Package leaflet: Information for the patient

Piasky 340 mg solution for injection/infusion crovalimab

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 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.

In addition to this leaflet, your doctor will give you a **'Patient Card'** which lists the signs of meningococcal infection and sepsis:

- Carry it with you at all times during treatment, and
- For 11 months after your last dose of Piasky

What is in this leaflet

- 1. What Piasky is and what it is used for
- 2. What you need to know before you use Piasky
- 3. How to use Piasky
- 4. Possible side effects
- 5. How to store Piasky
- 6. Contents of the pack and other information
- 7. Instructions for Use

1. What Piasky is and what it is used for

What Piasky is

Piasky contains the active substance crovalimab. It belongs to a class of medicines called 'monoclonal antibodies', which are proteins that are designed to attach to a specific target in the body. Piasky is also called a complement component 5 (C5) inhibitor.

What Piasky is used for

Piasky is used to treat a disease called paroxysmal nocturnal haemoglobinuria (PNH). It is used in adults and children aged 12 years and older who weigh 40 kg or more, including patients with haemolysis (the breakdown of red blood cells) and clinical symptoms indicating high disease activity and patients whose disease is stable after treatment with a C5 inhibitor for at least the past 6 months.

PNH can cause the immune system to attack the body's red blood cells, causing haemolysis that can lead to:

- Symptoms of anaemia (low levels of red blood cells), such as feeling tired or having low energy and dark urine
- Belly pain
- Difficulty swallowing

- Difficulty getting or keeping an erection (erectile dysfunction)
- The kidneys not working properly
- Blood clots, with symptoms such as progressive swelling in one leg or breathlessness when not performing strenuous activities

Patients with PNH can require regular blood transfusions.

How Piasky works

The active substance in Piasky, crovalimab, attaches to the complement 5 (C5) protein, which is a part of the body's defence system called the 'complement system'. By doing so, it 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. What you need to know before you use Piasky

Do not use Piasky

- if you are allergic to crovalimab or any of the other ingredients of this medicine (listed in section 6)
- if 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)
- if you have not been vaccinated against meningococcal infection, unless you will take preventive treatment with antibiotics until 2 weeks after you have received this vaccination.

Do not use Piasky if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Piasky.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before 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).

- Tell your doctor straight away if you have any of the following, 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 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 as a child, your doctor might decide that you need to be vaccinated again.

If you are not fully vaccinated but you need Piasky immediately, you should have the vaccine as soon as possible. Your doctor will prescribe you 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.

Patient card

Your doctor will give you a 'Patient Card' which lists the signs of meningococcal infection and sepsis:

- carry it with you at all times during treatment with Piasky, and
- for 11 months after your last dose of Piasky

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 pharmacist or doctor if you have any of the following, which may be signs of an infection:
 - Fever
 - Cough
 - Chest pain
 - Tiredness
 - Feeling short of breath
 - Painful rash
 - Sore throat
 - Burning pain when passing urine
 - Feeling weak or generally unwell

Talk to your doctor before you start 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 as a child, your doctor might decide that you need vaccination again.

If you are not fully vaccinated but you need Piasky immediately, you should have the vaccine as soon as possible. Your doctor will prescribe you antibiotics from the time you start 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 you take Piasky, tell your doctor if you have ever been treated with any other C5 inhibitor. This is because you can 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 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 problems related to the muscles, bones and 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 (drip into a vein) or subcutaneous injection (injection under the skin), you may have reactions to the infusion or injection. Tell your doctor or nurse straight away if you have any of the following, 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. Tell your doctor or nurse straight away if you have any of the following signs of severe allergic reactions:

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

If you have had an infusion or injection reaction, including an allergic reaction, you should confirm with your doctor or nurse if Piasky treatment should continue or not.

