APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

UNAMITY 2 mg film-coated tablets

UNAMITY 4 mg film-coated tablets

Baricitinib

Contains sugar: mannitol

Read all of this leaflet carefully before you start taking UNAMITY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- UNAMITY 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.

What is in this leaflet

1. What UNAMITY is and what it is used for
2. What you need to know before you take UNAMITY
3. How to take UNAMITY
4. Possible side effects
5. How to store UNAMITY
6. Contents of the pack and other information

1. What UNAMITY is and what it is used for

UNAMITY contains the active substance baricitinib. It belongs to a group of medicines called Janus kinase inhibitors, which help to reduce inflammation.

Rheumatoid Arthritis

UNAMITY is used to treat adults with moderate to severe rheumatoid arthritis, an inflammatory disease of the joints, if previous therapy did not work well enough or was not tolerated. UNAMITY can be used alone or together with some other medicines, such as methotrexate.

UNAMITY works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation. By reducing the activity of this enzyme, UNAMITY helps to reduce pain, stiffness and swelling in your joints, tiredness, and helps to slow damage to the bone and cartilage in the joints. These effects can help you to do normal daily activities and so improve the health-related quality of life for patients with rheumatoid arthritis.

COVID-19

UNAMITY is used to treat adults, adolescents and children (aged 10 years and above) with severe COVID-19 infection. It will only be given to patients who need extra oxygen to help them breathe.

UNAMITY works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation. This may also help your body to overcome the virus infection complications, and may help you get better faster.

UNAMITY can be used alone or in combination with remdesivir, which is another COVID-19 medicine.

2. What you need to know before you take UNAMITY

Do not take UNAMITY:

- if you are allergic to baricitinib or any of the other ingredients in this medicine (listed in section 6).
- if you have problems with your kidney(s) or have been diagnosed with kidney disease.
- if you have or have had TB (tuberculosis), an infection that affects your lungs.
- for the treatment of Rheumatoid Arthritis if you are pregnant or think you may be pregnant and if you are breastfeeding.

Warnings and precautions

Talk to your doctor or pharmacist before and during treatment with UNAMITY if you:

- have an infection, or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. UNAMITY can reduce your body's ability to fight infections and may make an existing infection worse or increase the chance of you getting a new infection
- have, or have previously had, tuberculosis. You may need tests to check for tuberculosis before you are given UNAMITY. Tell your doctor if you get persistent cough, fever, night sweats and weight loss during UNAMITY treatment as these can be signs of tuberculosis
- have had a herpes infection (shingles), because UNAMITY may allow it to come back. Tell your doctor if you get a painful skin rash with blisters during UNAMITY treatment as these can be signs of shingles
- have, or have previously had, hepatitis B or C
- are due to have a vaccine. You should not be given certain (live) vaccines while using UNAMITY
- have cancer, because your doctor will have to decide if you can still be given UNAMITY
- have poor liver function

- have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins

If you are using UNAMITY for the treatment of Rheumatoid Arthritis, you may need blood tests before you start UNAMITY, or while you are taking it, to check if you have a low red blood cell count (anaemia), low white blood cell count (neutropaenia or lymphopaenia), high levels of blood fat (cholesterol) or high levels of liver enzymes, to ensure that treatment with UNAMITY is not causing problems.

Children and adolescents

Rheumatoid Arthritis: UNAMITY is not for use in children and adolescents under 18 years old because there is no information on use in this age group.

COVID-19: UNAMITY is not for use in children under 10 years old because there is no information on use in this age group.

Other medicines and UNAMITY

Tell your doctor or pharmacist if you are taking, have recently taken, or might take, any other medicines.

In particular, tell your doctor or pharmacist before taking UNAMITY if you are taking:

- probenecid (for gout), since this medicine may increase the levels of UNAMITY in your blood. If you are taking probenecid, the recommended dose of UNAMITY is 2 mg once a day.
- injectable anti-rheumatic medicine
- medicines which are used to control the body's immune response, such as azathioprine, tacrolimus or ciclosporin
- other medicines belonging to the group of Janus kinase inhibitors, such as ruxolitinib

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Rheumatoid Arthritis: You should use an effective method of contraception to avoid becoming pregnant during treatment with UNAMITY and for at least one week after the last UNAMITY treatment. You must tell your doctor if you become pregnant as UNAMITY should not be used during pregnancy.

COVID 19: There is not enough information to be sure that UNAMITY is safe for use in pregnancy. UNAMITY will only be given to women after their doctor has explained the potential dangers to their unborn baby and the patient has decided that the treatment benefits exceed the risks.

You should not use UNAMITY while breastfeeding your baby.

Driving and using machines

UNAMITY has no effect on the ability to drive and use machines.

3. How to take UNAMITY

Treatment should be started by a doctor experienced in the diagnosis and treatment of the conditions for which baricitinib can be used. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Rheumatoid Arthritis

The recommended dose is 4 mg once a day. Your doctor may give you a lower dose of 2 mg once a day, particularly if you are over 75 years old or if you have an increased risk of infections. If the medicine is working well, your doctor may decide the dose can be reduced.

If you have reduced kidney function, the recommended dose of UNAMITY is 2 mg once a day.

