

# Yesintek™ Solution for Injection in Prefilled Syringe

Ustekinumab (45mg/0.5mL, 90mg/1mL)

## What is in this Leaflet:

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- 10) Date of Revision
- 11) Serial Number

### 1) What Yesintek is used for

Yesintek is a prescription medicine that is approved for the treatment of:

- Adults with moderate to severe plaque psoriasis that is chronic (doesn't go away)
- Adults with active psoriatic arthritis, an inflammatory disease of the joints that is usually accompanied by psoriasis
- Adults with moderately to severely active Crohn's disease or ulcerative colitis

### 2) How Yesintek works

Yesintek blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). IL-12 and IL-23 are made by your body's immune system. In people with psoriasis, psoriatic arthritis or Crohn's disease, IL-12 and IL-23 can cause their immune system to attack normal healthy parts of their body. Yesintek can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

### 3) Before you use Yesintek

#### When you must not use it

You should not receive Yesintek if you have:

- had an allergic reaction to Yesintek, or any of the other ingredients in Yesintek. See the end of this labeling for a complete list of ingredients in Yesintek.

#### Before you start to use it

Your doctor will assess your health before each treatment. Tell your doctor about all of your medical conditions before each treatment, including if you:

- ever had an allergic reaction to Yesintek. Ask your doctor if you are not sure.
- have any kind of infection, even if it is very minor.
- have an infection that won't go away or a history of infection that keeps coming back.
- have had TB (tuberculosis), or if you have recently been near anyone who might have TB.
- have or have had any type of cancer.
- have any new or changing lesions within psoriasis areas or on normal skin.
- have recently received or are scheduled to receive a vaccine. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system, and can cause serious problems.
- are receiving or have received 'allergy shots', especially for serious allergic reactions.
- are pregnant, planning to become pregnant, or breastfeeding. Ask your doctor for advice before taking this medicine. Yesintek should be used during a pregnancy if needed. Yesintek may pass into your breast milk in very small amounts. Women who are breastfeeding should talk to their doctor about whether or not to use Yesintek.
- have an allergy to latex.

#### Taking other medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines and show them to your doctor and pharmacist when you get a new medicine.

### 4) How to use Yesintek

- For treatment of psoriasis and psoriatic arthritis, Yesintek is given by injection under the skin.
- For treatment of Crohn's disease or ulcerative colitis, the first dose of Yesintek is given by an intravenous infusion, which means that the medicine will be given to you through a needle placed in a vein. This dose is given by your healthcare provider. After that,

Yesintek is given by injection under the skin.

- Yesintek is intended for use under the guidance and supervision of your doctor. If your doctor determines that it is appropriate, you may be able to administer Yesintek under the skin to yourself, after proper training in injection technique using the right type of syringe and the amount (volume) to be injected (see the "Instructions for Injecting Yesintek under the skin yourself").
- Your doctor will determine the right dose of Yesintek for you, the amount for each injection and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

#### How to use it

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

#### Solution for Injection for Subcutaneous Administration (Pre-filled Syringe)

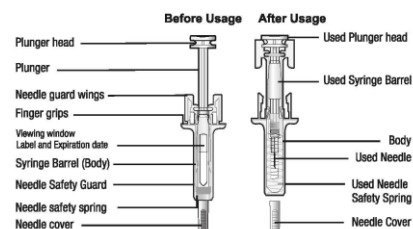


Figure 1: The pre-filled syringe

#### **Instructions for administration of Yesintek injection.**

At the start of treatment, your healthcare provider will assist you with your first injection. However, you and your doctor may decide that you may inject Yesintek yourself. If this happens, you will get training on how to inject Yesintek

# Yesintek™ Solution for Injection in Prefilled Syringe

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

- Do not mix Yesintek with other liquids for injection
- Do not shake Yesintek pre-filled syringes. This is because strong shaking may damage the medicine. Do not use the medicine if it has been shaken strongly

## 1. Check the number of pre-filled syringes and prepare the materials:

Preparing for use of the pre-filled syringe:

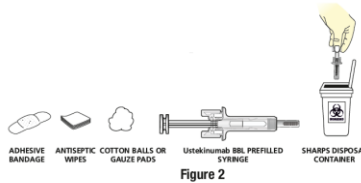
- Take the pre-filled syringe(s) out of the refrigerator. Let the pre-filled syringe stand outside the box for about half an hour. This will let the liquid come to a comfortable temperature for injection (room temperature). Do not remove the syringe's needle cover while allowing it to reach room temperature.
- Hold the pre-filled syringe by the body of the syringe with the covered needle pointing upward.
- Do not hold by the plunger head, plunger, needle guard wings, or needle cover.
- Do not pull back on the plunger at any time.
- Do not attempt to remove the needle safety guard from the pre-filled syringe.
- Do not remove the needle cover from the pre-filled syringe until instructed to do so.
- Check the pre-filled syringe(s) to make sure the number of pre-filled syringes and strength is correct.
- it is the right medicine.
- it has not passed its expiry date.
- the pre-filled syringe is not damaged.
- the solution in the pre-filled syringe is clear, colourless to pale yellow.
- the solution on the pre-filled syringe is not discoloured or cloudy and does not contain any foreign particles.

