

Package leaflet: Information for the user

Yesintek 45 mg solution for injection in pre-filled pen ustekinumab

▼ 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.

This leaflet has been written for the person taking the medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 Yesintek is and what it is used for
2. What you need to know before you use Yesintek
3. How to use Yesintek
4. Possible side effects
5. How to store Yesintek
6. Contents of the pack and other information

1. What Yesintek is and what it is used for

What Yesintek is

Yesintek contains the active substance ‘ustekinumab’, a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

Yesintek belongs to a group of medicines called ‘immunosuppressants’. These medicines work by weakening part of the immune system.

What Yesintek is used for

Yesintek is used to treat the following inflammatory diseases:

- Plaque psoriasis - in adults
- Psoriatic arthritis - in adults
- Moderate to severe Crohn’s disease - in adults
- Moderate to severe ulcerative colitis - in adults

Plaque psoriasis

Plaque psoriasis is a skin condition that causes inflammation affecting the skin and nails. Yesintek will reduce the inflammation and other signs of the disease.

Yesintek is used in adults with moderate to severe plaque psoriasis, who cannot use ciclosporin, methotrexate or phototherapy, or where these treatments did not work.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given Yesintek to:

- Reduce the signs and symptoms of your disease.
- Improve your physical function.
- Slow down the damage to your joints.

Crohn's disease

Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Yesintek to reduce the signs and symptoms of your disease.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough or are intolerant to these medicines, you may be given Stelara to reduce the signs and symptoms of your disease.

2. What you need to know before you use Yesintek

Do not use Yesintek

- **If you are allergic to ustekinumab** or any of the other ingredients of this medicine (listed in section 6).
- **If you have an active infection** which your doctor thinks is important.
- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Yesintek.

Warnings and precautions

Talk to your doctor or pharmacist before using Yesintek. Your doctor will check how well you are before each treatment. Make sure you tell your doctor about any illness you have before each treatment. Also tell your doctor if you have recently been near anyone who might have tuberculosis. Your doctor will examine you and do a test for tuberculosis, before you have Yesintek. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it.

Look out for serious side effects

Yesintek can cause serious side effects, including allergic reactions and infections. You must look out for certain signs of illness while you are taking Yesintek. See 'Serious side effects' in section 4 for a full list of these side effects.

Before you use Yesintek tell your doctor:

- **If you ever had an allergic reaction to Yesintek.** Ask your doctor if you are not sure.
- **If you have ever had any type of cancer** – this is because immunosuppressants like Yesintek weaken part of the immune system. This may increase the risk of cancer.
- **If you have been treated for psoriasis with other biologic medicines (a medicine produced from a biological source and usually given by injection)** – the risk of cancer may be higher.
- **If you have or have had a recent infection.**
- **If you have any new or changing lesions** within psoriasis areas or on normal skin.
- **If you are having any other treatment for psoriasis and/or psoriatic arthritis** – such as another immunosuppressant or phototherapy (when your body is treated with a type of ultraviolet (UV) light). These treatments may also weaken part of the immune system. Using these therapies together with Yesintek has not been studied. However, it is possible it may increase the chance of diseases related to a weaker immune system.
- **If you are having or have ever had injections to treat allergies** – it is not known if Yesintek may affect these.
- **If you are 65 years of age or over** – you may be more likely to get infections.
- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Yesintek.

Some patients have experienced lupus-like reactions including skin lupus or lupus-like syndrome during treatment with ustekinumab. Talk to your doctor right away if you experience a red, raised, scaly rash sometimes with a darker border, in areas of the skin that are exposed to the sun or with joint

pains.

Heart attack and strokes

Heart attack and strokes have been observed in a study in patients with psoriasis treated with ustekinumab. Your doctor will regularly check your risk factors for heart disease and stroke in order to ensure that they are appropriately treated. Seek medical attention right away if you develop chest pain, weakness or abnormal sensation on one side of your body, facial droop, or speech or visual abnormalities.

Children and adolescents

The Yesintek pre-filled pen is not recommended for use in children and adolescents under 18 years of age with psoriasis or Crohn's disease because it has not been studied in this age group. The pre-filled syringe or vial should be used instead for children 6 years of age and older and adolescents with psoriasis. The solution for infusion, pre-filled vial or syringe should be used instead for children weighing at least 40 kg with Crohn's disease.

