis* bacteria as it blocks part of the immune system. This includes serious infections such as septicaemia (blood poisoning) and meningitis (inflammation of the membranes that surround the brain and spinal cord).

Inform your doctor straight away if you have any of the following conditions, which may be signs of a meningococcal infection:

- Fever
- Feeling sick (nausea)
- Vomiting
- Headache
- Confusion or irritability
- Stiff neck or back
- Muscle aches, with flu-like signs or symptoms
- Sensitivity of the eyes to light
- Rashes or spots on your skin

Talk to your doctor before you start treatment with Piasky to make sure that your vaccination against meningococcal infections is up to date – you need to be fully vaccinated at least 2 weeks before you start using Piasky. Even if you were vaccinated in childhood, your doctor might decide that you need vaccination again.

If you are not fully vaccinated but you need treatment with Piasky immediately, you should get the vaccine as soon as possible. Your doctor will prescribe you treatment with antibiotics from the time you start Piasky until 2 weeks after vaccination to reduce your risk of infection.

Vaccination may not always prevent this type of infection. Your doctor might decide that you need extra measures to prevent infection.

Other serious infections

Piasky may also increase your risk of other serious infections, such as infections caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.

Tell your doctor or pharmacist straight away if you have any of the following conditions, which may be signs of infection:

- Fever
- Cough
- Chest pain
- Tiredness
- Feeling short breath
- Painful rash
- Sore throat
- Burning pain when passing urine
- Feeling weak or generally unwell

Talk to your doctor before you start treatment with Piasky to make sure that your vaccination against infections caused by *Streptococcus pneumoniae* and *Haemophilus influenzae* are up to date – you need to be fully vaccinated at least 2 weeks before you start using Piasky. Even if you were vaccinated in childhood, your doctor might decide that you need vaccination again.

If you are not fully vaccinated but you need treatment with Piasky immediately, you should get the vaccine as soon as possible. Your doctor will prescribe you treatment with antibiotics from the time you start treatment with Piasky until 2 weeks after vaccination to reduce your risk of infection.

Your doctor may recommend that you receive other vaccinations before treatment. Check with your doctor before treatment begins.

Reaction due to switching from another C5 inhibitor

Before treatment with Piasky, tell your doctor if you have ever been treated with any other C5 inhibitor. This is because you may have a type of temporary reaction, known as a Type III immune complex reaction, during the first 30 days after you switch from another C5 inhibitor to treatment with Piasky. This can also happen if you stop using Piasky and switch to a different C5 inhibitor.

Tell your doctor if you have any sign of this type of reaction, such as:

- Joint pain or other disorders related to the muscles, bones and connective tissues
- numbness and tingling or a feeling of pins and needles, especially of the hands and feet
- Rash or other skin problems
- Fever

Infusion and injection reactions

When Piasky is given as an intravenous infusion or subcutaneous injection, you may have reactions to the infusion or injection.

Inform your doctor or nurse straight away if you have any of the following conditions, which may be signs of an infusion or injection reaction:

- Headache
- Lower back pain
- Pain at infusion site and elsewhere
- Swelling
- Bruising or bleeding
- Red skin

- Itching and rash

You may also have an allergic reaction to the infusion or injection. **Inform your doctor or nurse straight away if** you have any of the following signs of a severe allergic reaction:

- Tight chest or wheezing
- Feeling short breath
- Fever or chills
- Severe dizziness, lightheadedness
- Swelling of the lips, tongue, face
- Skin itching, urticaria or rash

If you have an infusion or injection reaction, including an allergic reaction, you should confirm with your doctor or nurse if you can continue treatment with Piasky.

Stopping treatment with Piasky

If you stop taking Piasky and do not switch to another treatment for PNH, **inform your doctor immediately if** you develop symptoms that are signs of intravascular haemolysis (breakdown of red blood cells in blood vessels), including:

- Symptoms of anaemia (low level of red blood cells), such as feeling tired or having low energy and dark urine
- Belly pain
- Difficulty swallowing
- Erectile dysfunction – difficulty getting or keeping an erection (impotence)
- The kidneys not working properly
- Blood clots, with symptoms such as progressive swelling in one leg or breathlessness when not performing strenuous activities

Antibody formation (immunogenicity)

Your immune system may make antibodies (proteins made by the body against an unwanted substance) against crovalimab, potentially leading to reduced response or loss of response to Piasky. **Inform your doctor immediately if** one or more of the following symptoms appear:

- Symptoms of anaemia (low level of red blood cells), such as feeling tired or having low energy and dark urine
- Belly pain
- Difficulty swallowing
- Erectile dysfunction – difficulty getting or keeping an erection (impotence)
- The kidneys not working properly
- Blood clots, with symptoms such as progressive swelling in one leg or breathlessness when not performing strenuous activities

Children and adolescents

Do not give Piasky to children under 12 years of age or children weighing less than 40 kg. There is no information regarding the effectiveness and safety of use in this population.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. In particular if you are currently being treated or have ever been treated with any other C5 inhibitor. This is necessary

because you can have a certain temporary reaction known as a Type III hypersensitivity reaction (see 'Special warnings about using this medicine' - Reaction due to switching from another C5 inhibitor).