- the solution in the pre-filled syringe is not frozen.
- Get everything together that you need and lay out on a well-lit clean and flat surface. This includes antiseptic wipes, cotton ball or gauze, and a sharps container.

### Gather the supplies

Get everything together that you need and lay out on a well-lit, clean and flat surface. This includes:

- antiseptic wipes,
- a cotton ball or gauze,
- and a sharps container
- your prescribed dose of Yesintek injection (see **Figure 2**)



## 2. Choose and prepare the injection site:

Choose an injection site (see **Figure 3**)

- Yesintek is given by injection under the skin (subcutaneously).
- Good places for the injection are the upper thigh or around the belly (abdomen) at least 5 cm away from the navel (belly button).
- If possible, do not use areas of skin that show signs of psoriasis.
- If someone will assist in giving you the injection, then he or she may also choose the upper arms as an injection site



Figure 3

\*Areas in blue are recommended injection sites.

Prepare the injection site

- Choose a well-lit, clean, flat work surface.
- Wash your hands very well with soap and warm water

- Wipe the injection site on the skin with an antiseptic wipe
- Do not touch this area again before giving the injection. Let your skin dry before injecting.
- Remove pre-filled syringe tray from carton
- Open the tray by peeling away the cover. Hold the Needle safety guard
- (as shown in the **Figure 4**) to remove the pre-filled syringe from the tray

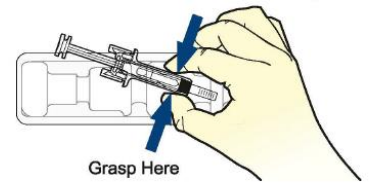


Figure 4

Hold the pre-filled syringe with the covered needle pointing upward.

## 3. Remove the needle cover (see **Figure 5**):

- The needle cover should not be removed until you are ready to inject the dose
- Pick up the pre-filled syringe, hold the body of the syringe with one hand
- Pull the needle cover straight off and throw it away. Do not touch the plunger while you do this.

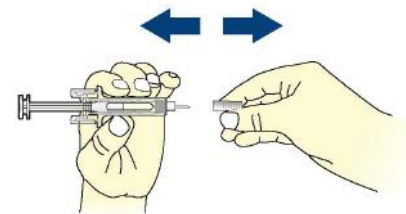


Figure 5

- You may notice an air bubble in the pre-filled syringe or a drop of liquid at the end of the needle. These are both normal and do not need to be removed
- Do not touch the needle or allow it to touch any surface
- Do not use the pre-filled syringe if it is dropped without the needle cover in place. If this happens, please contact your doctor or pharmacist

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- Inject the dose promptly after removing the needle cover.

## 4. Inject the dose

- Hold the pre-filled syringe with one hand between the middle and index fingers and place the thumb on top of the plunger head and use the other hand to gently pinch the cleaned skin between your thumb and index finger.
- Do not squeeze it tightly
- Do not pull back on the plunger at anytime
- In a single and swift motion, insert the needle through the skin as far as it will go (see **Figure 6**)

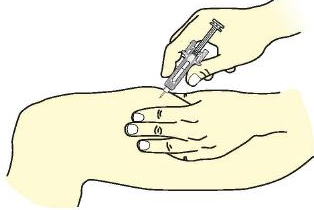


FIGURE 6

Inject all of the medication by pushing in the plunger until the plunger head is completely between the needle guard wings (see **Figure 7**).

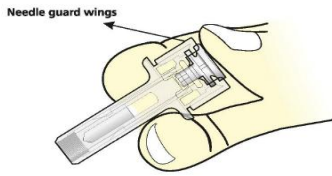


FIGURE 7

When the plunger is pushed as far as it will go, continue to keep the pressure on the plunger head, take out the needle and let go of the skin (see **Figure 8**)

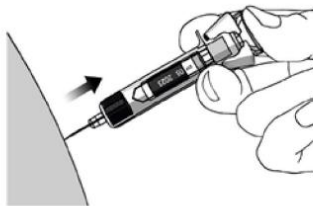


FIGURE 8

Slowly take your thumb off the plunger head to allow the empty syringe to move up until the entire needle is covered by the needle guard, as shown by **Figure 9**:

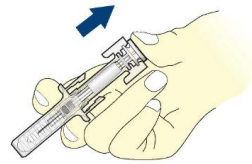


FIGURE 9

## 5. After the injection:

- Press an antiseptic wipe over the injection site for a few seconds after the injection.
- There may be a small amount of blood or liquid at the injection site. This is normal.
- You can press a cotton ball or gauze over the injection site and hold for 10 seconds.
- Do not rub the skin at the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

## 6. Disposal:

- Used syringes should be placed in a puncture-resistant container, like a sharps container (see **Figure 10**). Never re-use a syringe, for your safety and health and for the safety of others. Dispose of your sharps container according to your local regulations.
- Antiseptic wipes and other supplies can be disposed of in your garbage.



