FRAIZERON®

Secukinumab
(300mg/2ml, 150 mg/mL Solution for injection in a pre-filled pen)

What is in this leaflet

What Fraizeron® is used for

Fraizeron contains the active substance secukinumab. Secukinumab is a fully-human monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.
It belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by neutralising the activity of a protein called IL-17A, which is present at increased levels in diseases such as psoriasis, psoriatic arthritis, axial spondyloarthritis (ankylosing spondylitis and non-radiographic axial spondyloarthritis) and hidradenitis suppurativa.
Fraizeron is used for the treatment of the following inflammatory diseases:

Plaque psoriasis
Fraizeron is used to treat a skin condition called 'plaque psoriasis'. Plaque psoriasis causes inflammation affecting the skin. Fraizeron will reduce the inflammation and other symptoms of the disease.
Fraizeron is used in patients 6 years and older with moderate to severe plaque psoriasis.
Psoriatic arthritis
Fraizeron is used to treat a condition called 'psoriatic arthritis'. The condition is an inflammatory disease of the joints, often accompanied by psoriasis. Fraizeron is given to you to reduce the signs and symptoms of active psoriatic arthritis, improve physical function and slow down the damage to the cartilage and the bone of the joints involved in the disease.
Fraizeron is used in adults with active psoriatic arthritis and can be used alone or with another medicine called methotrexate.
Axial spondyloarthritis, including ankylosing spondylitis (axial spondyloarthritis with radiographic damage) and non-radiographic axial spondyloarthritis (axial spondyloarthritis without radiographic damage)
Fraizeron is used to treat conditions called 'ankylosing spondylitis' and 'non-radiographic axial spondyloarthritis. These conditions are inflammatory diseases primarily affecting the spine, which causes inflammation of the spinal joints. Fraizeron is given to you to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.
Fraizeron is used in adults with active ankylosing spondylitis and active non-radiographic axial spondyloarthritis.
Juvenile idiopathic arthritis, including Enthesitis Related (ERA) and Juvenile Psoriatic Arthritis (JPsA)
Fraizeron is used to treat the Enthesitis Related (ERA) and Juvenile Psoriatic Arthritis (JPsA) categories of Juvenile Idiopathic Arthritis (JIA) in patients 6 years and older.
Hidradenitis Suppurativa
Fraizeron is used to treat a condition called hidradenitis suppurativa, also sometimes called acne inversa or Verneuil's disease. This condition is a chronic and painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.
Fraizeron can reduce the number of nodules and abscesses you have and the pain that is often associated with the disease.
Fraizeron is used in adults with hidradenitis suppurativa and can be used alone or with antibiotics.

How Fraizeron® works

In patients with psoriasis, psoriatic arthritis and axial spondyloarthritis (including ankylosing spondylitis, non-radiographic axial spondyloarthritis) and hidradenitis suppurativa, the body produces increased amounts of a protein called IL-17A. This may lead to symptoms such as itching, pain and scaling in psoriasis, swollen and tender joints in psoriatic arthritis, pain in the spine in axial spondyloarthritis and boil-like lumps that may rupture and drain pus in hidradenitis suppurativa.
Fraizeron neutralises IL-17A thus reducing the symptoms of the disease by decreasing inflammation.
If you have any questions about how Fraizeron works or why this medicine has been prescribed for you, ask your doctor, pharmacist or healthcare provider.

Using Fraizeron in psoriasis will benefit you by leading to fast and sustained improvements of skin clearance and reducing your symptoms such as scaling, itching and pain.
Using Fraizeron in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities. Using Fraizeron in axial spondyloarthritis will benefit you by reducing the signs and symptoms of your disease and improving your physical function.
Using Fraizeron in the JIA categories of ERA and JPsA will benefit you by reducing the symptoms of your disease and improving your physical function. These conditions are inflammatory diseases affecting the joints and the places where tendons join the bone.
Using Fraizeron in hidradenitis suppurativa will benefit you by reducing the number of nodules and abscesses you have and the pain that is often associated with the disease.