Pregnancy, breast-feeding and fertility

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your doctor before this medicine is administered.

There is no information about the use of Piasky in pregnant women and the effects on an unborn baby are not known. Your doctor will discuss the potential risks of using Piasky during pregnancy with you.

There is no information about whether Piasky passes into human milk but given the characteristics of the medicine, it is expected to pass into the milk and a risk to a breast-fed baby cannot be ruled out. If you are breast-feeding, your doctor will discuss the potential risks of treatment with Piasky during breast-feeding with you.

Driving and using machines

This medicine has no or little influence on the ability to drive and use machines.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Vaccines given before you use Piasky

At least 2 weeks before you start treatment with Piasky, your doctor will give you a vaccine against meningococcal infections if you have not had one before, or if your vaccination is outdated.

If you start treatment with Piasky less than 2 weeks after receiving this vaccination, your doctor will prescribe treatment with antibiotics for at least 2 weeks after the vaccination to reduce the risk of infection.

Dosage

Piasky is given as an intravenous infusion (drip into a vein) or as a subcutaneous injection (injection under the skin).

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually determined according to your weight:

If you weigh 40 kg or more, but less than 100 kg:

Loading dose stage:

- The first loading dose on Day 1 will be 1,000 mg and will be given by intravenous infusion over 60 minutes.
- The next four doses on Days 2, 8, 15 and 22 will be 340 mg. Each dose will be given as a single subcutaneous injection.

Maintenance dose stage:

- A maintenance dose of 680 mg, given as two subcutaneous injections, will be given on Day 29 and then every 4 weeks thereafter.

If you weigh 100 kg or more:

Loading dose stage:

- The first loading dose on Day 1 will be 1,500 mg and will be given by intravenous infusion over 90 minutes.
- The next four doses on Days 2, 8, 15 and 22 will be 340 mg. Each dose will be given as a single subcutaneous injection.

Maintenance dose stage:

- A maintenance dose of 1,020 mg, given as three subcutaneous injections, will be given on Day 29 and then every 4 weeks thereafter.

The maintenance dose may change if your body weight changes during treatment with Piasky. Talk to your doctor if your weight goes above 100 kg, or falls below 100 kg. Your doctor or nurse should monitor your weight on an ongoing basis.

If you were previously receiving another medicine for PNH known as a 'complement inhibitor', the first loading dose of Piasky should be given when you were scheduled to receive the next dose of the other medicine.

Do not exceed the recommended dose.

Method of administration

Piasky is given as an intravenous infusion (drip into a vein) or as a subcutaneous injection (injection under the skin).

Only the first dose will be given as an intravenous infusion by a healthcare professional. The next doses are given as a subcutaneous injection. After training, you or your caregiver may do the subcutaneous injection of Piasky at home without medical supervision.

Your doctor or nurse will provide training to you or your caregiver on how to prepare this medicine and how to administer the subcutaneous injections. Read carefully and follow the instructions under '**Instructions for Use**' at the end of this leaflet.

If you accidentally used a higher dose than required, contact your doctor, pharmacist or nurse for advice.

If you have taken an overdose, or if a child or someone else has accidentally swallowed some medicine, **immediately see a doctor** or go to a hospital emergency room and bring the medicine package with you.

If you forget to take Piasky at the scheduled time

- If you missed an appointment with your doctor or nurse to get the medicine, make another appointment straight away.
- If you or your caregiver forget to inject all or some of your dose of Piasky, one or more injections out of the total dose, at home, take the injection(s) you did not receive as soon as possible and then take the next dose at the normal planned time. Do not take a double dose to make up for a forgotten dose. Check with your doctor, pharmacist or nurse if you are not sure what to do.

For the treatment to be fully effective, it is very important to take Piasky as prescribed.

Adhere to the treatment as recommended by your doctor. Even if your health improves, **do not** stop treatment with Piasky without consulting your doctor.

If you stop treatment with Piasky

Do not stop treatment with Piasky without consulting your doctor first. This is because stopping treatment will stop the effect of the medicine. This may make your PNH symptoms come back or get worse. See section 2: 'Stopping treatment with Piasky'.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Piasky may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Your doctor will discuss the possible side effects with you and explain the risks and benefits of Piasky before treatment - see also section 2.

