



What is enthesitis-related arthritis (ERA) and what does it mean for you and your family?

For UK patients prescribed Cosentyx® (secukinumab).

Please read all of the patient information leaflet provided with your medicine carefully, as it contains important additional information about what you need to know before you (or your child) start treatment.

This leaflet has been funded and developed by Novartis Pharmaceuticals UK Ltd.

You can find full information on how to report a side effect on page 7 of this booklet.

This leaflet has been developed to support the parents and caregivers of children with ERA.

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 **NOVARTIS**

A diagnosis of ERA can be a highly emotional time for everyone involved. You might feel shock, sadness, guilt, concern or anger at the situation, or even relief that you can put a name to the condition. **These feelings are all normal.**

Give yourself and your child* time to absorb the news and don't be afraid to reach out for support. The big positive change is that now we know what it is, we can start to treat it and you can learn more.

What is ERA and what causes it?

ERA is a type of **juvenile idiopathic arthritis (JIA)** that primarily affects the entheses (these are the points where tendons and ligaments attach to bones). We don't know the exact cause of ERA, but it is linked to having an overactive immune system.¹

This means the body can mistake healthy cells and tissues for invaders like bacteria or viruses and attack them. ERA affects slightly more boys than girls, and usually starts from late childhood to early teenage years.²

The place where a tendon or ligament meets your bone is called an enthesis. Enthesitis is when they get inflamed and become painful.

*This leaflet has been developed to support the parents and caregivers of children with ERA.

Breaking down JIA – it means:

Juvenile

- affecting young people

Idiopathic

- has an unknown cause

Arthritis

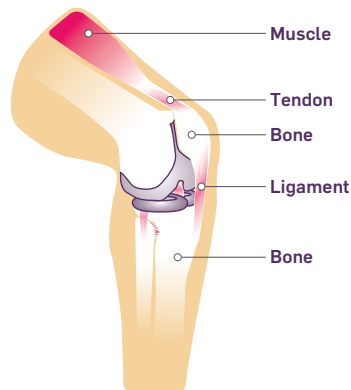
- a condition which can result in inflamed and stiff joints

What are the symptoms that your child may be feeling?

People's experience of ERA can be very varied. There are quite a few symptoms that someone could have, but it is very unlikely for one person to have them all. The symptoms can include:

- Joint stiffness, swelling, tenderness or pain (particularly around the lower back, hips, legs and feet)^{2,3}
- Inflammation of the eyes, which can result in redness, pain or fear of light^{2,3}
- Inflammation of the gut, which can result in stomach pain, weight loss, fever, tiredness or diarrhoea^{3,4}

For some people, symptoms can get better and then worse again at different times (**when things are worse it is called a flare**).⁵



How long does it last and how is it treated?

For some young people, arthritis can be a long-term condition, with symptoms that may come and go throughout life; other people find that with treatment they eventually 'outgrow' it.⁵⁻⁸ Although there is no 'cure', treatments and physical therapy are available to reduce the symptoms.⁹

There are several different treatments available for ERA. The ones that are prescribed will depend on the symptoms your child has. Some treatments, like Cosentyx (secukinumab), belong to a group of medicines called biologics. These are treatments designed to target a specific process or reaction that is causing the problem.⁹

What is Cosentyx and why has it been prescribed for your child?

This medication is an injection that works by blocking a protein called interleukin-17A, which can cause inflammation if the body produces too much of it. Blocking IL-17A may help reduce the inflammation that is causing the symptoms your child is feeling.¹⁰

Cosentyx is pronounced
co-sen-ticks



What do you need to know before your child takes Cosentyx?

Do not use this medication:

- if your child is allergic to secukinumab or any of the other ingredients of this medicine.
- if your child has an active infection which your doctor thinks is important.

Talk to your doctor, nurse or pharmacist before using Cosentyx:

- if your child currently has an infection
- if your child has long-term or repeated infections
- if your child has tuberculosis

- if your child has any allergies (including latex)
- if your child has Crohn's disease or ulcerative colitis
- if your child has recently had a vaccination or if your child is due to have one during treatment with Cosentyx
- if your child is receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy

This treatment may increase the risk of infections and may interact with certain medications. Your doctors, nurses or pharmacists can provide more information and guidance.^{10,11}



So how should your child take Cosentyx?