FIGURE 10

## How much to use

Your doctor will determine the right dose of Yesintek for you, the amount for each injection and how often you should receive it. Make sure to discuss with your doctor when you will receive injections and to come in for all your scheduled follow-up appointments.

## When to use it

Use as directed by your doctor or

pharmacist.

## How long to use it

Continue taking Yesintek for as long as your doctor recommends.

## If you forget to use it

Make the next injection as soon as you remember. Do not double up the injections.

If you have missed more than one dose, or are not sure what to do, check with your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

## If you use too much (Overdose)

Immediately telephone your doctor, or go to Accident and Emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

## 5) While you are using it

### Things you must do

Always follow your doctor's instructions carefully.

- Tell your doctor about your medical conditions before each treatment (see *Before you use Yesintek*).
- Tell your doctor if you become pregnant while using Yesintek.
- If you are about to start taking a new medicine, tell your doctor and pharmacist you are using Yesintek.

### Things you must not do

- You should not receive a live vaccine while taking Yesintek.
- If you used Yesintek while pregnant, tell your baby's doctor about your Yesintek use before the baby receives any vaccine, including live vaccines, such as the BCG vaccine (used to prevent tuberculosis), rotavirus vaccine, or any other live vaccines.
- Medicines are sometimes prescribed for purposes that are not mentioned in patient information sheets. Do not use Yesintek for a condition for which it was not prescribed.

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- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

## Things you must be careful of Driving and using machines

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

## 6) Side effects

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

### Serious Side Effects

**i. 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 Yesintek (may affect up to 1 in 1,000 people)
  - 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 Yesintek. 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.

**ii. 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 Yesintek.

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, skin infections, 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.

**iii. Shedding of skin** – increase in skin 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.

**iv. Allergy to latex** - The needle cover on the pre-filled syringe contain dry natural rubber (a form of latex). This may cause allergic reactions in people

who are sensitive to latex. Tell your doctor if you have ever had an allergic reaction to latex and developed any allergic reaction to Yesintek injection.

- v. Cancer** - Many drugs such as Yesintek that may decrease the activity of the immune system may increase the risk of cancer. Tell your doctor if you have ever had any type of cancer.

### 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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting side effects to medicines (ConSERF) or vaccines (AEFI)].

## 7) Storage and Disposal of Yesintek

### Storage:

- Store in refrigerator at 2°C to 8°C. Do not freeze. Do not shake.
- Keep the pre-filled syringe in the original carton to protect from light.
- If needed, individual prefilled syringes may be stored at room temperature up to 30°C for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the pre-filled syringe 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.

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- Discard the syringe if not used within 30 days at room temperature storage or by the original expiry date, whichever is earlier.
- Once a syringe has been stored at room temperature, it should not be returned to the refrigerator.

## 10) Date of Revision

27/05/2025

## 11) Serial Number

(R3)25/92

### *Disposal:*

Used syringes should be placed in a puncture-resistant container, like a sharps container. Dispose of your sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash. The syringe, needle and vial must never be re-used. Discard any unused portion of Yesintek in accordance with local requirements.

## 8) Product Description

### What it looks like

Yesintek is a clear, colorless to pale yellow solution for injection.

### Ingredients

#### - Active Ingredient

The active ingredient is ustekinumab

#### - Inactive Ingredients

The inactive ingredients include:

L-histidine, L-histidine monohydrochloride monohydrate, Polysorbate 80, Sucrose and Water for injections. No preservatives are present.

### MAL Number

Yesintek 45mg/0.5ml: MALXXXXXXXXXXXX

Yesintek 90mg/1ml : MALXXXXXXXXXXXX

## 9) Manufacturer:

Biocon Biologics Limited  
Block No. B1, B2, B3, Q13 of Q1 and W20  
& Unit S18, 1st Floor, Block B4,  
Special Economic Zone,  
Plot No. 2,3,4 & 5, Phase IV,  
Bommasandra-Jigani Link Road,  
Bengaluru 560099, India.

## Product Registration Holder:

Biocon Sdn. Bhd.  
No.1, Jalan Bioteknologi 1,  
Kawasan Perindustrian SiLC,  
79200 Iskandar Puteri, Johor, Malaysia.