Piasky may cause some side effects that you need to tell your doctor about straight away. The most serious side effects are **meningococcal infection and severe allergic reaction**.

If you have one or more of the following signs of a **meningococcal infection, you should immediately contact your doctor**:

- Fever
- Feeling sick (nausea or vomiting)
- Headaches
- Confusion or irritability
- Stiff neck or back
- Muscle aches with flu-like symptoms
- Sensitivity of the eyes to light
- Skin rashes or spots

Contact your doctor immediately if any other serious infections appear

If you have one or more of the following signs of a **severe allergic reaction, you should immediately contact your doctor**:

- Tight chest or wheezing
- Feeling short of breath
- Fever or chills
- Severe dizziness
- Lightheadedness
- Swelling of the lips, tongue, face
- Skin itching, urticaria or rash

Additional side effects:

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

- Fever
- A reaction caused by switching from another C5 inhibitor (Type III hypersensitivity reaction; symptoms may include red skin, itching or pain)
- Nose and throat (upper respiratory tract) infection. Symptoms may include runny nose, sneezing, sore throat and cough
- Reactions to the infusion
- Headache

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

- Allergic reactions (hypersensitivity)
- Urinary tract infection
- Lung infection (pneumonia)
- Reaction to the injection
- Sore throat and runny nose (nasopharyngitis, cold)
- Joint pain (arthralgia)
- Abdominal pain
- Diarrhoea
- Extreme tiredness/weakness (asthenia)
- Fatigue
- Rash
- Respiratory tract infection

Uncommon side effects: (may affect up to 1 in 100 patients)

- Bacterial infection (bacteraemia)
- Infection of the kidneys (pyelonephritis)
- Severe reaction to an infection (sepsis), which may be accompanied by severe low blood pressure (septic shock)
- Local reaction at the injection site

If you experience any side effect, if any side effect gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (<http://www.health.gov.il>), which opens an online form for reporting side effects or you can also use this link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:

For additional storage conditions for healthcare professionals, see the Prescribing Information.

Store in a refrigerator (2°C-8°C).

Keep the vial in the outer carton in order to protect from light. Do not freeze. Do not shake.

Prior to administration of the medicine, if necessary, the unopened vial may be stored out of the refrigerator, at room temperature, and then returned to refrigeration. For temperature excursions outside 2°C-8°C, unopened vials in their outer carton may be kept at room temperature (up to 30°C) for a total combined time of up to 7 days. You can tick one box on the medicine package for each day the vial is stored outside refrigeration. Discard if stored out of the refrigerator at room temperature for longer than 7 days.

The medicine should be used immediately after being drawn into the syringe. Do not store syringes filled with Piasky.

Do not use this medicine if it appears cloudy, discoloured or contains particles.

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist for instructions on how to dispose of medicines you no longer use. These measures will help protect the environment.

More details are provided under '**Instructions for Use**' at the end of this leaflet. Please read carefully before using a Piasky vial.

6. Additional information

Each glass vial contains 340 mg of crovalimab in 2 mL of solution.

In addition to the active ingredient crovalimab, the medicine also contains the following inactive ingredients:

L-Arginine Hydrochloride, L-Histidine, Poloxamer 188, L-Aspartic Acid, Water for Injection

What the medicine looks like and contents of the pack

- Piasky is a sterile clear to strongly opalescent and almost colourless to brownish-yellow solution for injection/infusion.
- Each pack of Piasky contains 1 glass vial of 2 mL.

Registration holder's name and address: Roche Pharmaceuticals (Israel) Ltd., 6 Hacharash, POB 6391, Hod Hasharon 4524079, www.roche.co.il.

Manufacturer's name and address: Hoffmann-La Roche Ltd., Basel, Switzerland.

Revised in January 2026.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
179-25-38166-00

7. Instructions for use for subcutaneous administration

For instructions for use by healthcare professionals for intravenous administration, see section 'The following information is intended for healthcare professionals only'.

Before using the vial

Read this entire Instructions for Use document before you or your caregiver start using Piasky vial and each time you get a new prescription. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment. Your doctor may decide that you or your caregiver can take or give the Piasky injections.

- In this case, your doctor or nurse will show you or your caregiver how to inject your dose of Piasky the right way.
- **Do not** use Piasky vial until your doctor or nurse has trained you or your caregiver on the right way to inject.
- **Do not** inject into a vein (intravenous injection).

