NOVARTIS

SCAPHO® 150 mg (powder for solution for injection)

(Each vial of powder contains 150 mg secukinumab. After reconstitution, 1,0 mL of solution contains 150 mg secukinumab)

PATIENT INFORMATION LEAFLET

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SCAPHO® 150 mg

Secukinumab

Contains sugar: A vial contains 110,92 mg sucrose

Read all of this leaflet carefully before you are given SCAPHO®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other health care provider.
- SCAPHO® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See **section 4.**

What is in this leaflet

1. What SCAPHO® is and what it is used for

What SCAPHO® is

SCAPHO® contains the active substance secukinumab. Secukinumab is a monoclonal antibody which 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, ankylosing spondylitis and hidradenitis suppurativa.

What SCAPHO® is used for

SCAPHO® is used for the treatment of the following inflammatory diseases:

- Plaque psoriasis
- Psoriatic arthritis
- Axial spondyloarthritis (axSpA)
    - Ankylosing spondylitis
    - Non-radiographic axial spondyloarthritis
- Juvenile idiopathic arthritis, including Enthesitis Related Arthritis (ERA) and Juvenile Psoriatic Arthritis (JPsA)
- Hidradenitis Suppurativa

Plaque psoriasis

SCAPHO® is used to treat a skin condition called “plaque psoriasis”, which causes inflammation affecting the skin. SCAPHO® reduces the inflammation and other symptoms of the disease.

SCAPHO® is used in patients 6 years and older with moderate to severe plaque psoriasis.

Using SCAPHO® in plaque psoriasis will benefit you by leading to improvements of skin clearance and reducing your symptoms such as scaling, itching and pain.

Psoriatic arthritis

SCAPHO® is used to treat a condition called “psoriatic arthritis”. The condition is an inflammatory disease of the joints, often accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given SCAPHO® to reduce the signs and symptoms of active psoriatic arthritis, improve physical function and slow down the damage to the cartilage and bone of the joints involved in the disease.

SCAPHO® is used in adults with active psoriatic arthritis and can be used alone or with another medicine called methotrexate.

Using SCAPHO® 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.

Axial spondyloarthritis (axSpA) with or without radiographic damage

Ankylosing spondylitis (AS) & Non-radiographic axial spondyloarthritis (nr-axSpA)

SCAPHO® is used to treat the 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. If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given SCAPHO® to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.

SCAPHO® is used in adults with active ankylosing spondylitis or non-radiographic axial spondyloarthritis.

Using SCAPHO® in ankylosing spondylitis or non-radiographic axial spondyloarthritis will benefit you by reducing the signs and symptoms of your disease and improving your physical function.

Juvenile idiopathic arthritis, including Enthesitis Related (ERA) and Juvenile Psoriatic Arthritis (JPsA)

SCAPHO® is used to treat the Enthesitis Related (ERA) and Juvenile Psoriatic Arthritis (JPsA) categories of Juvenile Idiopathic Arthritis (JIA) in patients 2 years and older.

Using SCAPHO® 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.

Hidradenitis Suppurativa

SCAPHO® 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.

SCAPHO® can reduce the number of nodules and abscesses you have and the pain that is often associated with the disease.

SCAPHO® is used in adults with hidradenitis suppurativa and can be used alone or with antibiotics.

Using SCAPHO® 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.

If you have any questions about SCAPHO®, how it works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before and while you use SCAPHO®

Do not use SCAPHO®:

- if you are allergic to secukinumab or any of the other ingredients of this medicine (listed in **section 6**).

  If you think you may be allergic, ask your doctor for advice before using SCAPHO®.
- if you have an active infection which your doctor thinks is important.

Warnings and precautions

Tell your doctor or pharmacist before using SCAPHO®:

- if you currently have an infection
- if you have long-term or repeated infections.

- if you have tuberculosis or have had a past history of tuberculosis.
- if you have ever been diagnosed with Crohn’s disease.
- if you have ulcerative colitis.
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with SCAPHO®.
- if you are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

If any of these applies to you, your doctor will decide whether you should be given SCAPHO®.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Stop using SCAPHO® and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhoea, weight loss, blood in the stool or any other signs of bowel problems.

Look out for infections and allergic reactions

SCAPHO® scan potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are taking SCAPHO®.

Stop using SCAPHO® and tell your doctor or seek medical help immediately if you notice any signs indicating a possible serious infection or an allergic reaction. Such signs are listed under “Serious side effects” in section 4.

Children and adolescents

SCAPHO® is not recommended for children under 2 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.

SCAPHO® is not recommended for children under 6 years of age with plaque psoriasis because it has not been studied in this age group.

SCAPHO® is not recommended for children and adolescents (under 18 years of age) in other indications because it has not been studied in this age group.

