

SIMPONI[®]

Golimumab (rmc)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about SIMPONI. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using SIMPONI against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What SIMPONI is used for

SIMPONI contains the active ingredient golimumab. Golimumab is a human monoclonal antibody that is produced by recombinant technology. Monoclonal antibodies are proteins that recognise and bind to other specific proteins in the body.

Golimumab acts by binding to a specific protein in the body called tumour necrosis factor (TNF) alpha. In people with diseases such as rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, the body produces too much TNF, which can cause the body's immune system to attack normal healthy parts of the body. SIMPONI can block the damage caused by too much TNF.

SIMPONI is used to treat:

- rheumatoid arthritis
- psoriatic arthritis
- ankylosing spondylitis
- ulcerative colitis

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

SIMPONI is used in patients who have not responded well enough to previous treatments with other disease-modifying medicines.

SIMPONI is used with a disease-modifying medicine called methotrexate.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints in which psoriasis usually occurs in association with arthritis. Often the fingers and toes are affected, although it may occur in other parts of the body.

SIMPONI is used in patients who have not responded well enough to previous treatments with other disease-modifying medicines.

SIMPONI can be used with or without a disease-modifying medicine called methotrexate.

Ankylosing Spondylitis

Ankylosing spondylitis is an inflammatory disease of the spine.

Ulcerative Colitis

Ulcerative colitis is an inflammatory disease of the bowel.

SIMPONI is used in patients who have not responded well enough to other treatments.

Ask your doctor if you have any questions about why SIMPONI has been prescribed for you.

Your doctor may have prescribed SIMPONI for another reason.

Before you use SIMPONI

When you must not use it

Do not use SIMPONI if:

- 1. You have an allergy to SIMPONI or to any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest, swelling of the face, lips, tongue or other parts of the body, rash, itching, hives or flushed red skin, dizziness or light-headedness.
- 2. You have a severe infection including tuberculosis, infection of the bloodstream, and other infections that can occur when the body's natural defences are lowered.**

SIMPONI can affect your body's ability to fight a serious infection.

If you are not sure whether you have a serious infection, check with your doctor.

- 3. You are already taking another medicine for arthritis, which contains either of the substances called anakinra (Kineret) or abatacept (Orencia).**

4. **You have moderate to severe heart failure.**
5. **The packaging is torn or show signs of tampering.**
6. **The expiry date on the pack has passed.**

Do not use SIMPONI in children.

There is not enough information at present to recommend use of SIMPONI in children.

Before you start to use it

Tell your doctor if:

1. You have an allergy to:

- latex, as the needle cover on the pre-filled syringe and the injector pen contains dry natural rubber
- any other medicines or substances

2. You are pregnant or plan to become pregnant

The effects of SIMPONI in pregnant women are not known. Therefore, the use of this medicine in pregnant women is not recommended.

Use appropriate contraception to avoid becoming pregnant while using SIMPONI and for at least 6 months after the last dose.

3. You are breastfeeding or plan to breastfeed.

It is not known whether SIMPONI passes into breast milk. If you are breastfeeding, your doctor may advise you to stop breastfeeding while you are using this medicine, and for at least six months after the last dose.

4. You currently have or previously had any other medical conditions, especially the following:

- congestive heart failure
- conditions affecting the nervous system, such as multiple sclerosis or Guillain-Barre syndrome, or if you experience any numbness, weakness, tingling, or sight disturbances

- tuberculosis, or have been in contact with someone who has had this condition.
You should tell your doctor, even if you have been treated for it.
- lung disease
- colon dysplasia
- infections, or if you are prone to infections, or if you have a history of infections.

SIMPONI may affect your body's immunity. You might get infections more easily. Some cases of serious infections, including tuberculosis, invasive fungal infections, and sepsis have been reported in patients treated with SIMPONI.

- hepatitis B, or have been in contact with someone who has this condition.

Reactivation of hepatitis B has been reported in people treated with TNF blockers. However, these reports are very rare.

- cancer

A type of blood cancer called lymphoma / has been reported in patients receiving TNF blockers. The reports are rare but are more frequent than expected for people in general. Cancers, other than lymphoma, including leukaemia, have also been reported.

- blood disorders, or a history of blood disorders.

5. You are a heavy smoker

5. You have lived in or travelled to an area where fungal infections called histoplasmosis, coccidioidomycosis, or blastomycosis, and tuberculosis are common.

These infections are caused by a fungus that can affect the lungs or other parts of your body.

Ask your doctor if you don't know whether these infections are common in the area in which you have lived in or travelled to.

