

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr} YESINTEK™ (pronounced yes-in-tek)

ustekinumab injection

Solution for Subcutaneous Injection

Read this carefully before you start taking YESINTEK and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about YESINTEK.

YESINTEK is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is YESINTEK used for?

- **Adults with Plaque Psoriasis**

YESINTEK is a prescription medicine that is approved for adults with moderate to severe plaque psoriasis that is chronic (doesn't go away).

- **Children 6 to 17 years of age with Plaque Psoriasis**

YESINTEK is a prescription medicine that is approved for children and adolescent patients 6 to 17 years of age with moderate to severe plaque psoriasis that is chronic (doesn't go away) and who have had an inadequate response to other treatments.

- **Adults with Psoriatic Arthritis**

YESINTEK is a prescription medicine that is approved for adults with active psoriatic arthritis.

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis, you will be given YESINTEK by injection under the skin, alone or in combination with methotrexate, to reduce signs and symptoms of your arthritis, help improve your ability to perform daily activities (such as dressing, walking, and climbing stairs) and improve your psoriasis.

- **Adults with Crohn's disease or ulcerative colitis**

YESINTEK is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease and for adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, YESINTEK I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of YESINTEK are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given YESINTEK to help relieve your symptoms and keep the disease under control.

YESINTEK may help reduce or stop the use of your corticosteroid medication.

How does YESINTEK work?

YESINTEK blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with psoriasis, psoriatic arthritis, Crohn's disease or ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

What are the ingredients in YESINTEK?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride monohydrate, polysorbate 80, sucrose and water for injection. No preservatives are present.

YESINTEK comes in the following dosage forms:

Pre-filled Syringe:

- 45 mg / 0.5 mL
- 90 mg / 1.0 mL

The needle cover and stopper plunger on the pre-filled syringe is not made with natural rubber latex.

Single-use Vial:

- 45 mg / 0.5 mL

The vial stopper is not made with natural rubber latex.

Do not use YESINTEK if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- you have had an allergic reaction to YESINTEK or any of the other ingredients in YESINTEK (see What are the ingredients in YESINTEK? section).
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine when taking YESINTEK.

If you used YESINTEK while pregnant, tell your baby's healthcare professional 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.

Always keep medicine out of the reach of children.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take YESINTEK. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to YESINTEK or YESINTEK I.V. Ask your healthcare professional 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 burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm 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 skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional 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, think you might be pregnant, planning to become pregnant, or breast-feeding. Ustekinumab may pass into your breast milk in small amounts.

Contact your healthcare professional immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with ustekinumab in pregnant and breast-feeding women. If you are a woman of childbearing potential, you should use effective contraception when starting YESINTEK and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breast-feeding your healthcare professional will help you decide whether or not to use YESINTEK.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

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

The following may interact with YESINTEK:

- YESINTEK may change the way the body responds to live vaccines. You should not receive a live vaccine while taking YESINTEK.
- YESINTEK may interact with other medications that decrease the activity of the immune system.

How to take YESINTEK:

Instructions for injecting YESINTEK under the skin yourself:

YESINTEK may be injected by your healthcare provider. In children 6 to 17 years of age, it is recommended that all doses of YESINTEK be administered by a health care provider. However, your healthcare professional may decide that it is right for you or your caregiver to learn how to inject YESINTEK under the skin (subcutaneously) yourself. Before you self-inject YESINTEK, you must be trained by a healthcare professional. If you or your caregiver have not been trained, please contact your healthcare provider to schedule a training session. Call your healthcare provider if you have any questions about giving yourself an injection. YESINTEK is not to be mixed with other liquids for injection.

INSTRUCTIONS FOR INJECTING YESINTEK USING A PRE-FILLED SYRINGE

Guide to Parts.