Yesintek is not recommended for use in children and adolescents under 18 years of age with psoriatic arthritis or ulcerative colitis or children with Crohn's disease who weigh less than 40 kg because it has not been studied in this age group.

Other medicines, vaccines and Yesintek

Tell your doctor or pharmacist:

- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. Some types of vaccines (live vaccines) should not be given while using Yesintek.
- If you received Yesintek while pregnant, tell your baby's doctor about your Yesintek treatment before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis). Live vaccines are not recommended for your baby in the first twelve months after birth if you received Yesintek during the pregnancy unless your baby's doctor recommends otherwise.

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
- A higher risk of birth defects has not been seen in babies exposed to Yesintek in the womb. However, there is limited experience with Yesintek in pregnant women. It is therefore preferable to avoid the use of Yesintek in pregnancy.
- If you are a woman of childbearing potential, you are advised to avoid becoming pregnant and must use adequate contraception while using Yesintek and for at least 15 weeks after the last Yesintek treatment.
- Yesintek can pass across the placenta to the unborn baby. If you received Yesintek during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals if you received Yesintek during your pregnancy before the baby receives any vaccine. Live vaccines such as the BCG vaccine (used to prevent tuberculosis) are not recommended for your baby in the first twelve months after birth if you received Yesintek during the pregnancy unless your baby's doctor recommends otherwise.
- Ustekinumab may pass into breast milk in very small amounts. Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you should breast-feed or use Yesintek - do not do both.

Driving and using machines

Yesintek has no or negligible influence on the ability to drive and use machines.

Yesintek contains Polysorbate 80 (E 433)

Yesintek contains 0.02 mg of polysorbate 80 (E 433) in each 45 mg/0.5 mL pre-filled pen which is equivalent to 0.02 mg/0.5 mL (0.0003 mg/kg/day). Polysorbates may cause allergic reactions. Tell

your doctor if you have any known allergies

3. How to use Yesintek

Yesintek is intended for use under the guidance and supervision of a doctor experienced in treating conditions for which Yesintek is intended.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Talk to your doctor about when you will have your injections and follow-up appointments.

How much Yesintek is given

Your doctor will decide how much Yesintek you need to use and for how long.

Adults aged 18 years or older Psoriasis or Psoriatic Arthritis

- The recommended starting dose is 45 mg Yesintek. Patients who weigh more than 100 kilograms (kg) may start on a dose of 90 mg instead of 45 mg.
- After the starting dose, you will have the next dose 4 weeks later, and then every 12 weeks. The following doses are usually the same as the starting dose.

Crohn's disease or Ulcerative Colitis

- During treatment, the first dose of approximately 6 mg/kg Yesintek will be given by your doctor through a drip in a vein in your arm (intravenous infusion). After the starting dose, you will receive the next dose of 90 mg Yesintek after 8 weeks, then every 12 weeks thereafter by an injection under the skin ('subcutaneously').
- In some patients, after the first injection under the skin, 90 mg Yesintek may be given every 8 weeks. Your doctor will decide when you should receive your next dose.

How Yesintek is given

- Yesintek is given as an injection under the skin ('subcutaneously'). At the start of your treatment, medical or nursing staff may inject Yesintek.
- However, you and your doctor may decide that you may inject Yesintek yourself. In this case you will get training on how to inject Yesintek yourself.
- For instructions on how to inject Yesintek, see 'Instructions for use' at the end of this leaflet.

Talk to your doctor if you have any questions about giving yourself an injection.

If you use more Yesintek than you should

If you have used or been given too much Yesintek, talk to a doctor or pharmacist straight away. Always have the outer carton of the medicine with you, even if it is empty.

If you forget to use Yesintek

If you forget a dose, contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop using Yesintek

It is not dangerous to stop using Yesintek. However, if you stop, your symptoms may come back. 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.

Serious side effects

Some patients may have serious side effects that may need urgent treatment.

Allergic reactions – these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs.

- Serious allergic reactions (‘anaphylaxis’) are rare in people taking ustekinumab (may affect up to 1 in 1000 people). Signs include:
 - difficulty breathing or swallowing
 - low blood pressure, which can cause dizziness or light-headedness
 - swelling of the face, lips, mouth or throat.
- Common signs of an allergic reaction include skin rash and hives (these may affect up to 1 in 100 people).

In rare cases, allergic lung reactions and lung inflammation have been reported in patients who receive ustekinumab. Tell your doctor right away if you develop symptoms such as cough, shortness of breath, and fever.