Storage and handling

- Store Piasky vial in its outer carton in the refrigerator between 2°C – 8°C until ready to use.
- Once removed from the refrigerator, an unopened Piasky vial in its outer carton may be kept at room temperature, up to 30°C, for a total combined time of no longer than 7 days.
- For temperature excursions outside 2°C – 8°C, when the medicine is stored at room temperature, you can tick one box on the medicine package for each day the vial is stored outside refrigeration. Discard if stored out of the refrigerator at room temperature for longer than 7 days.
- Keep the Piasky vial in the outer carton in order to protect from light.
- **After removing Piasky vial from the carton, keep it away from direct sunlight.**
- Keep vials, syringes and needles out of the reach of children.
- Each vial, syringe, and needle can be used only 1 time.
- Keep hands away from the end of needle during use and disposal of Piasky.
- **Do not** freeze the vial. **Do not** use the vial if it has been frozen. Safely throw away the vial in a sharps container (see step 43) and contact your doctor or pharmacist.
- **Do not** use the vial if it has been stored at room temperature, up to 30°C, for longer than 7 days. Safely throw away the vial in a sharps container (see step 43) and contact your doctor or pharmacist.
- **Do not** store syringes filled with Piasky. The medicine should be used immediately after being drawn into the syringe.
- **Do not** shake the vial.
- **Do not** reuse the vial, the syringe or the needles for another injection.
- **Do not** share your syringe and needles with other people.

Full dose and number of injections

Your Piasky dose may **require up to 3 injections, one after the other. You may need up to 3 Piasky vials to receive your full dose.** (See section 3: 'Dosage').

- Your doctor or pharmacist will tell you or your caregiver how many injections you need and how often you need to inject the medicine.
- **If your prescribed dose of Piasky is 680 mg, do 2 separate injections one after the other.**
- **If your prescribed dose of Piasky is 1,020 mg, do 3 separate injections one after the other.**
- Always use a new Piasky vial for each injection.
- If you are not sure of the dose, ask your doctor or pharmacist.
- **Do not** split your full dose if you do not have all the Piasky vials you need. Contact your doctor or pharmacist.

Supplies needed for one injection

This list is for a single injection. Change the number of the supplies according to the number of injections needed (see the 'Full dose and number of injections' section' above).

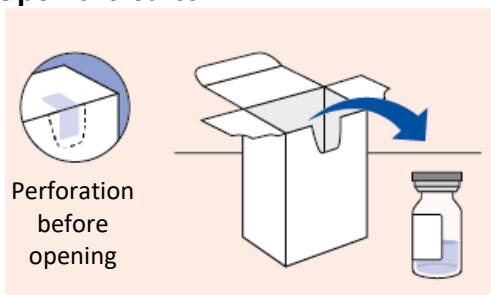
Each carton contains:

- 1 Piasky vial

Not included in the carton:

- For drawing up: 18 gauge with single bevel transfer needle or 21 gauge standard needle
- 25/26/27 gauge injection needle, preferably with safety shield. The needle length should be 9 mm-13 mm
- 2-mL or 3-mL syringe
- 2 alcohol pads (1 for your skin and 1 for the vial)
- 1 sterile cotton ball or gauze pad
- 1 small plaster (bandage)
- 1 sharps disposal or puncture-resistant container (see step 43)

Open the carton



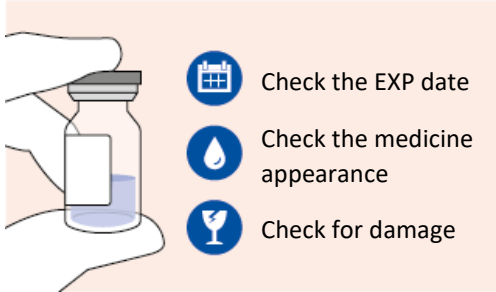
- 1 Take the Piasky vial cartons you need out of the refrigerator. Open the cartons and remove the vials.

Check the dose your doctor has prescribed. The full dose may require up to 3 injections one after the other. You may need up to 3 vials to receive a full dose. Gather all the vials you need.

2 Place the vials on a clean, flat surface.

- **Do not** use the vial if the carton is damaged. Safely throw away the vial in a sharps container (see step 43) and contact your doctor or pharmacist.

Check the vials



3 Check the expiry date (EXP) on the vials.

4 Check the appearance of the medicine.

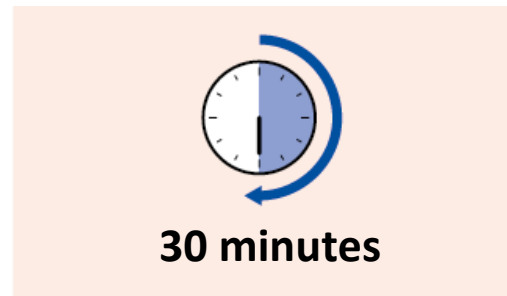
The solution must be clear to strongly opalescent and almost colourless to brownish-yellow.

5 Check the vials for any damage – for example, cracks or scratches.

- **Do not** use if the expiry date (EXP) has passed.
- **Do not** use the medicine if it appears cloudy, discoloured or contains particles.
- **Do not** use the medicine if the vial is cracked or broken.