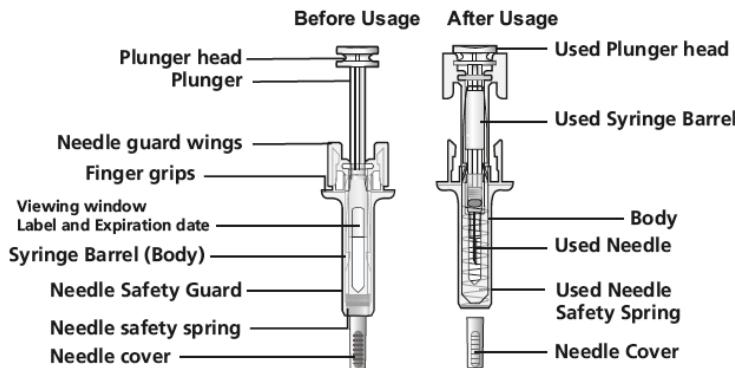


Figure A

Instructions for injecting YESINTEK injection using a prefilled syringe.

Read this Instructions for Use before you start using YESINTEK injection. Your doctor or nurse should show you how to prepare and give your injection of YESINTEK the right way.

If you cannot give yourself the injection:

- ask your doctor or nurse to help you, or
- ask someone who has been trained by a doctor or nurse to give your injections.

Do not try to inject YESINTEK injection yourself until you have been shown how to inject YESINTEK injection by your doctor, nurse or health professional.

Important information:

- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by your doctor.
 - If your dose is 45 mg, you will receive one 45 mg prefilled syringe.
 - If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes.

If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself two injections, one right after the other.

- Children 12 years of age and older with psoriasis who weigh 132 pounds or more may use a prefilled syringe.
- Check the expiration date on the prefilled syringe and carton. If the expiration date has passed or if the prefilled syringe has been kept at room temperature up to 30°C for longer than a maximum single period of 30 days or if the prefilled syringe has been stored above 30°C, do not use it. If the expiration date has passed or if the prefilled syringe has been stored above 30°C, call your doctor, pharmacist or call Biocon Biologics (1-833-986-1468) for help.

- Make sure the syringe is not damaged.
- Check your prefilled syringe for any particles or discoloration.
- Your prefilled syringe should look clear and colourless to pale yellow solution.
- Do not use if it is frozen, discolored, cloudy or has large particles. Get a new prefilled syringe.
- **Do not shake the prefilled syringe at any time.** Shaking your prefilled syringe may damage your YESINTEK injection medicine. If your prefilled syringe has been shaken, do not use it. Get a new prefilled syringe.
- To reduce the risk of accidental needle sticks, each prefilled syringe has a needle guard that is automatically activated to cover the needle after you have given your injection. Do not pull back on the plunger at any time. Do not attempt to remove the needle safety guard from the prefilled syringe.

Storage information

- YESINTEK prefilled syringes must be refrigerated at 2°C to 8°C in the original carton to protect from light until the time of use.
- Do not freeze. Do not shake.
- 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.
- Once a syringe has been stored at room temperature, it should not be returned to the refrigerator.
- Discard the syringe if not used within 30 days at room temperature storage.

Gather the supplies

You will need to prepare and to give your injection (See Figure B).

- your prescribed dose of YESINTEK injection (See Figure A)
- antiseptic wipes
- cotton balls or gauze pads
- adhesive bandage
- Sharps disposal container. **See "Step 4: Dispose of the syringe."**

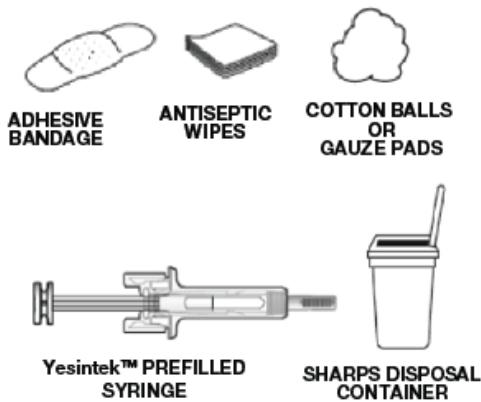


Figure B

Step 1: Prepare the injection

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water.
- Remove prefilled syringe tray from carton.
- Open the tray by peeling away the cover. Hold the Needle safety guard (as shown in the **Figure C**) to remove the prefilled syringe from the tray