If you have a serious allergic reaction, your doctor may decide that you should not use Yesintek again.

Infections – these may need urgent treatment. Tell your doctor straight away if you notice any of the following signs.

- Infections of the nose or throat and common cold are common (may affect up to 1 in 10 people)
- Infections of the chest are uncommon (may affect up to 1 in 100 people)
- Inflammation of tissue under the skin (‘cellulitis’) is uncommon (may affect up to 1 in 100 people)
- Shingles (a type of painful rash with blisters) are uncommon (may affect up to 1 in 100 people)

Yesintek may make you less able to fight infections. Some infections could become serious and may include infections caused by viruses, fungi, bacteria (including tuberculosis), or parasites, including infections that mainly occur in people with a weakened immune system (opportunistic infections). Opportunistic infections of the brain (encephalitis, meningitis), lungs, and eye have been reported in patients receiving treatment with ustekinumab.

You must look out for signs of infection while you are using Yesintek. These include:

- fever, flu-like symptoms, night sweats, weight loss
- feeling tired or short of breath; cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
- burning when passing water
- diarrhoea
- visual disturbance or vision loss
- headache, neck stiffness, light sensitivity, nausea or confusion.

Tell your doctor straight away if you notice any of these signs of infection. These may be signs of infections such as chest infections, or skin infections or shingles or opportunistic infections that could have serious complications. Tell your doctor if you have any kind of infection that will not go away or keeps coming back. Your doctor may decide that you should not use Yesintek until the infection goes away. Also tell your doctor if you have any open cuts or sores as they might get infected.

Shedding of skin – increase in redness and shedding of skin over a larger area of the body may be symptoms of erythrodermic psoriasis or exfoliative dermatitis, which are serious skin conditions. You should tell your doctor straight away if you notice any of these signs.

Other side effects

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

- Diarrhoea
- Nausea
- Vomiting
- Feeling tired
- Feeling dizzy

- Headache
- Itching ('pruritus')
- Back, muscle or joint pain
- Sore throat
- Redness and pain where the injection is given
- Sinus infection

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

- Tooth infections
- Vaginal yeast infection
- Depression
- Blocked or stuffy nose
- Bleeding, bruising, hardness, swelling and itching where the injection is given
- Feeling weak
- Drooping eyelid and sagging muscles on one side of the face ('facial palsy' or 'Bell's palsy'), which is usually temporary
- A change in psoriasis with redness and new tiny, yellow or white skin blisters, sometimes accompanied by fever (pustular psoriasis)
- Peeling of the skin (skin exfoliation)
- Acne

Rare side effects (may affect up to 1 in 1 000 people):

- Redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis). Similar symptoms sometimes develop as a natural change in the type of psoriasis symptoms (erythrodermic psoriasis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps, fever or joint pain (vasculitis)

Very rare side effects (may affect up to 1 in 10 000 people):

- Blistering of the skin that may be red, itchy, and painful (Bullous pemphigoid).
- Skin lupus or lupus-like syndrome (red, raised scaly rash on areas of the skin exposed to the sun possibly with joint pains).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <http://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 Yesintek

- Keep this medicine out of the sight and reach of children.
- Store in a refrigerator (2°C–8°C). Do not freeze.
- Keep the pre-filled pen in the outer carton in order to protect from light.
- If needed, individual Yesintek pre-filled pens may also be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton in order to protect from light. Record the date when the pre-filled pen is first removed from the refrigerator and the discard date in the space provided on the outer carton. The discard date must not exceed the original expiry date printed on the carton. Once a pre-filled pen has been stored at room temperature (up to 30°C), it should not be returned to the refrigerator. Discard the pre-filled pen if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Do not shake Yesintek pre-filled pens. Prolonged vigorous shaking may damage the medicine.

Do not use this medicine:

- After the expiry date which is stated on the label and the carton after 'EXP'. The expiry date refers to the last day of that month.
- If the liquid is discoloured, cloudy or you can see other foreign particles floating in it (see section 6 'What Yesintek looks like and contents of the pack').
- If you know, or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).
- If the product has been shaken vigorously.
- Yesintek is for single use only. Any unused product remaining in the pre-filled pen should be thrown away. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Yesintek contains

- The active substance is ustekinumab. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL.
- The other ingredients are L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80 (E 433), sucrose, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

What Yesintek looks like and contents of the pack

Yesintek is a clear, colorless to pale yellow solution for injection. The solution may contain a few small translucent or white particles of protein. This appearance is not unusual for proteinaceous solutions. It is supplied as a carton pack containing 1 single-dose, glass 1 mL pre-filled pen. Each pre-filled pen contains 45 mg ustekinumab in 0.5 mL of solution for injection in a type I glass 1 mL syringe with a fixed stainless steel needle is assembled with pre-filled pen components.