Before you use Fraizeron®

When you must not use it
Do not use Fraizeron:

- If you had a severe allergic reaction to secukinumab or any of the other ingredients of Fraizeron listed at the end of this leaflet.
- If you think you may be allergic, ask your doctor for advice before using Fraizeron.
- If you have active infection.

Before you start to use it
If any of these apply to you, tell your doctor or pharmacist before using Fraizeron:

- If you currently have an infection or if you have long-term or repeated infections.
- If you have tuberculosis.
- If you ever had an allergic reaction to latex.
- If you have ever been diagnosed with inflammatory bowel disease (e.g., Crohn's disease or ulcerative colitis).
- If you had a recent vaccination or if you will receive a vaccination during treatment with Fraizeron.
- If you are pregnant, think that you may be pregnant or are planning to have a baby.
- If you are breast-feeding or plan to breast-feed.

Fraizeron is not recommended during pregnancy unless the benefits clearly outweigh the potential risks.
Fraizeron may be used by people aged 65 years and over with no dose adjustment required.
Fraizeron is not recommended for children under 6 years of age with the Enthesitis Related Arthritis (ERA) and Juvenile Psoriatic Arthritis (JPsA) categories of Juvenile Idiopathic Arthritis (JIA) because it has not been studied in this age group.
Fraizeron is not recommended for children under 6 years of age with plaque psoriasis because it has not been studied in this age group. Fraizeron is not recommended for children and adolescents (under 18 years of age) in other indication because it has not been studied in this age group.
Taking other medicines

Tell your doctor or pharmacist:
- If you are taking, have recently taken or might take any other medicines.
- If you have recently had or are going to have a vaccination. You should not receive certain types of vaccines (live vaccines) while using Fraizeron.
- If you are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

How to use Fraizeron®
Always use Fraizeron as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.
Fraizeron is administered via injection under your skin ('subcutaneously').
You and your doctor should decide if you should inject Fraizeron yourself.
It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist. A caregiver may also give you your Fraizeron injection after proper training.

How much to use
Your doctor will decide how much Fraizeron you need.

Plaque psoriasis
In adults, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Further adjustments to your dose may be recommended by your doctor. Each 300 mg dose is given as one subcutaneous injection of 300mg or as two subcutaneous injections of 150 mg. For some patients, a dosage of 150mg may be acceptable.
In children 6 years and older, the recommended dose is based on body weight and is given by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.
Psoriatic Arthritis
The recommended dose is 150 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Based on your response, the doctor may increase your dose to 300 mg.
For psoriatic arthritis patients who also have moderate to severe plaque psoriasis, your doctor may adjust the dose recommendation as needed.For patients did not respond well to medicines called tumor necrosis factor (TNF) blockers, the recommended dose is 300 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Each 300 mg dose is given as one subcutaneous injection of 300mg or as two subcutaneous injections of 150 mg.
Ankylosing spondylitis
The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Based on your response, the doctor may increase your dose to 300 mg. Each 300 mg dose is given as one subcutaneous injection of 300mg or as two subcutaneous injections of 150 mg.
Non-radiographic axial spondyloarthritis
The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.
Juvenile idiopathic arthritis (JIA)
Enthesitis Related Arthritis (ERA) and juvenile psoriatic arthritis (JPsA)
The recommended dose is based on body weight and is given by subcutaneous injection at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. For patients weighing < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.
Hidradenitis Suppurativa
The recommended dose is 300 mg of secukinumab by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Based on your response, your doctor may increase your dose to 300 mg every 2 weeks. Each 300 mg dose is given as one subcutaneous injection of 300 mg or as two subcutaneous injections of 150 mg.

When to use it
Use as directed by your doctor or pharmacist.
How long to use it
This is a long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. Continue using Fraizeron for as long as your doctor tells you to.