Stopping treatment with Piasky

If you stop taking Piasky and do not switch to another treatment for PNH, tell 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 levels of red blood cells), such as feeling tired or having low energy and dark urine
- Belly pain
- Difficulty swallowing
- Difficulty getting or keeping an erection (erectile dysfunction)
- 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. If you experience any of the following symptoms, you should tell your doctor immediately

- Symptoms of anaemia (low levels of red blood cells), such as feeling tired or having low energy and dark urine
- Belly pain
- Difficulty swallowing
- Difficulty getting or keeping an erection (erectile dysfunction)
- 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. This is because it has not yet been studied in this group.

Other medicines and Piasky

Tell your doctor, pharmacist or nurse if you are using, have recently used, or might use any other medicines.

In particular, you must tell your doctor if you are currently being treated or have ever been treated with any other C5 inhibitor. This is because you can have a type of temporary reaction, known as a Type III immune complex reaction (see "Warnings and precautions").

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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 with you the potential risks of using Piasky during pregnancy.

If you are breast-feeding, it is not known whether Piasky passes into human milk but given its characteristics, it is expected to pass into the milk. Your doctor will discuss with you the potential risks of using Piasky during breast-feeding.

Driving and using machines

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

3. How to use Piasky

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

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 antibiotics for at least 2 weeks after you have been vaccinated - to reduce the risk of infection.

How to use Piasky

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

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 take or give the subcutaneous injections. Read carefully and follow the instructions provided in the '**Instructions for Use**' at the end of this leaflet.

When to use Piasky

Your first dose will be given on Day 1 by a healthcare professional. This is the first loading dose, which is higher than the doses given later in your treatment. Additional loading doses will be given on Days 2, 8, 15, and 22.

After this, Piasky will be given on Day 29 and then every 4 weeks as a subcutaneous injection. These are the maintenance doses.

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 that medicine.

How much Piasky to use

Your doctor will prescribe a dose and treatment plan based on how much you weigh.

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

- Your first loading dose on Day 1 will be 1 000 mg, given by intravenous infusion over 60 minutes
- Your next loading doses on Day 2, 8, 15 and 22 will be 340 mg, given as a single subcutaneous injection
- You will be given a maintenance dose of 680 mg, given as two subcutaneous injections, on Day 29 and then every 4 weeks thereafter.

If you weigh 100 kg or more:

- Your first loading dose on Day 1 will be 1 500 mg, given by intravenous infusion over 90 minutes
- Your next loading doses on Day 2, 8, 15 and 22 will be 340 mg, given as a single subcutaneous injection
- You will be given a maintenance dose of 1 020 mg, given as three subcutaneous injections, on Day 29 and then every 4 weeks thereafter.

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

If you use more Piasky than you should

If you think that you have used more Piasky than prescribed, please contact your doctor, pharmacist or nurse for advice.

If you forget to use Piasky

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

- If you miss an appointment with your doctor or nurse to get your injections, make another one straight away.
- If you or your caregiver forget to inject all or some of your dose of Piasky at home, take the missed dose or missed part of the dose as soon as possible and then take the next dose at the normal planned time. Do not double a dose to make up for a missed dose. Check with your doctor, pharmacist or nurse if you are not sure.

If you stop using Piasky

Do not stop treatment with Piasky unless you have discussed this with 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.

4. **Possible side effects**

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

Your doctor will discuss the possible side effects with you and explain the risks and benefits of Piasky with you before treatment.

Piasky can 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 any following signs of a **meningococcal infection**, you should immediately inform 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
- If you have any following signs of a **severe allergic reaction**, you should immediately inform your doctor:
 - Tight chest or wheezing
 - Feeling short of breath
 - Fever or chills
 - Severe dizziness
 - Light headedness
 - Swelling of the lips, tongue, face
 - Skin itching, hives, or rash

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

- Fever
- A reaction caused by switching from another C5 inhibitor (Type III immune complex 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 (may affect up to 1 in 10 people):

- Allergic reactions (hypersensitivity)
- Urinary tract infection
- Lung infection (pneumonia)
- Reaction to the injection
- Sore throat and runny nose (nasopharyngitis)
- Joint pain (arthralgia)
- Abdominal pain

- Diarrhoea
- Extreme tiredness/weakness (asthenia)
- Fatigue
- Rash

Uncommon (may affect up to 1 in 100 people)

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

Tell your doctor, pharmacist or nurse if you notice any of the other side effects listed above. If you are not sure what the side effects above are, ask your doctor to explain them to you.