If you identify any of the conditions described above, safely throw away the vial in a sharps container (see step 43) and contact your doctor or pharmacist.

Warm-up time

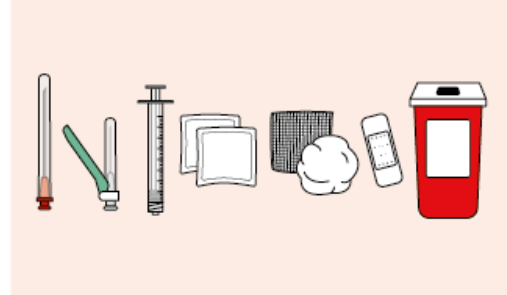


6 Place the vials on a clean, flat surface for 30 minutes, **away from direct sunlight**. This allows the medicine to reach room temperature.

If the vial is not at room temperature, the medicine will be cold and could make it difficult to withdraw and inject. This could also cause discomfort.

- **Do not** speed up the warming process in any way, such as microwave, warm water or direct sunlight.
- **Do not** remove the vial cap while the vial reaches room temperature.

Collect the additional supplies



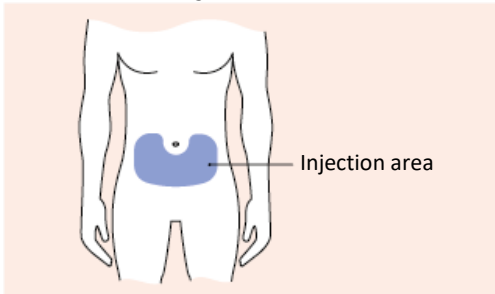
7 Collect the other supplies, while the vial reaches room temperature.

The list is for a single injection. Change the number of supplies according to the number of injections you need.

Note: the colour of your supplies might differ from the illustrations.

- 1 transfer needle
- 1 injection needle, preferably with safety shield
- 1 syringe
- 2 alcohol pads – one for your skin and one for the vial
- 1 sterile cotton ball or gauze pad
- 1 small plaster (bandage)
- 1 sharps disposal container

Choose the injection site

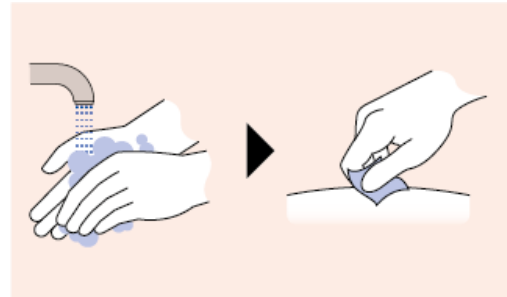


8 Piasky must only be injected in the stomach area (abdomen).

Make sure you do not inject into the same spot multiple times in a row. Each injection must be at least 5 cm apart from the previous injection.

- **Do not** inject into the arm or thigh.
- **Do not** inject into the 5 cm area around the belly button.
- **Do not** inject into moles, scars, or areas where the skin is tender, bruised, red, hard, or not intact.

Clean the injection site



9 Wash your hands with soap and water.

10 Wipe the injection site with an alcohol pad. Let the skin air dry.

- **Do not** touch, fan, or blow on the area you have cleaned.

Clean the vial top

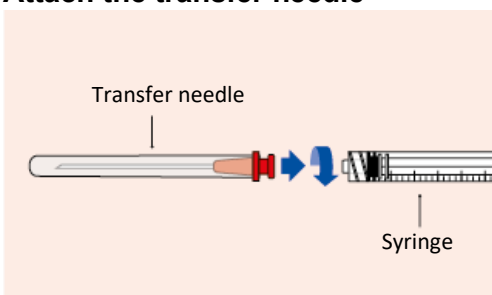


11 Remove the coloured cap from the vial. Throw away the coloured cap in the sharps container (see step 43).

12 Wipe the rubber stopper with the other alcohol pad.

- **Do not** touch the rubber stopper after it is cleaned.

Attach the transfer needle

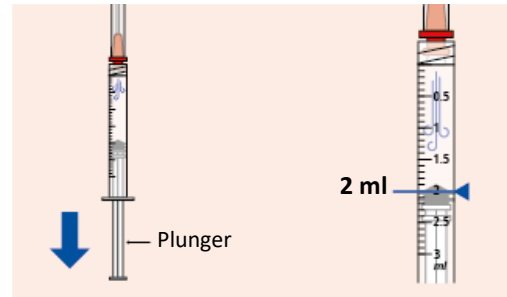


13 Remove the syringe and the transfer needle from their packaging.

14 Push and twist the transfer needle until it is fully attached to the syringe. Keep the cap on the needle.

- **Do not** use the injection needle to withdraw the medicine.