Always use this medication exactly as the doctor has advised you. Check with your doctor, nurse or pharmacist if you are not sure. This medication is given via injection under the skin (known as a subcutaneous injection). Your doctor should decide who, after proper training, is best to inject this medication: you might be injecting your child, or they may inject themselves. Your doctor will decide how much Cosentyx your child may need and for how long.¹¹

ERA (children aged 6 or older)^{10,11}

- The recommended dose is based on body weight as follows:
 - Weight below 25 kg: 75 mg by subcutaneous injection.
 - Weight 25 kg or above and below 50 kg: 75 mg by subcutaneous injection.
 - Weight below 50 kg: 75 mg by subcutaneous injection
 - Weight 50 kg or above: 150 mg by subcutaneous injection.*

Each 150 mg dose is given as one injection of 150 mg. Other dosage forms/strengths may be available for administration of the 75 mg dose. After the first dose, your child will receive further weekly injections at Weeks 1, 2, 3 and 4, followed by monthly injections.

If your child has received more Cosentyx than you (or they) should, or the dose has been administered sooner than according to your doctor's prescription, inform your doctor.

If you have forgotten to inject a dose of Cosentyx, inject the next dose as soon as you remember. Then talk to your doctor to discuss when you should inject the following dose.

But first, read this – it's really important!

Before you inject, it's important to be trained first by a doctor, nurse or pharmacist.

There are two different devices for Cosentyx in ERA with different sets of how-to-use instructions. Make sure you follow the right section and read ALL the way through these instructions before injecting.

If your child has been prescribed:

- Cosentyx 75 mg pre-filled syringe please read pages 12–15 only
- Cosentyx SensoReady® 150 mg pen please read pages 16–19 only

Possible Cosentyx side effects and how to report them

If your child gets side effects with any medication, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in the information leaflet that comes in the pack. You can report side effects via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard (UK). By reporting side effects you can help provide more information on the safety of the medication.¹¹

Serious side effects*⁹

Stop using this medication and speak to a doctor, nurse or pharmacist for medical help immediately if there are any of the following side effects:

Possible serious infection – the signs may include:

- fever, flu-like symptoms, night sweats
- 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 sensation when passing urine.

Serious allergic reaction – the signs may include:

- difficulty breathing or swallowing
- low blood pressure, which can cause dizziness or light-headedness
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

The doctor will decide if and when treatment may restart.

Other side effects*⁹

Most of the other side effects are mild to moderate. Upper respiratory tract infections (like a sore throat and stuffy nose) are very common. Cold sores, diarrhoea, runny nose, headache, nausea and fatigue are also common. If any side effects become severe, tell your doctor, nurse or pharmacist.

Reporting side effects

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack. You can report side effects via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of your medication.

*For a full list of side effects please consult the patient information leaflet provided with your medicine.

Top tips for well-being

ERA is only one part of a person's health. Make sure to carry on doing fun activities with your child – this will help everyone feel more positive!

Encourage your child to stay as healthy, by providing healthy food and helping them exercise. This is good for everyone, but can also help the symptoms of arthritis!^{7,10,12}

Swimming can be a great way to exercise even when feeling stiff.¹²

Keep going to school and study

It's a good idea for parents or carers to reach out to schools and teachers to help them understand about ERA. If you know certain activities or situations trigger ERA symptoms, it may be helpful to avoid or modify them. Teachers should also be made aware that with the flares of ERA, one day can look very different to another, so flexible support and accommodations will be needed. It is also important your child knows they should reach out if they have any concerns, including bullying. This isn't something they should face alone!

ERA isn't contagious and can't be passed from one person to another.

Talk, talk and talk some more!

Sharing is good. Encourage your child to talk to you, their friends and their family, when they are ready. But don't forget about yourself! No matter what you are feeling, keep talking to your family and friends. Doctors and nurses are also there for you. Talking with other people who are going through the same situation can also be a great help!

Here are just a few support groups you might want to consider:

- **Children's Chronic Arthritis Association**
<https://www.ccaa.org.uk/ccaa-support/>
- **Juvenile Arthritis Research Project**
<https://www.jarproject.org/journey>
- **Versus Arthritis**
<https://community.versusarthritis.org/categories/parents-of-children-with-arthritis>



Top tips for travelling with ERA

Sitting still for long periods may make your child stiff and uncomfortable. But a little preparation can help reduce this. If you are planning a long car journey, include extra time for plenty of rest stops. When you are travelling by plane or train, try to get an aisle seat so you can take regular short walks when it is safe to do so.