Marketing Authorisation Holder

Biosimilar Collaborations Ireland Limited

Unit 35/36 Grange Parade,
Baldoyle Industrial Estate,
Dublin 13, DUBLIN
Ireland,
D13 R20R

Manufacturers

Biosimilar Collaborations Ireland Limited

Block B, The Crescent Building,
Santry Demesne
Dublin
D09 C6X8
Ireland

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

United Kingdom

Biosimilars Newco Limited
Tel: 0080008250910

This leaflet was last revised in 04/2026.

Instructions for use Yesintek (ustekinumab) injection, for subcutaneous use Pre-filled pen

Read this Instructions for Use each time you use the Yesintek pre-filled pen. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important Information You Need to Know Before Injecting Yesintek

- Yesintek is a prescription medicine that is injected under the skin (subcutaneous) from a single-dose pre-filled pen.
- Do not reuse the Yesintek pre-filled pen. Always use a new Yesintek pre-filled pen for each injection.
- Your healthcare provider may decide that a caregiver can give you the injections at home. You and your caregiver should receive training on the right way to prepare and inject Yesintek before using it for the first time.
- Do not inject yourself or someone else until your healthcare provider has shown you how to inject Yesintek the right way.
- Do not use the Yesintek pre-filled pen if it is expired or damaged.
- If your dose is 45 mg, you will receive one 45 mg pre-filled pen.
- If your dose is 90 mg, you will receive two 45 mg pre-filled pens. If you receive two 45 mg pre-filled pens for a 90 mg dose, you will need to give yourself two injections, one right after the other.

Storage Information

- Store the Yesintek pre-filled pen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the Yesintek pre-filled pen in the original carton to protect it from light before use.
- If needed, the Yesintek pre-filled pen can be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to 30 days.
- Do not use the Yesintek pre-filled pen if it has been left out at room temperature for more than 30 days. Throw away (dispose of) the Yesintek pre-filled pen into a sharps disposal container. Refer to Step 15 for more information.
- Do not freeze the Yesintek pre-filled pen.
- Do not shake the Yesintek pre-filled pen.
- Keep Yesintek and all medicines out of the reach of children.

Yesintek Pre-filled pen Parts

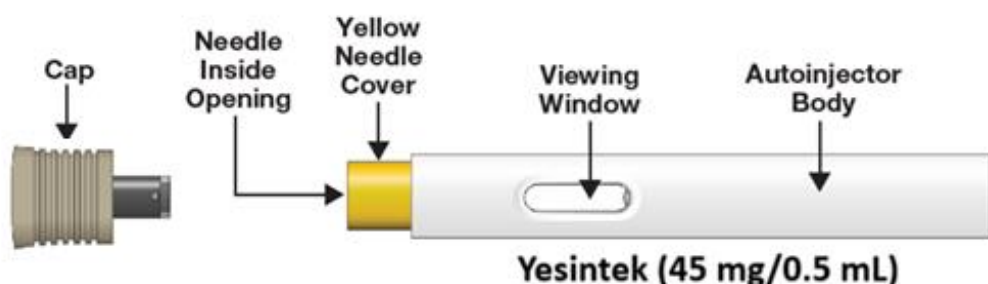


Figure A

Preparing Yesintek for Injection

1. Take out 1 Yesintek pre-filled pen

Remove the Yesintek pre-filled pen from the carton and set it down on a clean, flat surface (see Figure B).

Do not use the Yesintek pre-filled pen if the carton looks damaged or if tamper evident seal is broken.

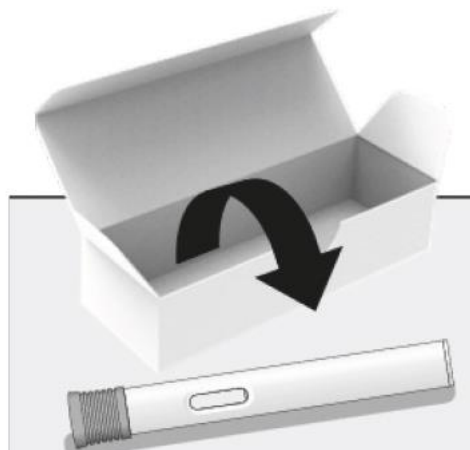


Figure B

2. Check the Yesintek pre-filled pen

- Check the Yesintek pre-filled pen for damage (see Figure C).