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: <u>www.mhra.gov.uk/yellowcard</u> 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 Piasky

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 carton and the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C). Once removed from the refrigerator, unopened vials in their original carton may be kept at room temperature (up to 30 °C) for no longer than 7 days. Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Do not store syringes filled with this medicine. Syringes filled with Piasky must be used right away.

Do not use this medicine if you notice it is cloudy, discoloured or contains particles.

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.

More details are provided in the Instructions for Use. Please read carefully before using Piasky vial.

6. Contents of the pack and other information

What Piasky contains

• The active substance is crovalimab. Each glass vial contains 340 mg of crovalimab in 2 mL of solution. Each mL of solution for injection/infusion contains 170 mg crovalimab.

• The other ingredients are histidine, aspartic acid, arginine hydrochloride, poloxamer 188 and water for injections.

What Piasky looks like and contents of the pack

Piasky is a 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.

Marketing Authorisation Holder and Manufacturer

Roche Products Limited 6 Falcon Way, Shire Park Welwyn Garden City AL7 1TW United Kingdom

This leaflet was last revised in July 2024.

7. Instructions for use

Before you use the vial

Read this entire Instructions for Use 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 original carton in the refrigerator between 2 °C 8 °C until ready to use. Piasky unopened vial in its original carton may be kept at room temperature up to 30 °C for no longer than 7 days.
- Keep the Piasky vial in the outer carton in order to protect from light.
- After you remove Piasky vial from the carton, keep Piasky away from direct sunlight.
- Keep Piasky vials, syringes, needles out of the reach of children.
- Each Piasky vial, syringe, and needle can be used only 1 time.
- Keep hands away from the end of needle during use and disposal.
- **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 kept 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. A syringe filled with the medicine must be used right away.
- **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.

- 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 1 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).

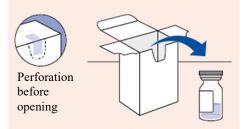
Included in the carton:

• 1 Piasky vial

Not included in the carton:

- 18 gauge with single bevel transfer needle or 21 gauge standard needle
- 25, 26 or 27 gauge injection needle with safety shield. The needle length should be from ³/₈" (9 mm) to ¹/₂" (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
- 1 small plaster
- 1 sharps disposal or puncture-resistant container (see step 43)

Open the carton

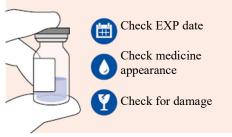


1 Take the Piasky vial carton(s) you need out of the refrigerator. Open the carton(s) and remove the vial(s).

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 vial(s) on a clean, flat surface.
- **Do not** use the vial if the carton is damaged, or if the perforation of the opening is broken. Safely throw away the vial in a sharps container (see step 43) and contact your doctor or pharmacist.

Check the vial(s)



- **3** Check the expiry date (EXP) on the vial(s).
- 4 Check the appearance of the medicine. The medicine must be clear to strongly opalescent and almost colourless to brownish-yellow.

- 5 Check the vial(s) for any damage like cracks or scratches.
- **Do not** use if the expiry date (EXP) has passed.
- **Do not** use if the medicine looks cloudy, discoloured, or has particles in it.
- **Do not** use if the vial is cracked or broken. If you find any of 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 vial(s) 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 cold medicine could make it difficult to withdraw, and harder to inject the medicine. It 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 other supplies

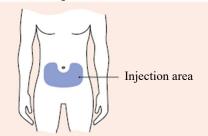


7 Collect the other supplies, while the vial reaches room temperature.
The list is for a single injection. Change the number of supplies according to the number of injections you need.

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

- 1 transfer needle
- 1 injection needle with safety shield
- 1 syringe
- 2 alcohol pads 1 for your skin and 1 for the vial
- 1 sterile cotton ball or gauze
- 1 small plaster
- 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 one.