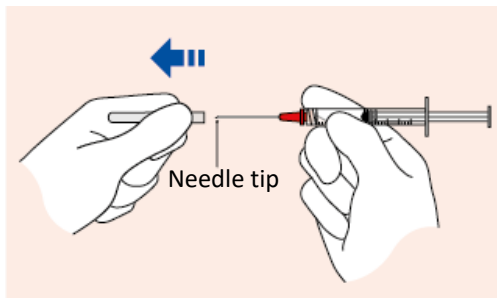
Fill the syringe with air



- 15** With the needle cap still on, slowly pull back on the plunger and draw air into the syringe **to the 2 mL line.**

Note: The vial does not contain air. The air injected into the vial will allow the medicine to be withdrawn more easily and prevent the plunger from moving.

Uncap the transfer needle



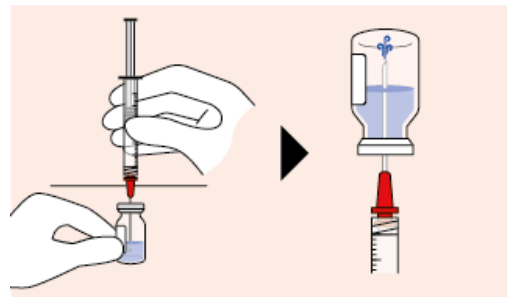
- 16** Hold the syringe in the middle and carefully pull the needle cap away from the syringe.

- 17** Keep the cap on the flat surface.

You will need to put it back on the needle after transferring the medicine.

- **Do not** throw the cap away.
- **Do not** touch the needle or let the needle touch any surface after the cap has been removed.

Inject the air into the vial



- 18** Hold the vial on the flat surface and insert the needle straight down into the centre of the rubber stopper.

- 19** Keep the needle in the vial and turn the vial upside down.

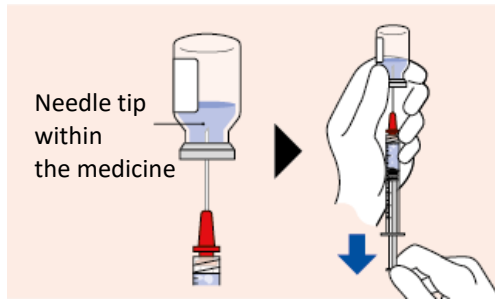
20 Make sure that the tip of the needle is higher than the level of the medicine solution.

21 With the vial on top, push on the plunger to inject the air into the vial.

22 Keep your fingers pressed down on the plunger to stop it from moving.

- **Do not** inject the air into the medicine solution so that it does not make bubbles in the medicine

Transfer all the medicine



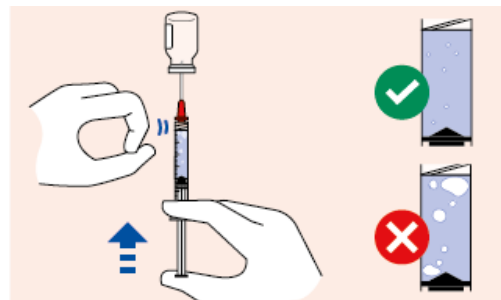
23 Slide the tip of the needle down so it is within the medicine solution.

24 Slowly pull back the plunger to **transfer all the medicine** into the syringe.

Make sure **that the tip of the needle remains within the medicine solution** at all times as the medicine is transferred into the syringe. **You may have to slide the needle down** so that air does not enter the syringe.

- **Do not** completely pull the needle out of the vial.
- **Do not** completely pull the plunger out of the syringe.

Remove the air bubbles

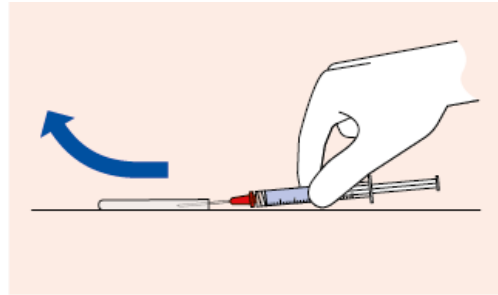


25 If you have any air bubbles or space filled with air in the syringe, gently tap the side of the syringe with your finger until the air bubbles rise to the top of the syringe.

26 Slowly push the plunger up to push the air bubbles back into the vial.

If you push some medicine into the vial, slowly pull back on the plunger (more slowly this time) to transfer all the medicine from the vial (see steps 23 and 24).