Do not use the Yesintek pre-filled pen if it is damaged.



Figure C

3. Check the expiration date

- Check the expiration date printed on the Yesintek pre-filled pen label (see Figure D).

Do not use the Yesintek pre-filled pen if it is expired.

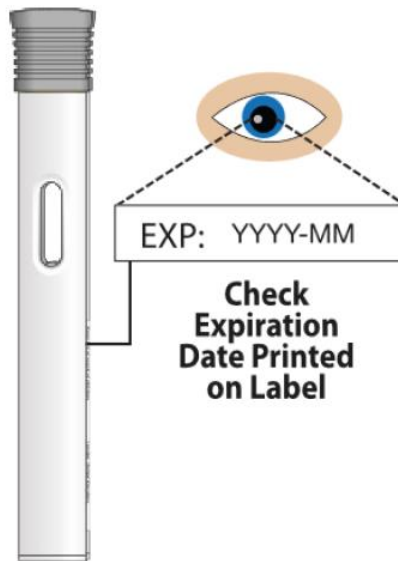


Figure D

4. Allow the Yesintek pre-filled pen to Warm to Room Temperature

- If the Yesintek pre-filled pen was stored in the refrigerator, let it sit for about 30 minutes to allow it to reach room temperature. Injecting cold medicine can be painful (see Figure E).

Do not warm any other way. For example, do not warm it in a microwave, or hot water, or near other heat sources.

Do not remove the cap until you are ready to inject.

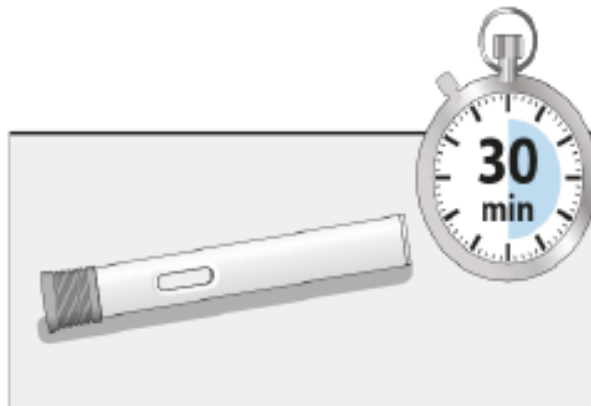


Figure E

5. Gather the supplies

- Gather the following additional supplies not included in the carton:

1 Alcohol Wipe (See Figure F)

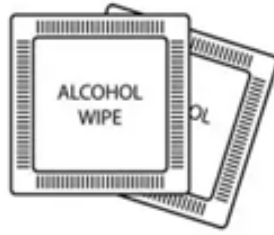


Figure F

1 Sharp Disposal Container (See Figure G). See Step 15 for instructions on how to throw away (dispose of) the used Yesintek pre-filled pen.



Figure G

1 Gauze Pad or Cotton Ball (See Figure H)

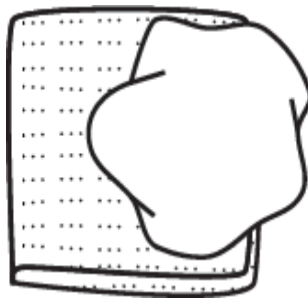


Figure H

1 Adhesive Bandage (See Figure I)

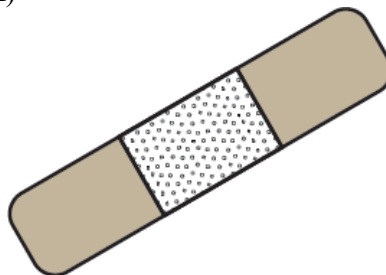


Figure I

6. Check the medicine

After the Yesintek pre-filled pen warms to room temperature, **check the medicine in the viewing window** (see Figure J). The medicine should look clear and colorless to pale yellow. It is

normal to see small air bubbles.

Do not use if the medicine is cloudy, discolored, or has large particles.