With any journey, make sure you pack drinks, healthy snacks and plenty of entertainment for distraction! Squeeze balls or putty can help keep fingers active. You might also like to have hot and cold packs or travel pillows to hand.

Remember to reach out to your doctor, nurse or pharmacist for additional advice, and pack Cosentyx plus any other medications you will need (including them in your carry-on if you are flying). Cosentyx should be stored in the refrigerator (between 2 °C and 8 °C), but it can be taken out for a single period of up to four days at room temperature (not above 30 °C) for travel.¹⁰

Finally, make sure to include some rest and recovery time when you arrive – a warm bath or swimming are a great option to loosen stiff joints.



FAQs

You and your child may have lots of questions about ERA and how it might affect their life. Explaining a serious topic to a child can be tough, especially since you might be struggling to come to terms with the diagnosis yourself. Remember that there is lots of help and support out there, both online and from your doctor, nurse or pharmacist. You don't need to have all the answers right now: you can find them together. In the meantime, here are some common questions people have.

How should I explain ERA to my child?

Your child's doctor or nurse should help you explain ERA. How you explain it will depend on your child's age. Here are the absolutely key things your child should know:

- ERA is only one part of their life – it doesn't define them.
- When it's well controlled it shouldn't prevent them from doing or achieving what they want in life.
- You are there for them.

No matter how well you explain ERA or how comforting you are, coming to terms with a diagnosis can be difficult. If your child is very young, you might need to explain ERA several times as they get older. If you feel that your child is struggling to cope, reach out to your doctor or nurse. Sometimes talking with a mental health professional can help.

Can my child have a normal life?

You have every reason to be positive! Many children 'outgrow' their arthritis. Even in those who don't, treatment should give long stretches of time where the condition isn't active.^{5,6} It can be hard at the beginning when you are learning how to adjust and manage ERA – give yourself and your child time.

What causes ERA?

While we don't fully understand what causes ERA, we think it's a combination of genetic and environmental factors. Sometimes family also have autoimmune conditions, sometimes they don't. This isn't something you or your child caused or could have avoided – it's more like a storm of circumstances. The important thing is that now you know what it is, you can help treat it.

How common is JIA?

Around 6 in every 100 000 children in the UK will develop JIA.¹¹ You might think this is low, but it actually makes JIA the most common rheumatic childhood illness.²

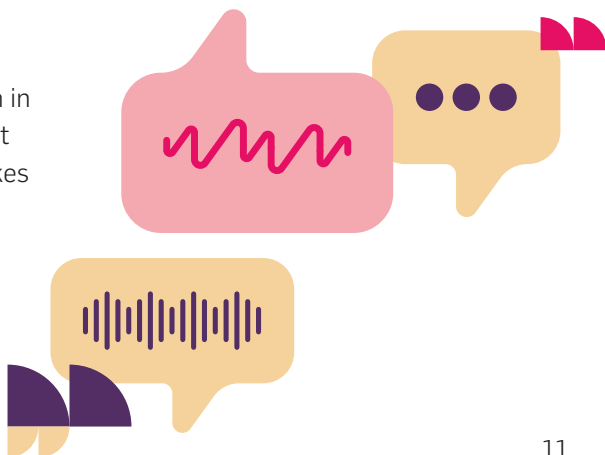
Does my child need to keep using treatment if they feel better?

Yes – they shouldn't stop even if they are feeling better. If treatment stops, the symptoms might come back, so don't stop without talking to your doctor (they should be able to tell you more and give you advice).

Will exercise make ERA worse?

No – exercise is good for everyone! Even when ERA is active, exercise won't harm the joints – but high-impact sports can sometimes be more painful, so switch to a low-impact exercise like cycling or swimming.⁷

Final tip: Caring for yourself is important too! Build up a support network so you can have breaks to support your own emotional health



How to use the Cosentyx 75 mg pre-filled syringe

These instructions on pages 12–15 are to help you to inject correctly using the Cosentyx 75 mg pre-filled syringe only



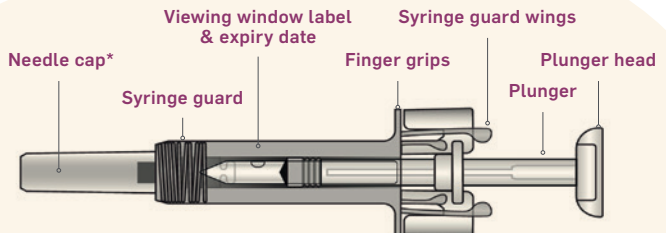
Read ALL the way through these instructions before injecting.