△ **For safety reasons:**

- Do not “touch” or “grasp” the plunger
- Do not grasp the gray needle cover

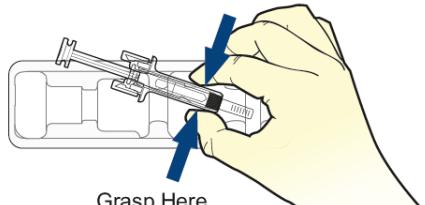


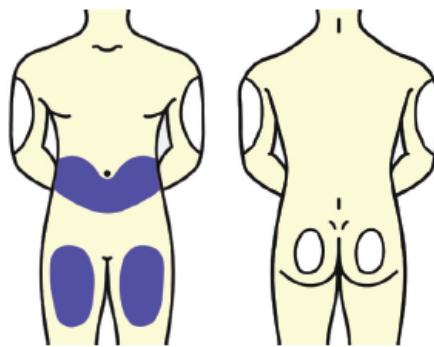
Figure C

- Hold the prefilled syringe with the covered needle pointing upward.

Step 2: Prepare your injection site

- Choose an injection site around your stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. (**See Figure D**)
- **Use a different injection site for each injection. Do not** give an injection in an area of the skin that is tender, bruised, red or hard.
- Clean the skin with an antiseptic wipe where you plan to give your injection.

- **Do not** touch this area again before giving the injection. Let your skin dry before injecting.
- **Do not** fan or blow on the clean area



White: caregivers only
 Blue: self-injection and caregivers

Figure D

*Areas in blue are recommended injection sites.

Step 3: Inject YESINTEK injection

- Remove the needle cover when you are ready to inject your YESINTEK injection.
- **Do not** touch the plunger while removing the needle cover.
- Hold the body of the prefilled syringe with one hand, and pull the needle cover straight off. (see **Figure E**)
- Put the needle cover in the trash.
- You may also see a drop of liquid at the end of the needle. This is normal.

- **Do not** touch the needle or let it touch anything.
- **Do not** use the prefilled syringe if it is dropped without the needle cover in place. Call your doctor, nurse or health

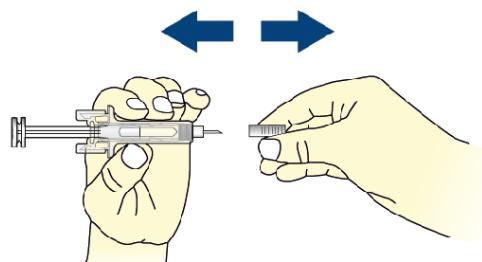


Figure E

- Hold the body of the prefilled syringe in one hand between the thumb and index fingers. (See **Figure F**)

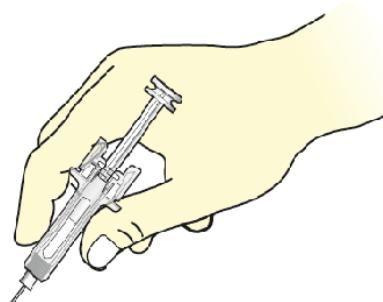


Figure F

- **Do not** pull back on the plunger at any time.
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at about a 45-degree angle. **(See Figure G)**

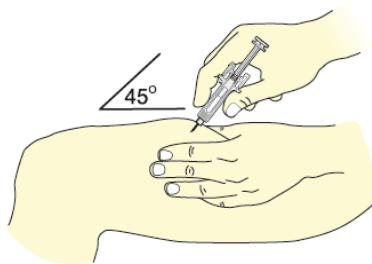


Figure G

- Inject all of the liquid by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. **(See Figure H)**

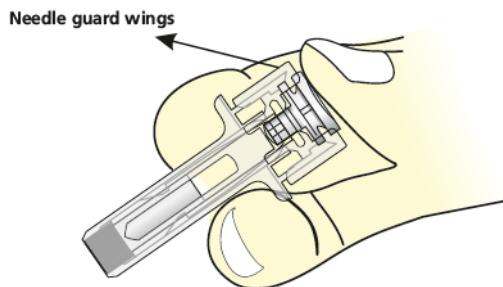


Figure H

When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin.

- Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is covered by the needle guard. **(See Figure I)**

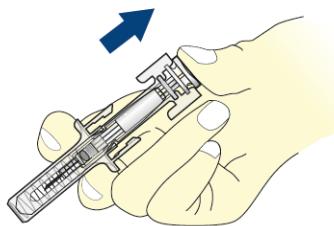


Figure I

When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes. If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself a second injection right after the first. Repeat Steps 1-3 for the second injection using a new syringe. Choose a different site for the second injection.