- **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



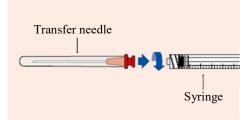
- **9** Wash your hands with soap and water.
- **10** Wipe the injection site with an alcohol pad and let it air dry.
- **Do not** touch, fan, or blow on the area you have cleaned.

Clean the vial top



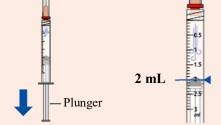
- 11 Remove the coloured cap from the vial. Throw away the coloured cap in the sharps container (see step 43).
- 12 Wipe the rubber stopper with the other alcohol pad.
- **Do not** touch the rubber stopper after it is cleaned.

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 onto the syringe. Keep the cap on the needle.
- **Do not** use the injection needle (with the safety shield) to withdraw the medicine.

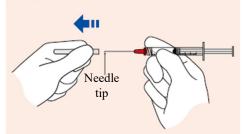




15 With the needle cap still on, slowly pull back on the plunger and draw air into the syringe to the 2-mL line.

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



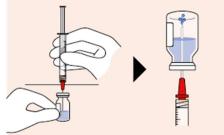
16 Hold the syringe in the middle and carefully pull the needle cap away from the syringe.

17 Keep the cap on the flat surface.

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

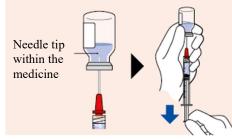
- **Do not** throw the cap away.
- **Do not** touch the needle or let the needle touch any surface after the cap has been removed.

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 above the medicine.
- 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, as this would make bubbles in the medicine.

Transfer all the medicine



- 23 Slide the tip of the needle down so it is within the medicine.
- 24 Slowly pull back the plunger to **transfer all the medicine** into the syringe.

Make sure you **keep the tip of the needle within the medicine** at all times as the medicine is transferred into the syringe. **You may have to slide the needle down** or you may transfer some air into the syringe.

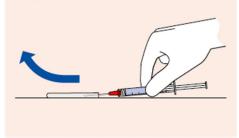
- **Do not** completely pull the needle out of the vial.
- **Do not** completely pull the plunger out of the syringe.

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 entire vial (see steps 23 and 24).

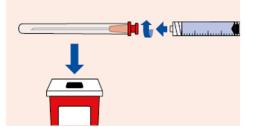
Recap the transfer needle



- **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 in it.

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

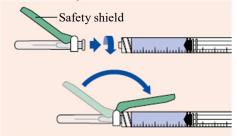
Remove the transfer needle



- **30** Hold the syringe, 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.

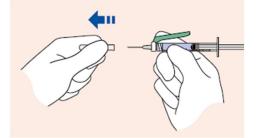
Attach the injection needle



32 Remove the injection needle from its packaging.

- **33** Push and twist the injection needle until it is fully attached onto the syringe.
- **34** Move the safety shield back toward the syringe as shown in the figure above.

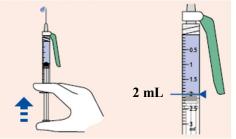
Uncap the injection needle



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

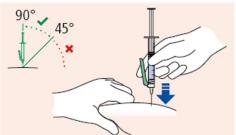
- **Do not** twist or bend the cap while you are pulling it.
- **Do not** touch the needle or let it touch any surfaces after removing the needle cap.
- **Do not** put the cap back on after it has been removed because this may damage the needle.
- **Do not** use the syringe if it has been dropped or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

Adjust the plunger



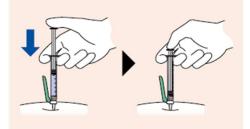
36 Slowly push the plunger **to the 2-mL line**.

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 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 your loose needles, syringe and vial, 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 at the injection site.

You can press a cotton ball or gauze until any bleeding stops. If needed, cover the injection site with a small plaster. If 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 used.

Disposal of syringes and vials



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

Ask your pharmacist how to throw away medicines you no longer use. These will help protect the environment.

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