Recap the transfer needle



27 Remove the syringe from the vial.

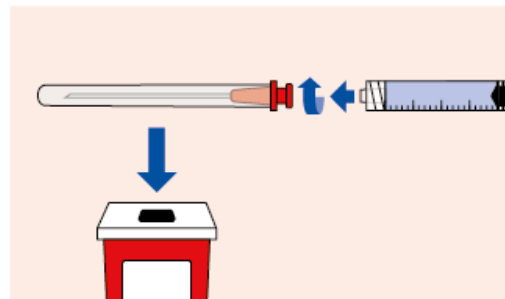
28 Using only one hand, slide the needle into the cap placed on the flat surface.

29 When the needle is covered, lift the syringe up and push the cap to fully attach over the needle.

- **Do not** hold the cap with your fingers while you slide the needle into it.

Warning: Do not use the transfer needle to inject the medicine. The transfer needle is too big to inject the medicine.

Remove the transfer needle

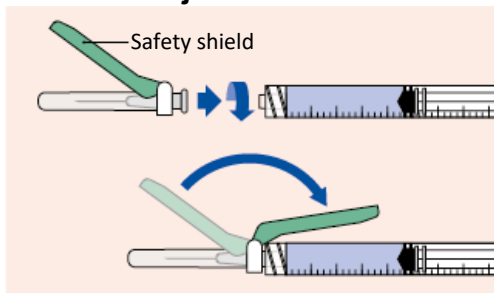


30 Hold the syringe, and twist the transfer needle to remove it.

31 Throw away the transfer needle into a sharps disposal container (see step 43).

- **Do not** touch the tip of the syringe after the transfer needle has been removed.

Attach the injection needle

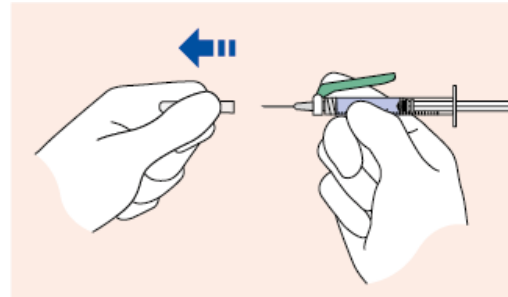


32 Remove the injection needle from its packaging.

33 Push and twist the injection needle until it is fully attached to the syringe.

34 Move the safety shield, if any, back toward the syringe as shown in the figure above.

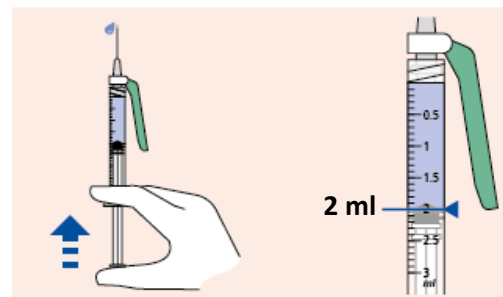
Uncap the injection needle



35 Hold the syringe in the middle and carefully pull the needle cap away from the syringe.

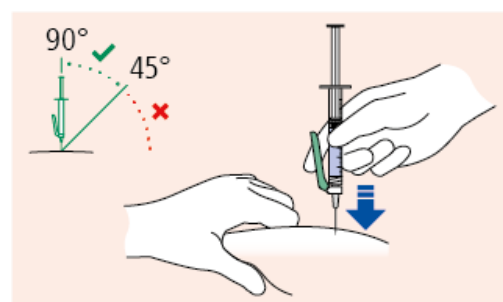
- **Do not** twist or bend the cap while you are pulling it.
- **Do not** touch the needle or let the needle touch any surface after the cap has been removed.
- **Do not** put the cap back on after it has been removed because this may damage the needle.
- **Do not** use the syringe if it has been dropped or damaged.

Adjust the plunger to dose volume



36 Slowly push the plunger **until it reaches the 2 mL line.**

Insert the needle



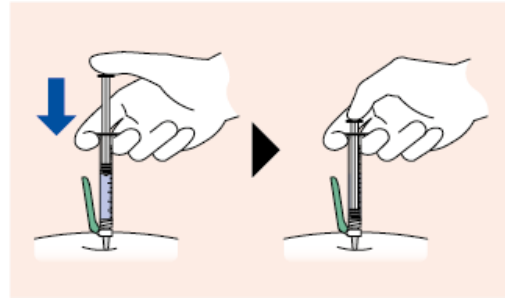
37 With one hand, pinch the cleaned skin area.

38 With the other hand, hold the syringe by the middle, at an angle between 45° to 90° to the skin.

39 With a quick motion, insert the needle all the way into the pinched skin.

- **Do not** hold or push the plunger while inserting the needle.