Step 4: Dispose of the syringe.

- Put the syringe in a sharps disposal container right away after use. **Do not throw away (dispose of) loose syringes in your household trash.**
- If you do not have a sharps disposal container, you may use a household container that is:
 - made of 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 local or state laws about how to throw away syringes and needles.
- Do not dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.
- If you have any questions, talk to your doctor or pharmacist.

Keep YESINTEK injection and all medicines out of the reach of children.

INSTRUCTIONS FOR INJECTING YESINTEK FROM A 45 mg/0.5 mL VIAL

Do not shake YESINTEK Solution for Subcutaneous Injection at any time. Prolonged vigorous shaking may damage the product. If the product has been shaken vigorously, don't use it. YESINTEK is not to be mixed with other liquids for injection.

1: CHECK VIAL(S) AND ASSEMBLE MATERIALS

Take the Vial(s) out of the Refrigerator

If your dose is 45 mg you will receive one 45 mg vial. If your dose is 90 mg, you will receive two 45 mg vials. If you receive two 45 mg vials for a 90 mg dose, you will need to give yourself two injections one right after the other. Use a new needle and syringe. Choose a different site for the second injection.

Children weighing less than 60 kg require a dose lower than 45 mg. Make sure you know the proper amount (volume) and type of syringe needed for dosing. If you don't know the amount or type of syringe needed, contact your healthcare provider for further instructions.

Check Expiration Date

Open the box and remove the vial. Check the expiration date on the vial and the label of the box. If the expiration date has passed, don't use it.

Check Solution in Vial

Make sure the vial is not damaged. Look at the solution or liquid in the vial to make sure that it is clear, colorless to pale yellow solution. **DO NOT** use if it is frozen, discolored, cloudy or contains particles and contact your healthcare provider for assistance.

Assemble Additional Supplies

Assemble the additional supplies you will need for your injection. These include an antiseptic wipe, a cotton ball or gauze, and a sharps container for syringe disposal.

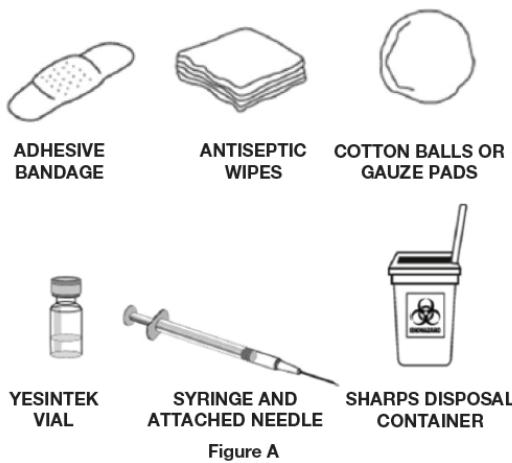
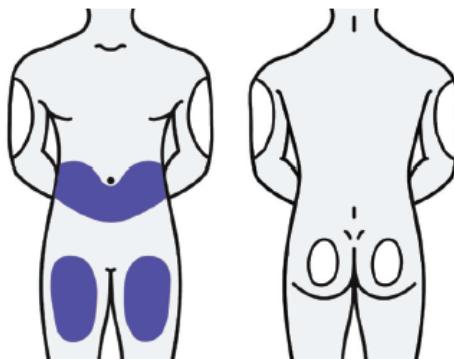


Figure A

2: CHOOSING AND PREPARING THE INJECTION SITE

Choose the Injection Site*

Good sites are the top of the thigh and around the tummy (abdomen) but about 2 inches away from the belly button (navel). Avoid, if possible, skin involved with psoriasis. If your caregiver is giving you the injection, they may use the upper arms or buttocks as well.



White: caregivers only
Blue: self-injection and caregivers

Figure B

*Areas in blue are recommended injection sites

Prepare the Injection site

Thoroughly wash your hands with soap and warm water. Wipe the injection site with an antiseptic wipe. DO NOT touch this area again before giving the injection.

3: PREPARING THE DOSE

Remove the cap from the top of the vial but do not remove the stopper. Clean the stopper with an antiseptic wipe.