6. You are scheduled to receive any vaccines

Patients receiving SIMPONI should not receive some type of vaccines.

7. You are receiving other medicines for the treatment of cancer

Patients receiving SIMPONI should not receive some medicines used for the treatment of cancer.

If you have not told your doctor about any of the above, tell them before you start using SIMPONI.

Your doctor will discuss with you the benefits of using it against the potential risks.

Taking or being given other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking a medicine containing the substance anakinra (Kineret), abatacept (Orencia) or rituximab (Mabthera).

Using SIMPONI together with any of these medicines may increase the risk of infection.

Tell your doctor if you are receiving other scheduled to receive any vaccines.

Tell your doctor if you are receiving other treatments

- for rheumatoid arthritis
- for psoriatic arthritis
- for ankylosing spondylitis
- for ulcerative colitis

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while using SIMPONI.

How to use SIMPONI

SIMPONI is only available on prescription.

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to use

For Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

The recommended dose is 50 mg given as a single injection under the skin (subcutaneous use).

For Ulcerative Colitis:

The recommended dose is given by injection under the skin (subcutaneous use).

The starting dose is 200 mg, followed by a dose of 100 mg 2 weeks later.

100 mg is then given 4 weeks after your last treatment, then every 4 weeks thereafter.

Inject all the solution in the syringe or injector pen.

This ensures that the correct dose is administered.

When to use it

SIMPONI should be injected once a month, on the same date each month.

SIMPONI can be used with or without food or drink.

How to use it

At the start of your therapy, your doctor or nurse may inject SIMPONI for you. However, you and your doctor can decide that you may inject SIMPONI yourself. If this is the case, you will receive training on how to inject SIMPONI yourself.

If you are injecting SIMPONI yourself, follow closely the instructions provided in the instruction leaflet inside your pack.

Ask your doctor or nurse if you have any questions about SIMPONI or about giving yourself an injection.

How long to use it

Continue injecting SIMPONI for as long as your doctor has told you to.

Do not stop using SIMPONI because you are feeling better, unless your doctor tells you to.

Your condition may flare up if you stop using SIMPONI.

If you forget to use it

If you forget to use SIMPONI on your scheduled date, inject a dose as soon as you remember.

Inject your next dose at your next regularly scheduled date.

This will put you back on your schedule.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your pharmacist, support nurse or doctor.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia - Ph: 13 11 26; New Zealand - Ph: 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much SIMPONI.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Always have the outer carton of the medicine with you, even if it is empty.

While you are using SIMPONI

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are using SIMPONI.

Tell your doctor, nurse or pharmacist if the medicine starts to upset you or your symptoms become worse.

Tell your doctor immediately if:

- symptoms of hepatitis B (upset stomach, loss of appetite, vomiting, tiredness, dark yellow or brown urine, and yellow eyes or skin) appear
- symptoms of TB (persistent cough, weight loss, listlessness, fever), or any other infection appear
- you have symptoms such as persistent fever, sore throat, bruising, bleeding or paleness.

These symptoms may be due to the development of a blood disorder, which may need close monitoring by your doctor.

- if you develop a skin rash or hives.

If you suffer from congestive heart failure, tell your doctor immediately if your condition worsens.

If you are planning to have surgery, tell your doctor or surgeon you are using SIMPONI.

Use appropriate contraception to avoid becoming pregnant while using SIMPONI and for at least 6 months after the last dose.

Tell your doctor if you did receive SIMPONI while you were pregnant as your baby may be at higher risk for getting an infection. It is important to tell your baby's doctor and other health care professionals about your SIMPONI use before the baby receives any vaccines as certain vaccines may put your baby at higher risk for infection.

Your doctor will also advise you not to breastfeed.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not shake the solution of SIMPONI.

Do not give SIMPONI to anyone else even if they have the same condition as you.

Do not stop using SIMPONI, or lower the dose, unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how SIMPONI affects you.

SIMPONI should not affect your ability to drive or use machines. However, make sure you know how you react to it before you do anything that could be dangerous if you feel dizzy.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by the following list of possible side effects.

You may not get any of them.

Ask your doctor, support nurse or pharmacist any questions you may have.

Stop taking SIMPONI and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have any signs of an allergic reaction such as:

- wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed red skin
- dizziness or light-headedness.

Tell your doctor immediately if you notice any of the following:

1. Signs of infection such as:

- fever, flu-like symptoms, chills or night sweats
- tiredness, persistent cough or shortness of breath
- weight loss
- diarrhoea
- wounds not healing, are swollen, red or have pus
- dental problems
- burning on urination or a reduction in the amount of urine that is passed
- vision loss
- muscle weakness
- muscle stiffness
- muscle spasms
- changes in how well your bladder and bowels work

2. Signs of a kidney infection such as:

- back pain, side pain or severe abdominal pain
- fever or chills
- tiredness
- need to pass urine more frequently or pain when urinating
- changes in the colour or smell of urine.