If you forget to use it
If you have forgotten to inject a dose of Fraizeron, inject the next dose as soon as you remember. Then talk to your doctor to discuss when you should inject the next dose.

If you use too much (overdose)
If you accidentally injected more Fraizeron or sooner than according to your doctor's prescription, inform your doctor.

While you are using it
Things you must do
Tell all doctors, dentists and pharmacists who are treating you that you are using Fraizeron. Be sure to keep all of your appointments with your doctor so that your progress can be checked.
Discontinue treatment and tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with Fraizeron:
Signs or symptoms of a potentially serious infection. These 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 when passing water

Signs or symptoms of an allergic reaction. These may include:
- difficulty breathing or swallowing
- low blood pressure, which can cause dizziness or light-headedness
- swelling of the face, lips, mouth or throat

Things you must not do
Do not give this medicine to anyone else, even if they have the same condition as you.
Do not use it to treat any other complaints unless your doctor tells you to.
Things to be careful of
It is not dangerous to stop using Fraizeron. However, if you stop, your psoriasis, psoriatic arthritis or axial spondyloarthritis symptoms may come back.

Side Effects
As with all medicines, patients treated with Fraizeron may experience side effects, although not everybody gets them.
STOP using Fraizeron and seek medical help immediately if you experience any of the following, which are signs of an allergic reaction:
- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Other possible side effects include the following listed below. Most of the side effects are mild to moderate. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common: *may affect more than 1 in 10 people*
- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis, rhinitis)

Common: *may affect up to 1 in every 10 people*
- Cold sores (oral herpes)
- Diarrhoea
- Itchy rash (urticaria)
- Runny nose (rhinorrhoea)

Uncommon: *may affect up to 1 in every 100 people*
- Oral thrush (oral candidiasis)
- Signs of low levels of white blood cells such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- Athlete's foot (tinea pedis)

- Discharge from the eye with itching, redness and swelling (conjunctivitis)
- Nausea, diarrhea, vomiting, abdominal pain and fever (symptoms of inflammatory bowel disease)
- Small, itchy blisters on the palms of hands, soles of feet and edges of the fingers and toes (dyshidrotic eczema)

Not known: *frequency cannot be estimated from the available data*

- Fungal infections of the skin and mucous membranes (thrush)
  Painful swelling and skin ulceration (pyoderma gangrenosum)

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist. 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.moh.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Fraizeron®

Storage

- Keep this medicine out of the sight and reach of children.
- Store Fraizeron SensoReady or UNOREADY pens sealed in its box to protect from light.
- Store in the refrigerator between 2°C and 8°C. DO NOT FREEZE.
- Do not shake.
- When necessary, Fraizeron can be left out of the refrigerator for up to 4 days at room temperature, not above 30°C.
- Do not use Fraizeron SensoReady or UNOREADY pens:
  - After the expiration date shown on the outer box or the label on the pen.
  - If the liquid contains easily visible particles, is cloudy or is distinctly brown.

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

What it looks like

Fraizeron solution for injection is a clear liquid. Its color may vary from colorless to slightly yellow. Fraizeron is available in packs containing 1 or 2 pen(s).

Ingredients

Active ingredient(s)

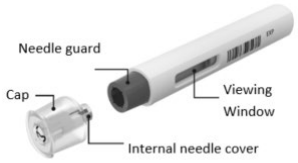
The active substance(s) of Fraizeron is secukinumab. The SensoReady pen contains 150 mg and the UNOREADY pen contains 300mg secukinumab.

Inactive ingredients

The other ingredients(s) of Fraizeron are trehalose dihydrate, L-histidine/histidine hydrochloride monohydrate, L-methionine, polysorbate 80, water for injection.
This information might differ in some countries.

Instructions for use of Fraizeron

Your Fraizeron UNOREADY pen 300mg:



Fraizeron UNOREADY pen is shown above with the cap removed. **Do not** remove the cap until you are ready to inject

The needle is covered by the needle guard and the needle will not be seen. **Do not** touch or push the needle guard because you could get a needle stick.