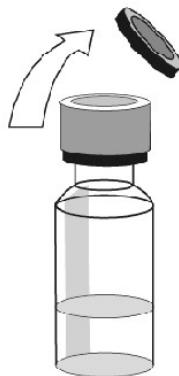


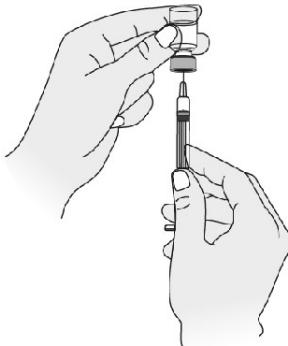
Figure C

Remove the needle cover from the syringe. Do not touch the needle or allow the needle to touch anything.

Put the vial on a flat surface and push the syringe needle through the rubber stopper. Turn the vial and the syringe upside down.

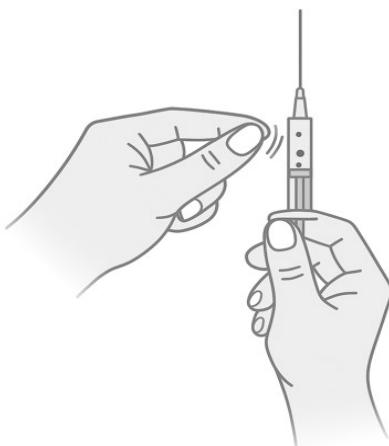
For adults and children 6 to 17 years of age, who weigh 60 kg or more, pull on the syringe plunger to fill the syringe with the entire amount (volume) of liquid prescribed by your healthcare provider. It is important that the needle is always in the liquid in order to prevent air bubbles from forming in the syringe.

For children 6 years of age or older who weigh less than 60 kg, the amount of liquid prescribed by your health care provider may be less than 0.5 mL. Your health care provider will recommend how much liquid is needed.



Remove the needle from the vial

Hold the syringe with the needle pointing up to see if it has any air bubbles inside. If there are air bubbles tap the side gently until the air bubbles, go to the top of the syringe and press the plunger until all of the air (but none of the liquid) has been removed. Do not lay the syringe down or allow the needle to touch anything.



4: INJECTING THE MEDICATION

Gently pinch the cleaned skin between your thumb and index finger. Don't squeeze it.



Push the syringe needle into the pinched skin.

Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.

When the plunger is pushed as far as it will go, take out the needle and let go of the skin.

Press an antiseptic wipe over the injection site for a few seconds after the injection.

Dispose the Empty Syringe and Vial(s)

Discard any unused portion of YESINTEK in accordance with local requirements. Immediately dispose of the empty syringe into the sharps container. For your safety and health and for the safety of others, vials, needles and syringes must NEVER be re-used. Dispose of sharps container according to your local regulations. Empty vials, antiseptic wipes, and other supplies can be placed in your regular trash.

Use a Cotton Ball or Gauze

There may be a small amount of blood or liquid at the injection site, which is normal. You can press a cotton ball or gauze over the injection site and hold for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.

Usual dose:

Psoriasis

For treatment of psoriasis, YESINTEK is given by injection under the skin.

Adults:

The recommended dose of YESINTEK is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Your healthcare professional may consider treating you as often as every 8 weeks.

90 mg may be used in patients with a body weight greater than 100 kg. Pediatric Psoriasis (6 years of age or older):

The recommended dose of YESINTEK based on body weight (as shown below) is given at Week 0 and 4, and then every 12 weeks thereafter.

Weight	Recommended dose of YESINTEK	Dosage Form
< 60kg	0.75 mg/kg*	Vial
≥ 60 to ≤ 100 kg	45 mg	Pre-filled syringe, vial
> 100 kg	90 mg	Pre-filled syringe

* For patients with body weight < 60 kg, use the vial presentation only. To calculate the volume of injection (mL) for patients < 60 kg, use the following formula: body weight (kg) x 0.0083 (mL/kg). The calculated volume should be rounded to the nearest 0.01 mL and administered using a 1 mL graduated syringe. The calculated volume of injection per kg body weight at time of dosing are also provided in table below. A 45 mg vial is available for pediatric patients who need to receive less than the full 45 mg dose.

