

PATIENT INFORMATION ON ANIFROLUMAB

[An-i-frol-ue-mab]

Brand name: Saphnelo

This information sheet has been produced by the Australian Rheumatology Association to help you understand anifrolumab. It includes important information about:

- **how you should take your medication**
- **possible side (harmful) effects**
- **what tests you will have to monitor your condition and detect unwanted effects**
- **other precautions you should take while you are taking anifrolumab.**

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- While taking anifrolumab you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- You should have regular blood tests as suggested by your rheumatologist
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you develop any infections including shingles while taking anifrolumab.
- If you are taking anifrolumab and plan to become pregnant you must discuss the timing with your doctor.

For more information about inflammatory conditions associated with arthritis, see Arthritis Australia's website:
www.arthritisaustralia.com.au

What is anifrolumab?

Anifrolumab is a biological disease modifying antirheumatic drug (bDMARD) used for the specific treatment of systemic lupus erythematosus (SLE).

Type 1 Interferons (INFs) are a type of protein that are released by cells during viral infection and are important for host defence against them. In SLE it has been found that there is an overproduction of INFs even in the absence of infection which results in the clinical burden of symptoms of SLE that can result in skin, joint, and other organ involvement.

By temporarily inhibiting the production of interferons, anifrolumab reduces inflammation and lessens the symptoms associated with SLE.

What benefit can you expect from your treatment?

You may notice improvements in skin disease and reduction in joint pain, stiffness, and swelling within the first 12 weeks of starting. Your doctor may be able to gradually reduce the dose of steroids if you are currently taking this medication.

Stopping anifrolumab

Continue with your treatment unless advised by your doctor or unless side effects develop (see *Side effects*). If you stop anifrolumab for any reason you **must** contact your doctor.

How will your condition be monitored?

Regular clinical examinations and blood tests will be required during your treatment to monitor your condition and to determine the effectiveness of treatment.

If you have an active infection then please see your doctor to have this treated as soon as possible.

How is anifrolumab given?

Anifrolumab is given as an intravenous infusion at a dose of 300mg every 4 weeks. The dosage and frequency may change however this will be determined by your rheumatologist.

Can other medications be taken with anifrolumab?

Anifrolumab can be taken with other lupus medications including steroids. Anifrolumab cannot be used with other bDMARDs.

How long is the treatment continued?

Anifrolumab has been given for up to 48 weeks in clinical trials. Your response will be regularly monitored by your rheumatologist.

Are there any side effects?

You might experience side effects with your treatment. Contact your doctor if you have any concerns about possible side effects. Many side effects disappear when anifrolumab is discontinued.

Most common possible side effects:

The most common side effects with anifrolumab include:

- Upper respiratory tract infections
- Nasopharyngitis
- Infusion-related reaction
- Bronchitis
- Herpes zoster (7.2%)

Clinical trials showed that all cases of herpes zoster presented as skin manifestations and resolved without discontinuation of anifrolumab.

Less common or rare possible side effects:

The serious side effects with anifrolumab include:

- Pneumonia which can lead to death
- Non-opportunistic serious infections (2.8%)
- Worsening of SLE characterised by flares
- Infusion related hypersensitivity reaction (1.1%)
- It is still unclear from research if there is an increased risk of cancer from anifrolumab.

What precautions are necessary?

Infections

Anifrolumab will not be given if you have an active infection. Due to the risks associated with infection the following tests may be conducted prior to starting anifrolumab:

- Blood tests for hepatitis B and C, chicken pox, and tuberculosis
- Chest X-ray
- HIV tests for those who are at risk for this infection.

Vaccines

- If you are on anifrolumab it is recommended you should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), OPV (oral polio virus), BCG (Bacillus Calmette Guerin) or yellow fever vaccine. Talk with your rheumatologist before receiving any vaccines.
- The Zostavax is also another live vaccine given for the prevention of shingles and should not be given while taking anifrolumab. The Shingrix vaccine however is the inactivated version and is safe to be given prior or during anifrolumab therapy.
- Pneumococcal, the yearly seasonal flu and COVID vaccinations are safe and encouraged whilst on anifrolumab.
- More detailed information on vaccination is available on the ARA website: <https://rheumatology.org.au/For-Patients/Medication-Information/Vaccinations-in-Rheumatology>

Cancer risk

- The impact of anifrolumab on the potential development of cancer is unknown. Caution should be taken when considering the use of anifrolumab if you have a history of cancer.
- For general cancer prevention, stopping smoking and taking skin cancer prevention measures are recommended. It is important to use sunscreen and avoid prolonged sun exposure. A yearly skin check is recommended.
- Talk to your doctor if you have any concerns about issues relating to cancer risk.

Use with other medications

- Anifrolumab can interact with other medications.
- You should tell your doctor (including your general practitioner, rheumatologist, and other health professionals) about all medications you are taking, including herbal and naturopathic medications. This includes over-the-counter medications.

Use with alcohol

- You may drink alcohol while taking anifrolumab. However, if you are also taking other medications such as methotrexate then you need to be cautious with your alcohol intake.

- To reduce the risk of harm from alcohol related disease the NHMRC recommend consuming no more than 10 standard drinks a week and no more than 4 standard drinks on any one day.

Use in pregnancy and when breastfeeding

- There is insufficient data about the possible side effects of anifrolumab on the unborn baby. If you plan to become pregnant it is important to discuss this with your doctor and ensure that the SLE is under control.
- You should not breastfeed while taking anifrolumab as it is unknown if it passes to human breast milk.
- More detailed information is available at <https://rheumatology.org.au/For-Healthcare-Professionals/Clinical-Resources/Pregnancy-Prescribing-Info>

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medications mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medication. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.

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