Do not use the Fraizeron UNOREADY pen if the seal on the outer carton is broken.

Keep the Fraizeron UNOREADY pen in the sealed outer carton until you are ready to use it to protect it from light.
Store your Fraizeron UNOREADY pen in a **refrigerator** between 2°C and 8°C and **out of the reach of children**.
Do not **freeze** the Fraizeron UNOREADY pen.
Do not **shake** the Fraizeron UNOREADY pen.
Do not use the Fraizeron UNOREADY pen if it has been **dropped** with the cap removed.

What you need for your injection:

Included in the carton:

- A new and unused Fraizeron UNOREADY pen.

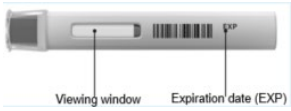
Not Included in the carton:

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

See "How should I dispose of used Fraizeron UNOREADY pens?" at the end of this Instructions for Use.

Before your injection

For a more comfortable injection, take the Fraizeron UNOREADY pen out of the refrigerator **30 to 45 minutes before injecting** to allow it to reach room temperature.



1. Important safety checks before you inject:

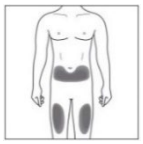
For the "viewing window":

The liquid should be clear. Its color may vary from colorless to slightly yellow.
Do not use if the liquid contains visible particles, is cloudy or is distinctly brown.
You may see air bubbles, which is normal.

For the "Expiration date":

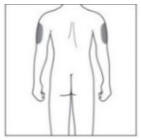
Look at the expiration date (EXP) on your Fraizeron pen. **Do not use** the pen if the **expiration date** has passed.

Check that your pen contains the correct medicine and dosage.
Contact your pharmacist if the pen fails any of these checks.



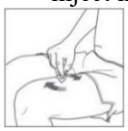
2a/ Choose your injection site:

- The recommended site is the front of the thighs. You may also use the lower abdomen, but not the area 2 inches around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks



2b/ Caregivers and Healthcare Professionals Only:

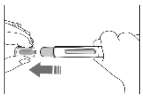
- If a **caregiver** or **healthcare professional** is giving you your injection, they may also inject into your outer upper arm.



3/ Cleaning your injection site:

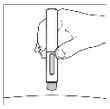
- Wash your hands with hot soapy water.
- Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting.
- Do not touch the cleaned area again before injecting

Your injection



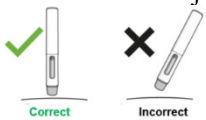
4/ Removing the cap:

- Only remove the cap when you are ready to use the pen.
- Pull the cap straight off in the direction of the arrow that is shown in the figure on left.
- Once removed, throw away the cap. **Do not try to re attach the cap** as you may bend the needle.
- Use the pen within 5 minutes of removing the cap.



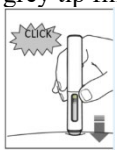
5/ Holding your Fraizeron UNOREADY pen:

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



YOU MUST READ THIS BEFORE INJECTING.

During the injection you will hear **2 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 your skin until you see a **green indicator** with a grey tip fill the window and stop moving.



6/ 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 your skin.
- The **green indicator with the grey tip** shows the progress of the injection.

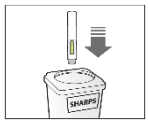
7/ Completing your injection:

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

After your injection

8/ Check the green indicator fills the window:

- This means the medicine has been delivered. Contact your doctor or pharmacist 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.



9/ Disposing of your Fraizeron UNOREADY pen:

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

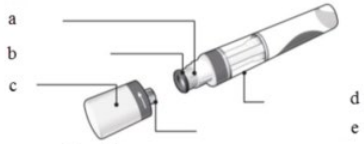
Instructions for use of Fraizeron Sensoready solution for injection in pre-filled pen

Fraizeron SensoReady pen 150 mg
Solution for injection in a pre-filled pen
Secukinumab
Patient Instructions for Use

Read ALL the way through these instructions before injecting.