Older people (65 years or above)

SCAPHO® may be used by people aged 65 years and over with no dose adjustment required.

Other medicines and SCAPHO®

Always tell your healthcare professional if you are taking any other medicine, including complementary or traditional 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 due to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using SCAPHO®.

Pregnancy and breastfeeding and fertility

SCAPHO® is not to be used during pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

If you are breastfeeding or plan to breastfeed your baby, you should not be administered SCAPHO®.

Driving and using machines

SCAPHO® is unlikely to influence your ability to drive and use machines.

Important information about some of the ingredients of SCAPHO®:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SCAPHO®.

3. How to use SCAPHO®

SCAPHO® is given via injection under your skin (known as a subcutaneous injection) by a healthcare professional.

Make sure you discuss with your doctor when you will have your injections and your follow up appointments.

For detailed instructions on how to inject SCAPHO®, see “Instructions for use of SCAPHO®” in this leaflet.

How much SCAPHO® is given and for how long

Your doctor will decide how much SCAPHO® you need and for how long.

Plaque psoriasis

- In adults the recommended dose is 300 mg by subcutaneous injection.
- Each 300 mg dose is given as two injections of 150 mg.
- 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.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections. Further adjustments to your dose may be recommended by your doctor. At each timepoint you will receive a 300 mg dose given as two injections of 150 mg.

Psoriatic arthritis

For psoriatic arthritis patients who also have moderate to severe plaque psoriasis, your doctor may adjust the dose recommendation as needed.

For patients who did not respond well to medicines called tumour necrosis factor (TNF) blockers:

- The recommended dose is 300 mg by subcutaneous injection.
- Each 300 mg dose is given as two injections of 150 mg.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by

monthly injections. At each timepoint you will receive a 300 mg dose given as two injections of 150 mg.

For other psoriatic arthritis patients:

- The recommended dose is 150 mg by subcutaneous injection.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Based on your response, your doctor may increase your dose to 300 mg.

Axial spondyloarthritis (axSpA)

Ankylosing spondylitis

- The recommended dose is 150 mg by subcutaneous injection.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Based on your response, your doctor may increase your dose to 300 mg. Each 300 mg dose is given as two injections of 150 mg.

Non-radiographic axial spondyloarthritis

- The recommended dose is 150 mg by subcutaneous injection.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Enthesitis Related (ERA) and Juvenile Psoriatic Arthritis (JPsA) forms of Juvenile Idiopathic Arthritis (JIA)

In children 2 years and older, 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 by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by an injection every two weeks.

Each 300 mg dose is given as one subcutaneous injection of 300 mg or two subcutaneous injections of 150 mg.

SCAPHO® is for long term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you use more SCAPHO® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SCAPHO®

If you have missed a SCAPHO® injection, talk to your doctor.

If you stop using SCAPHO®

It is not dangerous to stop using SCAPHO®. However, if you stop, your psoriasis, psoriatic arthritis or ankylosing spondylitis symptoms may come back.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Instructions for use of SCAPHO® powder for solution for injection

The following information is intended for medical or healthcare professionals only.

The preparation of the solution for subcutaneous injection must be done without interruption and ensuring that aseptic technique is used. The preparation time from piercing the stopper until end of reconstitution takes 20 minutes on average and should not exceed 90 minutes.

To prepare SCAPHO® 150 mg powder for solution for injection, please adhere to the following instructions:

1. Bring the vial of powder to room temperature and ensure that the sterile water for injections is at room temperature.

2. Withdraw slightly more than 1,0 mL sterile water for injections into a 1 mL graduated disposable syringe and adjust to 1,0 mL.

3. Remove the plastic cap from the vial.

4. Insert the syringe needle into the vial containing the powder through the centre of the rubber stopper and reconstitute the powder by slowly injecting 1,0 mL of sterile water for injections into the vial.

   The stream of sterile water for injections should be directed onto the powder.

5. Tilt the vial to an angle of approx. 45° and gently rotate between the fingertips for approx. 1 minute. Do not shake or invert the vial.

6. Keep the vial standing at room temperature for a minimum of 10 minutes to allow for dissolution. Note that foaming of the solution may occur.
7. Tilt the vial to an angle of approx. 45° and gently rotate between the fingertips for approx. 1 minute. Do not shake or invert the vial.

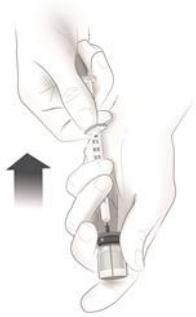
8. Allow the vial to stand undisturbed at room temperature for approximately 5 minutes. The resulting solution should be clear. Its colour may vary from colourless to slightly yellow. Do not use if the lyophilised powder has not fully dissolved or if the liquid contains easily visible particles, is cloudy or is distinctly brown.