It is important not to try give an injection until you have been trained by a doctor, nurse or pharmacist.

- Keep the syringe out of the sight and reach of children
- Don't take the cap* off until you are ready to inject

- Store your boxed syringe (to protect it from light) in a refrigerator between 2 °C and 8 °C. It's best a parent or carer stores them for younger children
- To make the injection more comfortable, you should take the syringe out of the refrigerator 15–30 minutes before injecting so it can warm up to room temperature
- Don't freeze the syringe or shake it
- Be careful not to touch the syringe guard wings before use as the syringe guard may be activated too early
- If necessary, Cosentyx can be left out of the refrigerator for a single period of up to 4 days at room temperature, not above 30 °C
- This medicine is for single use only

This is what it looks like – along with the names of the most important parts.

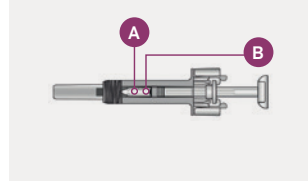


What you will also need for your injection:



- Alcohol swab
- Cotton ball or gauze
- Sharps disposal container

1



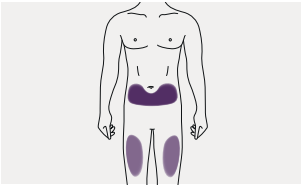
Important safety checks before the injection:

The liquid should be clear. Its colour may vary from colourless to slightly yellow.

- A. **Do not use** if the liquid contains easily visible particles, is cloudy or is distinctly brown. You may see a small air bubble, which is normal
- B. **Do not use** the syringe if the **expiry date** has passed

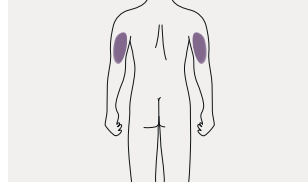
Contact your pharmacist if the syringe fails any of these checks.

2



Choose the injection site:

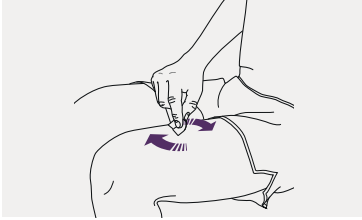
- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 5 centimetres around the navel (belly button)
- Choose a different site each time you give an injection
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars. Avoid areas with scars or stretch marks



Caregivers and healthcare professionals only:

- If a caregiver or healthcare professional is giving an injection, they may also inject into the outer upper arm

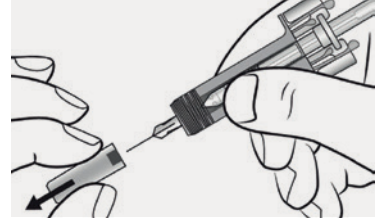
3



Cleaning the injection site:

- Wash your hands thoroughly with soap and hot water
- Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting
- Do not touch the cleaned area again before injecting

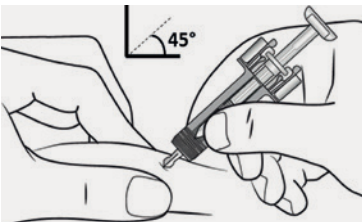
4



Preparing the injection:

- Carefully remove the needle cap from the syringe by holding the syringe guard body
- Discard the needle cap. You may see a drop of liquid at the end of the needle. This is normal

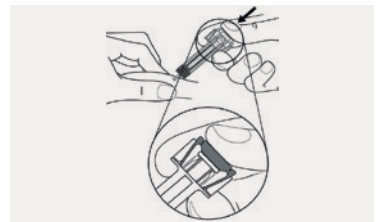
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Holding the syringe:

- Gently pinch the skin at the injection site and insert the needle as shown
- Push the needle all the way in at an angle of approximately 45 degrees to ensure that the medicine can be fully administered

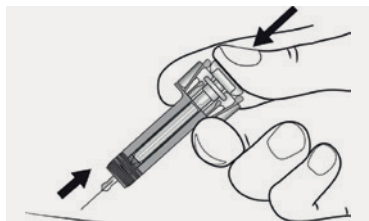
6



Starting the injection:

- Hold the syringe as shown. **Slowly** depress the plunger **as far as it will go so** that the plunger head is completely between the syringe guard wings
- Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds

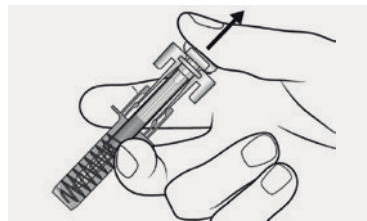
7



During the injection:

- **Keep the plunger fully depressed** while you carefully lift the needle straight out from the injection site

8



Completing the injection:

- Slowly release the plunger. After the medicine has been injected the syringe guard will be activated to cover the needle to help prevent accidental needle stick injuries
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed

9



Disposing of the Cosentyx pre-filled syringe:

- Dispose of the used syringe in a sharps container (closable, puncture resistant container). For the safety and health of you and others, needles and used syringes **must never** be re-used

How to use the Cosentyx SensoReady[®] 150 mg pen

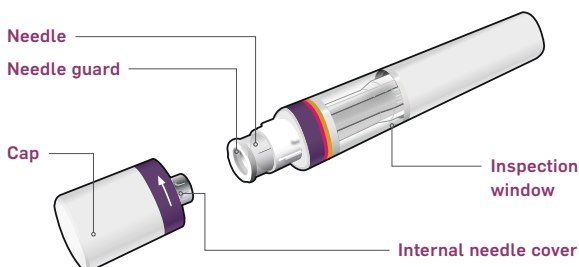
These instructions on pages 16–19 are to help you to inject correctly using the Cosentyx SensoReady[®] 150 mg pen only

! Read ALL the way through these instructions before injecting.

It is important not to try to give an injection until you have been trained by a doctor, nurse or pharmacist.

- **Don't take the cap off until you are ready to inject**

This is what it looks like – along with the names of the most important parts.



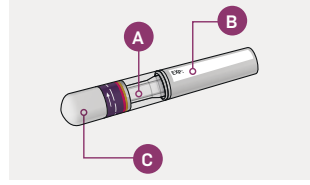
- Store your boxed pen (to protect it from light) in a refrigerator between 2 °C and 8 °C. It's best a parent or carer stores them for younger children
- To make the injection more comfortable, you can take the pen out of the refrigerator 15–30 minutes before injecting so it can warm up to room temperature
- Don't freeze the pen, shake it or use it if it has been dropped with the cap removed
- If necessary, Cosentyx can be left out of the refrigerator for a single period of up to 4 days at room temperature, not above 30 °C
- This medicine is for single use only

What you will also need for your injection:



- Alcohol swab
- Cotton ball or gauze
- Sharps disposal container

1



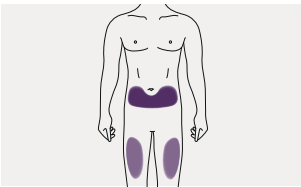
Important safety checks before the injection:

The liquid should be clear. Its colour may vary from colourless to slightly yellow.

- A. **Do not use** if the liquid contains easily visible particles, is cloudy or is distinctly brown. You may see a small air bubble, which is normal
- B. **Do not use** the pen if the **expiry date** has passed
- C. **Do not use** if the **safety seal** has been broken

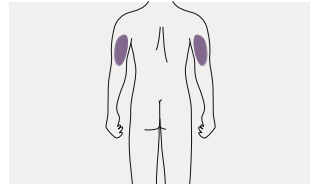
Contact your pharmacist if the pen fails any of these checks.

2



Choose the injection site:

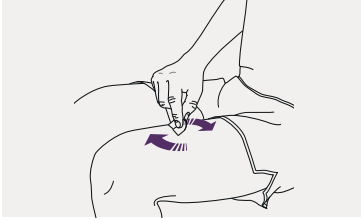
- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 5 centimetres around the navel (belly button)
- Choose a different site each time you give an injection
- Do not inject into areas where the skin is tender, bruised, red, scaly, hard or has scars. Avoid areas with scars or stretch marks



Caregivers and healthcare professionals only:

- If a caregiver or healthcare professional is giving an injection, they may also inject into the outer upper arm

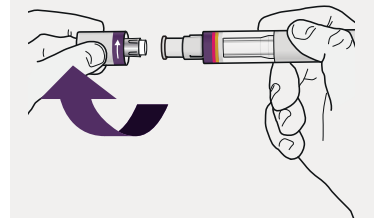
3



Cleaning the injection site:

- Wash your hands thoroughly with soap and hot water
- Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting
- Do not touch the cleaned area again before injecting

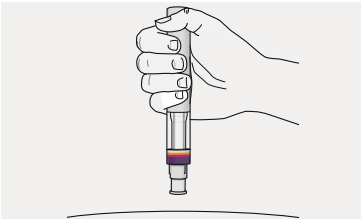
4



Removing the cap:

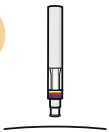
- Only remove the cap when the pen is ready to be used
- Twist off the cap in the direction of the arrows
- Once removed, throw away the cap.
Do not try to re-attach the cap
- Use the pen within 5 minutes of removing the cap

5



Holding the SensoReady® pen:

- Hold the pen at 90 degrees to the cleaned injection site



Correct

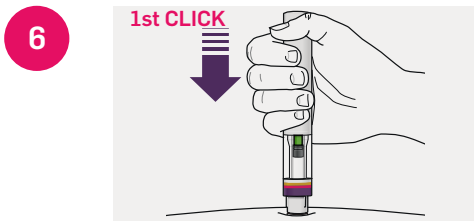


Incorrect



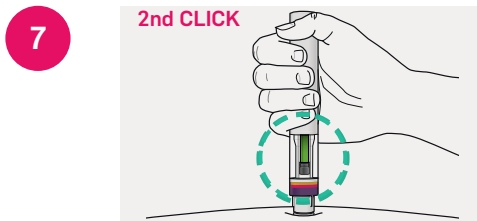
You must read this before injecting.

- During the injection you will hear **2 loud clicks**
- The **1st click** indicates that the injection has started. Several seconds later a **2nd click** will indicate that the injection is almost finished
- You must keep holding the pen firmly against the skin until you see a **green indicator** fill the window and stop moving



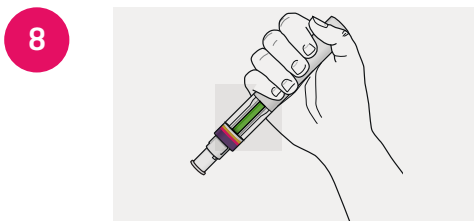
Starting your injection:

- Press the pen firmly against the skin to start the injection
- The **1st click** indicates the injection has started
- **Keep holding** the pen firmly against the skin
- The **green indicator** shows the progress of the injection



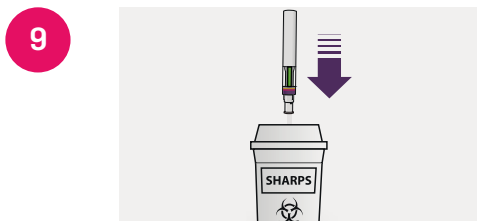
Completing the injection:

- Listen for the **2nd click**. This indicates the injection is **almost** complete
- Check the **green indicator** fills the window and has stopped moving
- The pen can now be removed



Check the green indicator fills the window:

- This means the medicine has been delivered. Contact your doctor if the **green indicator** is not visible
- There may be a small amount of blood at the injection site
- You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed



Disposing of the Cosentyx SensoReady® pen:

- Dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container)
- Never try to reuse the pen

What does that mean? (glossary)

arthritis

- A condition that results in swelling and pain of the joints

biologic(s)

- A medicine that targets a particular function of the body to treat disease. They are called biologic because they are made by living organisms

Cosentyx

- A biological therapy for ERA (it's made with cells in a laboratory)

entheses

- The spot where ligaments and tendons attach to bones

enthesitis

- Inflammation of the entheses

genetic

- Related to genes (instructions in your cells that tell them what to do)

idiopathic

- A disease with an unknown cause

inflammation

- A response of the body caused by the immune system causing it to be red, swollen and painful

interleukin-17A

- A protein related to inflammation

juvenile

- Related to children

ligament

- The part of the body that attaches bone to bone

secukinumab

- The active ingredient in Cosentyx

subcutaneous

- Below the skin

symptom

- A sign of a condition or illness

tendon

- The part of the body that attaches muscle to bone

Notes

Notes

Thanks for reading

We hope this information is useful to you.
Stay positive, and never be afraid to
share how you feel or ask for help.



References

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Reporting side effects

If you get side effects with any medication you are taking, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the information leaflet that comes in the pack. You can report side effects via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of your medication.