Injection volumes of YESINTEK for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
15	11.3	0.12
16	12.0	0.13
17	12.8	0.14
18	13.5	0.15
19	14.3	0.16
20	15.0	0.17
21	15.8	0.17
22	16.5	0.18
23	17.3	0.19
24	18.0	0.20
25	18.8	0.21
26	19.5	0.22
27	20.3	0.22
28	21.0	0.23
29	21.8	0.24
30	22.5	0.25
31	23.3	0.26
32	24.0	0.27
33	24.8	0.27
34	25.5	0.28
35	26.3	0.29
36	27.0	0.30
37	27.8	0.31
38	28.5	0.32
39	29.3	0.32
40	30.0	0.33
41	30.8	0.34
42	31.5	0.35
43	32.3	0.36
44	33.0	0.37
45	33.8	0.37
46	34.5	0.38
47	35.3	0.39
48	36.0	0.40
49	36.8	0.41
50	37.5	0.42
51	38.3	0.42
52	39.0	0.43
53	39.8	0.44
54	40.5	0.45
55	41.3	0.46
56	42.0	0.46
57	42.8	0.47
58	43.5	0.48

Injection volumes of YESINTEK for pediatric psoriasis patients < 60 kg		
Body weight at time of dosing (kg)	Dose (mg)	Volume of injection (mL)
59	44.3	0.49

In children 6 to 17 of age with psoriasis, it is recommended that YESINTEK be administered by a health care provider. If your healthcare professional determines that it is appropriate, your caregiver or you may be able to administer YESINTEK 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".)

Psoriatic Arthritis

For treatment of psoriatic arthritis, YESINTEK is given by injection under the skin. The recommended dose of YESINTEK is 45 mg at Weeks 0 and 4 then every 12 weeks thereafter. Alternatively, 90 mg may be used in patients with a body weight greater than 100 kg.

Crohn's disease and ulcerative colitis

For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of YESINTEK I.V. based on body weight (as shown below) followed by 90 mg YESINTEK given by injection under the skin (subcutaneous).

Weight	Recommended Dose of YESINTEK I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (YESINTEK I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (YESINTEK)
Further treatment	Every 8 weeks* Subcutaneous injection (YESINTEK)

* your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks

Overdose:

Call your healthcare professional if you accidentally inject YESINTEK more frequently than instructed.

If you think you, or a person you are caring for, have taken too much YESINTEK, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss a dose, contact your healthcare professional for guidance.

What are possible side effects from using YESINTEK?

These are not all the possible side effects you may have when taking YESINTEK. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of YESINTEK are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea
- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

YESINTEK is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- YESINTEK may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using YESINTEK. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with YESINTEK and during treatment with YESINTEK.

Cancers

- YESINTEK may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving YESINTEK treatment.

Serious Skin Conditions

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 contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	x		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	x		
Allergic reaction (skin rash)		x	
UNCOMMON (≥0.1% and <1%)			
Cellulitis (skin infection)		x	
Vaginal yeast infections	x		
Tooth abscess/tooth infection		x	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			x
Increase in redness and shedding of skin		x	

Very common: at least 1 in 10 patients; Common: at least 1 in 100 and less than 1 in 10 patients; Uncommon: at least 1 in 1,000 and less than 1 in 100 patients; Rare: at least 1 in 10,000 and less than 1 in 1,000.

In general, the side effects of YESINTEK seen in children 6 to 17 years of age are similar to those in adults.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

If you are using YESINTEK at home, it is important to store the product in your refrigerator at 2-8°C although not in the freezer compartment. YESINTEK should not be frozen. Keep the product in the original carton to protect from light until the time of use. Do not shake.

If needed, individual YESINTEK pre-filled syringes 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 with protection from light. Record the date when the pre-filled syringe is first removed from the refrigerator and the new expiry date on the carton in the spaces provided. The new expiry date must not exceed the original expiry date printed on the carton. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage.

Always keep medicine out of the reach and sight of children.

If you want more information about YESINTEK:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>, the manufacturer's <https://www.bioconbiologics.com> or contact the manufacturer, Biosimilar Collaborations Ireland Limited at 1-833-986-1468.

This leaflet was prepared by Biosimilar Collaborations Ireland Limited (BCIL), a Biocon Biologics company.