COVID-19

The recommended dose is 4 mg once a day. If you have mildly or moderately reduced kidney function, the recommended dose of UNAMITY is 2 mg once a day. If you have severely reduced kidney function, the recommended dose of UNAMITY is 2 mg every 48 hours.

It is recommended that your doctor prescribes a medicine to reduce the chance of developing a blood clot.

UNAMITY is for oral use. You should swallow your tablet with a drink of water.

You can take the tablets either with or without food. To help you remember to take UNAMITY, you may find it easier to take it at the same time every day.

If you are in the hospital, you may be given this tablet mixed with some water and given through a tube via the nose (nasogastric tube). If you are not able to swallow and have a gastric tube, your doctor might suggest that the medicine is given to you via the tube.

If you take more UNAMITY than you should

If you take more UNAMITY than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take UNAMITY

- If you miss a dose, take it as soon as you remember.
- If you forget your dose for an entire day, just skip the missed dose and take only a single dose as usual the following day.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking UNAMITY

Do not stop taking UNAMITY unless your doctor tells you to stop taking it.

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

4. Possible side effects

UNAMITY can have side effects.

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

If any of the following happens, stop taking UNAMITY and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face
- rash or itching,

These are all very serious side effects. If you have them, you may have had a serious reaction to UNAMITY.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- painful skin rash with blisters and fever which may be signs of shingles (herpes zoster).

Frequent side effects

- nausea (feeling sick in the stomach)
- abdominal pain (stomach cramps or pains)

- throat and nose infections
- cold sores (herpes simplex)
- painful skin rash with blisters and fever
- urinary infection
- headache
- high levels of blood fat (cholesterol) shown by blood test
- infection causing a sick stomach or diarrhoea (gastroenteritis)
- pneumonia
- high number of platelets (cells involved in blood clotting), shown by blood test (this is very common in COVID-19)
- high levels of liver enzymes, shown by blood (this is very common in COVID-19)

Less frequent side effects

- low number of white bloods cells (neutrophils), shown by blood test (this was common in COVID-19)
- increase in an enzyme called creatine kinase, shown by blood test
- high levels of blood fat (triglycerides), shown by blood test
- acne
- swelling of the face
- weight gain
- urticaria
- blood clots in the blood vessels of the lungs (this was common in COVID 19)
- blood clot in the veins of the legs or pelvis, called a deep vein thrombosis (DVT) (this was common in COVID 19)

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. Alternatively, suspected side effects can be reported to the holder of the certificate of registration at ade_za@lilly.com. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store UNAMITY

Store at or below 30 ºC.

Keep this medicine out of sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of any unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What UNAMITY contains

- The **active** substance is baricitinib. Each tablet contains 2 or 4 milligrams of baricitinib.
- The **other** ingredients are: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, mannitol, iron oxide red, lecithin, macrogol, polyvinyl alcohol, talc and titanium dioxide.

What UNAMITY looks like and contents of the pack

UNAMITY 2 mg film-coated tablets are light pink, oblong tablets, with “Lilly” on one side and “2” on the other.

UNAMITY 4 mg film-coated tablets are medium pink, round tablets, with “Lilly” on one side and “4” on the other.

UNAMITY 2 mg and 4 mg are available in blister packs of 14, 18, 28, 35, 56, 84 and 98 tablets in a carton. Not all the pack sizes may be marketed.

Holder of the Certificate of Registration

Eli Lilly (S.A.) (Pty) Ltd

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Registration number

UNAMITY 2 mg film-coated tablets: 52/3.1/0231.229

UNAMITY 4 mg film-coated tablets: 52/3.1/0232.230

Patient Alert Card

Rheumatoid Arthritis: Please remove this portion of the patient information leaflet and keep it with you at all times:

Information for Patients about UNAMITY® (baricitinib)

This document contains important information you should be aware of before and during treatment with UNAMITY.

Keep this information with you and share it with other healthcare professionals involved in your medical care or treatment.

Your name:

_____

Doctor's name (who prescribed UNAMITY):

_____

Doctor's phone number:

_____

Pregnancy:

- Do not take UNAMITY if you are pregnant or suspect you may be pregnant.
- Use effective contraception while taking UNAMITY (and for one week after, if you stop treatment).
- Tell your doctor immediately if you become (or wish to become) pregnant.

Infections:

UNAMITY may make an existing infection worse or increase the chance of you getting a new infection or increase the chance of viral reactivation. Inform your doctor immediately if you get symptoms of infection, such as:

- Fever, wounds, feeling more tired than usual, or dental problems.
- A cough that won't go away, night sweats, and weight loss. These could be symptoms of tuberculosis (an infectious disease of the lings).
- A painful skin rash with blisters. This could be a sign of a herpes zoster infection.

Blood fat:

Your doctor may check for levels of fat in the blood, such as cholesterol, while you are taking UNAMITY.

Blood clots:

UNAMITY may cause a condition in which a blood clot forms in your leg that may travel to your lungs. Inform your doctor immediately if you experience any of the following symptoms:

- Swelling or pain in one leg
- Warmth or redness in one leg
- Shortness of breath which is unexpected
- Rapid breathing
- Chest pain