These instructions are to help you to inject correctly using the Fraizeron SensoReady pen. It is important not to try to inject yourself or a person in your care until you have been trained by your doctor, nurse or pharmacist.

Your Fraizeron SendoReady pen:



a. Needle
b. Needle guard
c. Cap
d. Inspection window
e. Internal needle cover

Fraizeron SensoReady pen shown with the cap removed. **Do not** remove the cap until you are ready to inject.

Store your boxed Fraizeron SensoReady pen in a **refrigerator** between 2°C and 8°C and **out of the reach of children**.
Do not **freeze** the Fraizeron SensoReady pen.
Do not **shake** the Fraizeron SensoReady pen.
Do not use the Fraizeron SensoReady pen if it has been **dropped** with the cap removed.
For a more comfortable injection, take the Fraizeron SensoReady pen out of the refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature.

What you need for your injection:
Included in the carton:

- A new and unused Fraizeron SensoReady pen. 1 pen is needed for a 150 mg dose and 2 pens are needed for a 300 mg dose

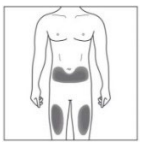
Not Included in the carton:

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

Before your injection

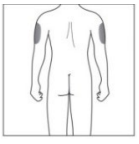
1/ Important safety checks before you inject:

- The liquid should be clear. Its color may vary from colorless to slightly yellow.
- **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.
- **Do not use** your Fraizeron SensoReady pen if the **expiration date** has passed.
- **Do not use** if the **safety seal** has been broken.
- Contact your pharmacist if the Fraizeron SensoReady pen fails any of these checks.



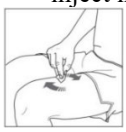
2a/ Choose your injection site:

- The recommended site is the front of the thighs. You may also use the lower abdomen, but not the area 2 inches around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks



2b/ Caregivers and Healthcare Professionals Only:

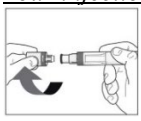
- If a **caregiver** or **healthcare professional** is giving you your injection, they may also inject into your outer upper arm.



3/ Cleaning your injection site:

- Wash your hands with hot soapy 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

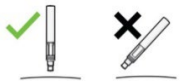
Your injection



4/ Removing the cap:

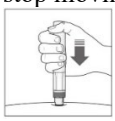
- Only remove the cap when you are ready to use the Fraizeron SensoReady pen.
- Twist off the cap in the direction of the arrows.
- Once removed, throw away the cap. **Do not try to re-attach the cap.**
- Use the Fraizeron SensoReady pen within 5 minutes of removing the cap

5/ Holding your Fraizeron SensoReady pen:
Hold the Fraizeron SensoReady 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 Fraizeron SensoReady pen firmly against your skin until you see a **green indicator** fill the window and stop moving.



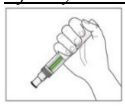
6/ Starting your Injection:

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

7/ Completing your 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 Fraizeron SensoReady pen can now be removed.

After your injection



8/ 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.

9/ Disposing of your Fraizeron SensoReady pen:

- Dispose of the used Fraizeron SensoReady pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar).
- Never try to reuse your Fraizeron SensoReady pen

MAL Number
300mg/2ml:
PEN: MAL22086010ARZ

150mg/ml:
PEN: MAL16045048ARZ

Manufacturer
Novartis Pharma Stein AG,
Schaffhauserstrasse 4332-Stein,
Switzerland.

Product Registration Holder
Novartis Corporation (Malaysia) Sdn. Bhd.
Level 18, Imazium,
No. 8, Jalan SS21/37,
Damansara Uptown,
47400 Petaling Jaya, Selangor

Information issued
20-Jan-2023

Date of Revision
Jan 2024 - HS

Serial Number
NPRA (R3/01)26122023/0282