Manufactured by:

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PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr} YESINTEK™ I.V. (pronounced yes-in-tek)

Ustekinumab for injection

Solution for Intravenous Injection

Read this carefully before you start taking YESINTEK I.V.. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about YESINTEK I.V..

YESINTEK I.V. is a biosimilar biologic drug (biosimilar) to the reference biologic drug STELARA®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

What is YESINTEK I.V. used for?

Adults with Crohn's disease or ulcerative colitis

YESINTEK I.V. / YESINTEK is a prescription medicine that is approved for adults with moderately to severely active Crohn's disease or adults with moderately to severely active ulcerative colitis. For patients with Crohn's disease or ulcerative colitis, the first dose, YESINTEK I.V., is given by an intravenous infusion, through a needle placed in a vein. Subsequent doses of YESINTEK are given by injection under the skin.

Crohn's disease (CD) is a chronic inflammatory bowel disorder. Ulcerative colitis is an inflammatory disease of the colon. If you have moderately to severely active Crohn's disease or ulcerative colitis that has not responded to other medications and you are an adult, you may be given YESINTEK I.V. / YESINTEK to help relieve your symptoms and keep the disease under control. YESINTEK I.V. / YESINTEK may help reduce or stop the use of your corticosteroid medication.

How does YESINTEK I.V. work?

YESINTEK I.V. blocks the action of two proteins in your body called interleukin 12 (IL-12) and interleukin 23 (IL-23). In people with Crohn's disease and ulcerative colitis, their immune system may attack parts of their body and that attack uses IL-12 and IL-23. Ustekinumab can block the IL-12 and IL-23 from causing the immune system to attack the skin, nails, joints or the digestive tract.

What are the ingredients in YESINTEK I.V.?

Medicinal ingredients: ustekinumab

Non-medicinal ingredients EDTA disodium salt dihydrate, L-histidine and L-histidine monohydrochloride monohydrate, L-methionine, polysorbate 80 and sucrose. No preservatives are present.

YESINTEK I.V. comes in the following dosage forms:

YESINTEK I.V. is available as a sterile solution in single-use vials. Each vial contains 130 mg ustekinumab in 26 mL. The vial stopper is not made with natural rubber latex.

Do not use YESINTEK I.V. if:

- you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).

- you have had an allergic reaction to YESINTEK, YESINTEK I.V., or any of the other ingredients in YESINTEK (see What are the ingredients in YESINTEK I.V.? section).
- after the expiration date on the label.
- the seal is broken.
- the liquid is discoloured, cloudy or you can see other particulate matter floating in it.
- you know or think that it may have been exposed to extreme temperatures (such as accidentally frozen or heated).

You should not receive a live vaccine when taking YESINTEK I.V.

If you used YESINTEK I.V. while pregnant, tell your baby's healthcare professional about your YESINTEK I.V. 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.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take YESINTEK I.V. Talk about any health conditions or problems you may have, including if you:

- ever had an allergic reaction to YESINTEK or YESINTEK I.V. Ask your healthcare professional 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 burning when you urinate.
- have diarrhea or abdominal pain.
- have had TB (tuberculosis), notice blood in your phlegm 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 skin lesions.
- have recently received or are scheduled to receive a vaccine. Tell your healthcare professional 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, think you might be pregnant, planning to become pregnant, or breast-feeding.

Ustekinumab may pass into your breast milk in small amounts.

Contact your healthcare professional immediately:

- if you develop signs of a serious allergic reaction such as skin rash, swollen face, lips, mouth, throat, wheezing, dizziness, trouble swallowing or breathing.
- if you develop headache, vision problems, seizures or change in mental status (for example, confusion).

There is limited experience with ustekinumab in pregnant and breast-feeding women. If you are a woman of childbearing potential, you should use effective contraception when starting YESINTEK I.V. and talk to your healthcare professional before planning to conceive a child. If you are pregnant or breast-feeding your healthcare professional will help you decide whether or not to use YESINTEK I.V.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with YESINTEK I.V.:

- YESINTEK I.V. may change the way the body responds to live vaccines. You should not receive a live vaccine while taking YESINTEK I.V.
- YESINTEK I.V. may interact with other medications that decrease the activity of the immune system.