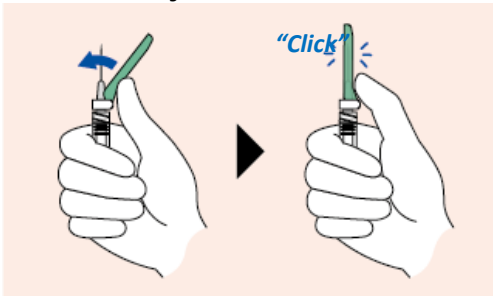
Inject the medicine



40 Slowly push the plunger all the way down to inject all the medicine.

41 Let go of the pinched skin and remove the needle.

Cover the injection needle



42 After your injection, press the safety shield, if exists, over the needle with the thumb **until you hear or feel a “click”**. If you do not hear a “click”, look to see that the needle is fully covered by the safety shield.

- **Do not** recap the needle with the original cap.
- **Do not** use your two hands to cover the needle.
- **Do not** remove the needle from the syringe.

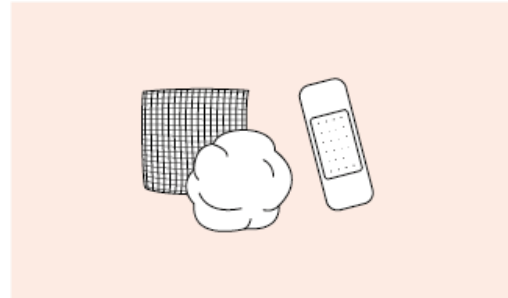
Dispose of the syringe and vial



43 Put your used Piasky vial, syringe, needles and remaining material in a sharps disposal container right after use.

- **Do not** throw away the vial, needles, and syringes in your household waste.
- **Do not** try to take the syringe apart.

Check the injection site



44 There may be a small amount of blood or medicine on your skin at the injection site.

You can press a cotton ball or gauze pad until the bleeding stops. If needed, cover the injection site with a small plaster (bandage). If the bleeding does not stop, contact your doctor.

Your injection is now complete.

- **Do not** rub or massage the area where you have injected.

Second or third injections

If the prescribed dose is 2 or 3 injections one after another, start again at step 8 with another Piasky vial and new supplies. You may need up to 3 vials for a full dose. Make sure the next injection is not at the same spot you already injected.

Disposal of the syringes and vials



Do not throw away any medicines via wastewater or household waste.

Ask the pharmacist for instructions on how to dispose of medicines you no longer use. These measures will help protect the environment.

When the container is full, make sure you dispose of it as instructed by your doctor, nurse or pharmacist.

The following information is intended for healthcare professionals only

Special precautions for disposal and other handling

Piasky vial is for single use only.

Piasky is used diluted for intravenous infusion or undiluted for subcutaneous injection.

Piasky should be inspected visually to ensure there is no particulate matter or discolouration prior to administration. Piasky is clear to strongly opalescent, and almost colourless to brownish-yellow solution. Piasky should be discarded if the medicinal product looks cloudy, discoloured or has particles in it.

Intravenous administration

Piasky must be prepared by a healthcare professional under aseptic technique. Piasky solution must be diluted in sodium chloride 9 mg/mL (0.9%) solution for infusion prior to administration. A 0.2 µm in-line filter must be used with the infusion set during administration.

A dedicated infusion line must be used during intravenous administration.

Dilution

1. Withdraw the required volume of Piasky from the vial (see Table 5) using a sterile syringe and dilute into the infusion bag. Multiple vials need to be used to meet the required volume of Piasky to be added to the infusion bag. Discard any unused portion left in the vial.

Dilution of Piasky in infusion bags containing sodium chloride 9 mg/mL (0.9%) solution for infusion must be in the range of 4-15 mg/mL (final concentration after dilution).

Intravenous infusion bags of a volume of 100 mL or 250 mL can be used.

Table 5: Dose example volume determination

Size of infusion bags (mL)	Volume of Piasky in 0.9% sodium chloride solution* (mL)	Concentration in bag (mg/mL)	Dose (mg)
250	5.9	4	1 000
250	8.8	6	1 500
100	5.9	10	1 000
100	8.8	15	1 500

* Each 340 mg vial contains a nominal fill volume of 2.0 mL

2. Gently mix the infusion bag by slowly inverting the bag. Do not shake.
3. Inspect the infusion bag for particles and discard if present.
4. Flushing of infusion line is required in order to ensure complete administration of the entire dose.

No incompatibilities have been observed between Piasky and intravenous infusion bags with product-contacting materials made of polyvinyl chloride (PVC), or polyolefins (PO) such as polyethylene (PE) and polypropylene (PP). In addition, no incompatibilities have been observed with infusion sets or infusion aids with product-contacting materials made of PVC, PE, polyurethane (PU), polybutadiene (PBD), acrylonitrile butadiene styrene (ABS), polycarbonate (PC), or polytetrafluorethylene (PTFE).

For storage conditions of the infusion bags, see section 6.3 in Prescribing Information.