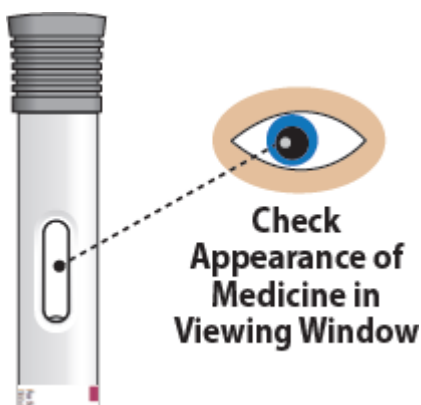


Figure J

7. Choose the injection site

- **You can inject into** (see Figure K):
 - The **front of the thigh** (Recommended), or
 - The **stomach area (abdomen)**, at least 5 cm away from the belly button.
- **If your caregiver is giving you the injection**, you may also use the **outer area of the upper arms** (see Figure K):

Do not inject into skin that is tender, bruised, red, scaly or hard.

Do not inject into areas with scars or stretch marks.

Always rotate (change) injection sites between injections. Your injection site should be at least 5 cm away from your last injection site.

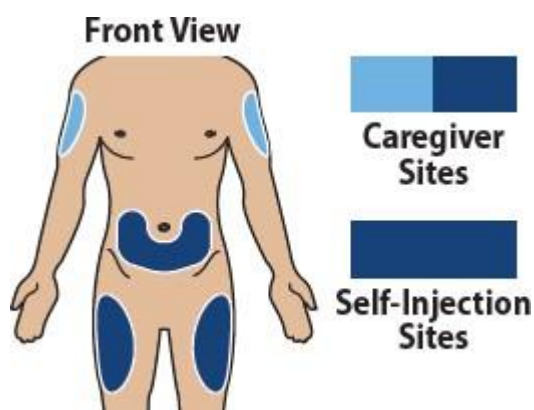


Figure K

8. Wash Hands and Clean the Injection Site

Wash your hands well with soap and water (see Figure L).



Figure L

Clean the chosen injection site with an alcohol wipe (see Figure M). Then let it air dry.

Do not touch, fan or blow on the injection site after you have cleaned it.



Figure M

Injecting Yesintek

9. Remove the Yesintek pre-filled pen cap and throw it away

- **While holding the body of the Yesintek pre-filled pen with one hand, use the other hand to pull the cap straight off** (see Figure N).
- **Throw away (dispose of) the cap** into the household trash.

Do not put the cap back on, this may damage the hidden needle.

Do not touch the yellow needle cover or put your fingers near the needle opening.

Do not use the pre-filled pen if you drop it without the cap on.

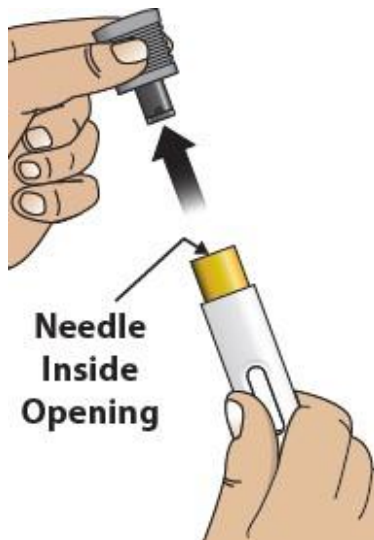


Figure N

10. Position the Yesintek pre-filled pen

Position the Yesintek pre-filled pen at the cleaned injection site.

Place the yellow needle cover of the pre-filled pen flat against the skin (90 degree angle). Make sure you can see the viewing window (see Figure O).

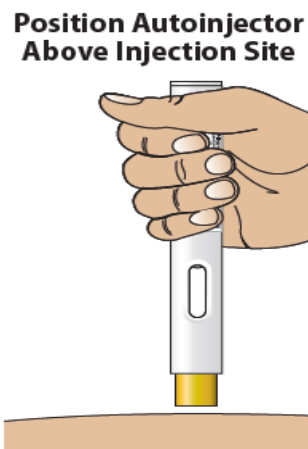


Figure O

11. Start the injection

To start the injection, press the Yesintek pre-filled pen straight down against the skin (see Figure P).

You will hear the “1st CLICK” as the injection starts.