How to take YESINTEK I.V.:

Crohn's disease and ulcerative colitis

Usual dose: For treatment of Crohn's disease or ulcerative colitis, the recommended dose is a single intravenous dose of YESINTEK I.V. based on body weight (as shown below) followed by 90 mg YESINTEK given by injection under the skin (subcutaneous).

Weight	Recommended Dose of YESINTEK I.V.
≤ 55 kg	260 mg
> 55 kg to ≤ 85 kg	390 mg
> 85 kg	520 mg

The recommended dosing schedule for Crohn's disease and ulcerative colitis is as follows:

Treatment number	Time of treatment Route of administration
Treatment 1	Week 0 Intravenous infusion (YESINTEK I.V.)
Treatment 2	8 weeks after Treatment 1 Subcutaneous injection (YESINTEK)
Further treatment	Every 8 weeks* Subcutaneous injection (YESINTEK)

*Your healthcare professional will decide whether the treatment interval between injections should be maintained at every 8 weeks or may be extended to every 12 weeks
The initial dose of YESINTEK I.V. for intravenous infusion for Crohn's disease or ulcerative colitis will be given over a period of at least one hour.

Overdose:

Call your healthcare professional if you accidentally inject YESINTEK more frequently than instructed.

If you think you, or a person you are caring for, have taken too much YESINTEK I.V., contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844-764-7669 immediately, even if there are no signs or symptoms.

What are possible side effects from using YESINTEK I.V.?

These are not all the possible side effects you may have when taking YESINTEK I.V. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of YESINTEK are:

- Upper respiratory tract infections such as the common cold
- Infection of the nose and throat
- Dizziness
- Headache
- Sore throat
- Diarrhea

- Nausea
- Vomiting
- Itching
- Back pain
- Muscle aches
- Joint pain
- Feeling very tired
- Redness of the skin where the injection is given
- Pain where the injection is given
- Sinus infection

YESINTEK I.V. is a medicine that affects your immune system. It can increase your risk of getting serious side effects including:

Serious Infections

- YESINTEK I.V. may lower your ability to fight infections. Some infections could become serious and lead to hospitalization. If you have an infection or have any open cuts, tell your healthcare provider before you start using YESINTEK I.V. If you get an infection, have any sign of an infection such as fever, feel very tired, cough, flu-like symptoms, or warm, red, or painful skin or sores on your body, tell your healthcare provider right away. These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications.
- Your healthcare professional will examine you for tuberculosis (TB) and perform a test to see if you have TB. If your healthcare professional feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with YESINTEK I.V. and during treatment with YESINTEK I.V..

Cancers

- YESINTEK I.V. may decrease the activity of your immune system, and increase the risk for certain types of cancer. Tell your healthcare professional if you notice any unusual changes to your skin or health status while receiving YESINTEK I.V. treatment.

Serious Skin Conditions

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 contact your healthcare professional immediately if you notice any of these signs.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON (>10%)			
Infected nose, sinuses or throat (cold)	x		
COMMON (≥1% and <10%)			
Sore throat, nasal congestion	x		
Allergic reaction (skin rash)		x	
UNCOMMON (≥0.1% and <1%)			

Cellulitis (skin infection)		x	
Vaginal yeast infections	x		
Tooth abscess/tooth infection		x	
RARE (≥0.01% and <0.1%)			
Serious allergic reactions (e.g.: swollen face or trouble breathing; symptoms such as cough, shortness of breath, and fever may also be a sign of an allergic lung reaction)			x
Increase in redness and shedding of skin		x	

Very common: at least 1 in 10 patients; Common: at least 1 in 100 and less than 1 in 10 patients; Uncommon: at least 1 in 1,000 and less than 1 in 100 patients; Rare: at least 1 in 10,000 and less than 1 in 1,000.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

YESINTEK I.V. must be stored in the original package in the refrigerator at 2-8°C before use. YESINTEK I.V. should not be frozen. Keep the product in its original carton to protect from light until the time of use. Do not shake. It must be kept out of the reach and sight of children.

If you want more information about YESINTEK I.V.:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; <https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drug-product-database.html>, the manufacturer's <https://www.bioconbiologics.com> or contact the manufacturer, Biosimilar Collaborations Ireland Limited at 1-833-986-1468.

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