9. Prepare the required number of vials (1 vial for the 150 mg dose, 2 vials for the 300 mg dose).

After storage at 2 °C to 8 °C, the solution should be allowed to come to room temperature for approximately 20 minutes before administration.

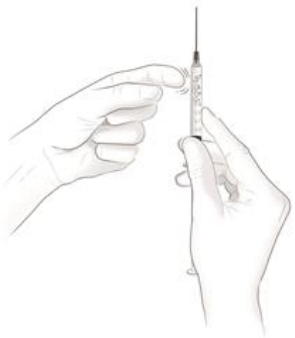
Instructions for administration of SCAPHO® solution

1. Tilt the vial to an angle of approximately 45° and position the needle tip at the very bottom of the solution in the vial when drawing the solution into the syringe. DO NOT invert the vial.



2. Carefully withdraw slightly more than 1,0 mL of the solution for subcutaneous injection from the vial into a 1 mL graduated disposable syringe using a suitable needle (e.g. 21G x 2″). This needle will only be used for withdrawing SCAPHO® into the disposable syringe. Prepare the required number of syringes (1 syringe for the 150 mg dose, 2 syringes for the 300 mg dose).

3. With the needle pointing upward, gently tap the syringe to move any air bubbles to the top.



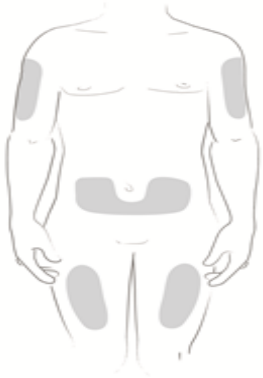
4. Replace the attached needle with a 27G x ½″ needle.

5. Expel the air bubbles and advance the plunger to the 1.0 mL mark.

6. Clean the injection site with an alcohol swab.

7. Inject the SCAPHO® solution subcutaneously into the front of thighs, lower abdomen (but not the area 2 inches (~50 mm around the navel (belly button) or outer upper arms. Choose

a different site each time an injection is administered. Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.



8. Any remaining solution in the vial must not be used and should be discarded in accordance with local requirements. Vials are for single use only. Dispose of the used syringe in a sharp's container (closable, puncture resistant container). For the safety and health of you and others, needles and used syringes must never be re-used.

4. Possible side effects

SCAPHO® can have side effects.

Not all side effects reported for SCAPHO® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SCAPHO®, please consult your health care provider for advice.

Serious side effects

Stop using SCAPHO® and tell your doctor or seek medical help immediately if you get 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.

Your doctor will decide if and when you may restart the treatment.

Other side effects

Most of the following side effects are mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse.

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 10 people):

- cold sores (oral herpes)
- diarrhoea
- runny nose (rhinorrhoea)

Uncommon (may affect up to 1 in 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)
- infection of the external ear (otitis externa)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- itchy rash (urticaria)
- lower respiratory tract infections
- nausea, abdominal cramps and pain, diarrhoea, vomiting, weight loss or blood in the stool (signs of bowel problems) 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)

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

- severe allergic reaction with shock (anaphylactic reaction)
- redness and shedding of skin over a larger area of the body, which may be itchy or painful (exfoliative dermatitis)

Not known (frequency cannot be estimated from the available data):

- fungal infections of the skin and mucous membranes (including oesophageal candidiasis)

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SCAPHO®.

5. How to store SCAPHO®

Store all medicines out of reach of children.

- **Before reconstitution:** Store the vial of SCAPHO® 150 mg powder for solution for injection in the refrigerator between 2 °C to 8 °C.
- **After reconstitution:** The solution for subcutaneous injection can be used immediately or can be stored at 2 °C to 8 °C for up to 24 hours. Do not freeze. The solution should be administered within one hour after removal from 2 °C to 8 °C storage.

- Do not use SCAPHO® powder for solution for injection after the expiration date shown on the outer box or vial has passed. If it has expired, return the entire product pack to the pharmacy.

Do not use this medicine if you notice that the powder has not fully dissolved or if the liquid contains easily visible particles, is cloudy or is distinctly brown.

This medicine is for single use only.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What SCAPHO® contains

- The active substance is secukinumab. Each vial of powder for solution for injection contains 150 mg secukinumab. After reconstitution, 1 ml of solution contains 150 mg secukinumab.
- The other ingredients are sucrose, histidine, histidine hydrochloride monohydrate and polysorbate 80.

What SCAPHO® looks like and contents of the pack

SCAPHO® powder for solution for injection is a white solid powder in a glass vial.

SCAPHO® is supplied in a pack containing one vial.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd.

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South Africa

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Registration numbers

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Access to the corresponding Professional Information

TBA