Press Down

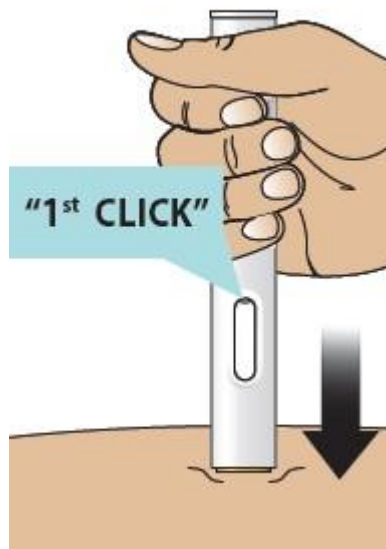


Figure P

12. Hold down

Hold the Yesintek pre-filled pen down against your skin and watch the viewing window.

The window will turn completely yellow (see Figure Q), and you will hear a “2nd CLICK”. This may take up to 15 seconds.

Hold Down

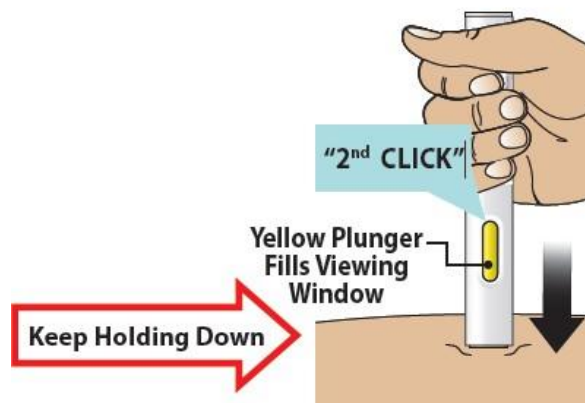


Figure Q

13. Wait 5 seconds

- **Continue holding the pre-filled pen down and wait for 5 seconds** after the window turns yellow to make sure all the medicine has been injected (see Figure R).

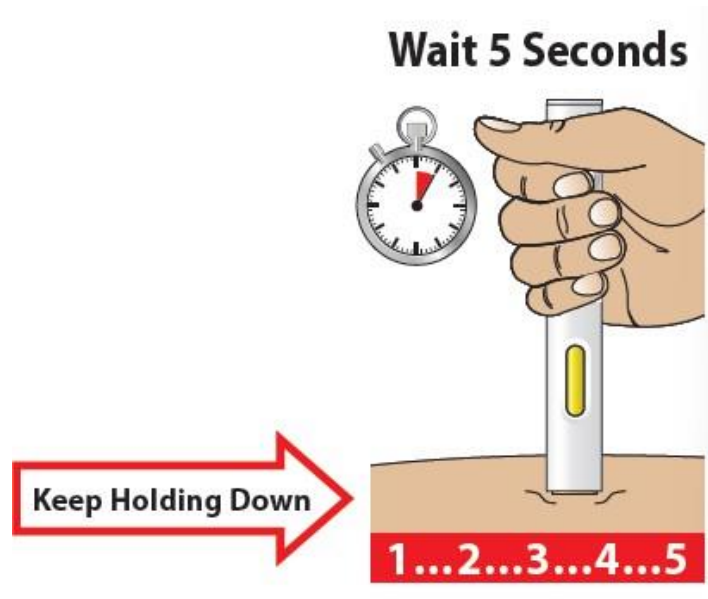


Figure R

14. Remove the pre-filled pen from the skin

- Lift the Yesintek pre-filled pen straight up from the skin (see Figure S).
- The yellow needle cover will extend to lock into place, covering the needle.



Figure S

After Injection

15. Throw away (dispose of) the used Yesintek pre-filled pen

- Throw away the used Yesintek pre-filled pen in a sharps disposal container (see Figure T).

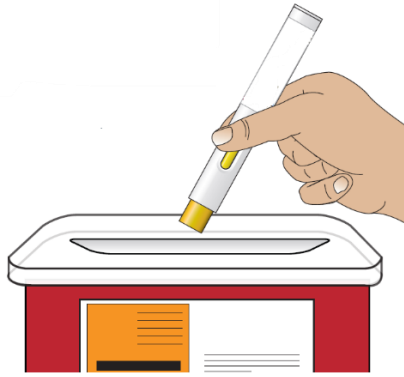


Figure T

If you do not have a cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

16. Check the injection site

- If there is bleeding at the injection site, you can press a cotton ball or gauze pad over the injection site (see Figure U).
- If needed, you may cover the injection site with an adhesive bandage.



Figure U