3. Signs of liver problems such as:

- yellowing of the skin and eyes
- dark coloured urine or pale stools
- stomach pains or severe pain in the abdomen
- tiredness or fever
- feeling sick or being sick.

4. Signs of new or worsening heart failure such as:

- shortness of breath
- swelling of your feet.

5. Signs of blood disorders such as:

- persistent fever
- sore throat
- bruising or bleeding
- paleness.

Tell your doctor if you notice problems at the injection site such as:

- swelling, pain or bruising
- itching or redness

Tell your doctor if you notice any of the following:

- headache
- dizziness
- numbness or tingling
- difficulty sleeping
- depression
- constipation or indigestion
- gastrointestinal and abdominal pain
- hair loss
- symptoms of upper respiratory tract infections such as runny nose, blocked sinus or sore throat
- lower respiratory tract infections such as bronchitis or pneumonia
- chest discomfort
- flu, cold sores or fever
- hoarseness
- infection of the skin or soft tissue
- high blood pressure
- pain or swelling of the joints
- pain or swelling of the elbow or shoulder
- feeling weak.

This is not a complete list of all possible side effects. Other may occur in some people and there may be some side effects not yet known.

Tell your doctor if you do not feel well or if you notice any other effects, even if they are not on this list.

In clinical studies, certain kinds of cancers, such as cancers that affect the lymph system (lymphomas), occurred more frequently in patients who received medicines that block TNF, including SIMPONI, than patients who did not receive these treatments.

Cancers, other than lymphoma, have also been reported. There have also been cases of cancers, including unusual types, in children and teenage patients taking medicines that block TNF.

For children and adults taking TNF blockers, the chances of getting lymphoma or others cancers may increase.

Talk to your doctor if you are concerned about this.

Skin cancers (including melanoma) have been reported rarely in patients treated with TNF-blockers, including SIMPONI.

Tell your doctor if you notice any new skin lesions during or after therapy or if existing lesions change appearance.

Some side effects may develop even after you stop taking SIMPONI.

Talk to your doctor, support nurse or pharmacist if you notice anything unusual even after you stop using SIMPONI.

How to store SIMPONI

Storage

Keep SIMPONI in the outer carton until it is time to use it.

This helps protect it from light.

Keep SIMPONI in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Do not shake.

Keep SIMPONI in a refrigerator in a way children cannot get to it.

If needed, you may store SIMPONI at room temperature up to 25°C for one period of time up to 30 days.

- Write the date when you remove SIMPONI from the refrigerator on the carton.
- If SIMPONI has reached room temperature, do not put it back in the refrigerator.
- Throw away SIMPONI if it has been kept at room temperature for 30 days and has not been used.

After using SIMPONI

Disposal

After injecting SIMPONI, place the injection device immediately into a sharps container. Do not put the used injection device into your normal household or recycling waste.

If your doctor tells you to stop taking SIMPONI or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

SIMPONI is a clear to slightly opalescent, colourless to light yellow solution.

Do not use SIMPONI if the solution is discoloured, cloudy, or you can see foreign particles in it.

SIMPONI is available in the following presentations for subcutaneous injection:

- SIMPONI pre-filled syringe: a single-use pre-filled syringe in a carton pack.
- SIMPONI SmartJect injector pen: a single-use injector pen in a carton pack. A pre-filled syringe

is contained in this single-use injector pen.

SIMPONI pre-filled syringes and pre-filled injector pens are supplied in containers of 1 unit.

An instruction leaflet explaining how to self-administer the product is included in the pack.

Ingredients

Active ingredient:

- golimumab (rnc) 50 mg or 100 mg

Inactive ingredients:

- sorbitol
- histidine
- histidine hydrochloride monohydrate
- polysorbate 80
- water for injections

Supplier/Manufacturer

JANSSENCILAG Pty Ltd
1-5 Khartoum Road
Macquarie Park NSW 2113 Australia
Telephone: 1800 226 334

NZ Office: Auckland New Zealand
Telephone: 0800 800 806

Australian Registration Number

Pre-filled syringe 50mg: AUST R 153767

SmartJect Injector pen 50mg: AUST R 153181

Pre-filled syringe 100mg: AUST R 208278

SmartJect Injector pen 100mg: AUST R 208279

Date of Preparation

10 July 2019