Australian Rheumatology Association

Arthritis AUSTRALIA

PATIENT INFORMATION ON

UPADACITINIB

Pronunciation - ue PAD a SYE ti nib

(Brand names: Rinvoq®)

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

- how you should take your medicine
- what are the possible side effects
- what tests you must have to monitor your condition and to detect unwanted effects
- other precautions you should take when you are taking UPADACITINIB

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking upadacitinib you must see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.
- If you stop upadacitinib for any reason you must contact your doctor. Failure to do so may mean that your continued treatment will no longer be subsidised.
- If you are worried about any possible side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you have had cancer or if you develop cancer while you are taking upadacitinib .
- If you are taking upadacitinib and plan to become pregnant you must discuss the timing with your doctor.

For more information about RHEUMATOID ARTHRITIS and other inflammatory conditions see Arthritis Australia's Empowered website:
www.arthritisaustralia.com.au

What is Upadacitinib?

Upadacitinib (brand name: Rinvoq®) is a tablet that belongs to a class of medicines called Janus Kinase (JAK) inhibitor. JAK inhibitors work by blocking signals involved in inflammation. Blocking these signals in Rheumatoid Arthritis reduces pain, stiffness, swelling and damage in the joints.

What benefit can you expect from your treatment?

Unlike standard antirheumatic drugs (DMARDs), upadacitinib may work relatively quickly. You may notice some relief of joint swelling, pain and stiffness within the first 2 to 4 weeks of treatment, though it can take up to 3 months to improve.

Stopping upadacitinib

If you stop upadacitinib treatment for more than a few weeks there is a risk that your condition may worsen. Continue with your treatment unless advised by your doctor or unless side effects develop (see *Side effects*).

If you stop upadacitinib for any reason you **must** contact your doctor.

How will your condition be monitored?

In view of the current prescribing restrictions, upadacitinib will only be given if your disease is active and if standard treatments have been unsuccessful.

- It will not be continued unless it helps your condition. This will be assessed at about 12 weeks after the start of treatment.
- Blood tests will be needed during your treatment to monitor your condition, possible side effects

and to determine the effectiveness of treatment.

- The frequency of blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will determine the frequency of tests required.

How is Upadacitinib taken?

Upadacitinib is taken by mouth in tablet form. It is a modified release tablet and must be swallowed whole. Do not crush, break, or chew it.

When should it be taken?

Take this medicine with a full glass of water at the same time each day, swallow the tablet whole and do not crush, chew, or break it. It can be taken with or without food.

If you miss a dose: Take a dose as soon as you remember. If it is almost time for your next dose, wait until then and take a regular dose. Do not take extra medicine to make up for a missed dose.

What is the dosage?

The usual dose for adults with rheumatoid arthritis is one 15 mg tablet taken orally once a day

Can other medicines be taken with Upadacitinib?

This medicine may be used alone or with other arthritis medicines including:

- Other Disease Modifying Anti Rheumatic Drugs (DMARDs) such as methotrexate;
- Steroid medicines such as prednisolone or cortisone injections into the joint;
- Anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn®) or ibuprofen (Brufen®, Nurofen®);
- Simple pain medicines such as paracetamol.

There are separate information sheets for the medicines mentioned above.

Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you notice side effects that you think are caused by this medicine. Many side effects disappear when upadacitinib treatment is stopped.

Most common possible side effects:

The most common side effects reported are more frequent mild upper respiratory tract infections (common cold, sinus infections), nausea, cough, and fever. More serious infections such as tuberculosis reactivation can also occur and screening for this is needed before starting upadacitinib. Infections may need treatment and upadacitinib may need to be stopped for a while if you develop infection, so it is important to contact your doctor for advice.

Less common or rare possible side effects:

Blood clots in the veins of the legs or lungs and arteries are possible in some people taking upadacitinib.

Increases in lipid (cholesterol) levels have been noted in some patients when taking upadacitinib. This effect may be seen early in treatment and your doctor will monitor your blood results.

Liver function abnormalities have been seen. It is recommended to have regular liver function tests.

Upadacitinib increases the risk of getting shingles and vaccination for this should be discussed with your rheumatologist before starting treatment.

Tell your doctor if you get a painful skin rash with blisters as this can be a sign of shingles and you may have to stop the treatment and start medication for shingles straight away.

Upadacitinib may increase the chance of bowel perforation, though this is rare.

Tell your doctor or pharmacist immediately of any of side effects you experience.

What precautions are necessary?

Infections

If you have an active infection of any kind, treatment with upadacitinib will not be started until the infection is treated successfully.

If you have latent (inactive) tuberculosis (TB), preventative anti-TB treatment will need to be started at least 4 weeks before upadacitinib. The anti-TB treatment will usually need to be taken for 9 months.

Blood tests:

Your doctor will do blood tests before you start taking upadacitinib and regularly while you take it. If there are changes in these blood test results your doctor may stop your upadacitinib treatment for a period of time.

Use with other medicines:

Some medicines can affect how upadacitinib works. Always tell your doctor if you are using any other medications including:

- Medicines for fungal or bacterial infections
- Rifampicin or phenytoin
- Medicines that affect your immune system

Use with alcohol

You may drink alcohol while taking upadacitinib. However, if you are also taking methotrexate you should be cautious about your alcohol intake.

Vaccines

This medicine may interfere with some vaccines. Ask your doctor before you get a vaccine. Generally:

- Pneumovax and the combined yearly seasonal flu vaccinations are safe and recommended to reduce your risk of those infections.
- You should not be immunised with 'live' vaccines such as MMR (measles, mumps and rubella), OPV (oral polio virus), Zostavax (Herpes Zoster), BCG (Bacillus Calmette-Guerin) or yellow fever. Talk with your rheumatologist before receiving any vaccines.

Surgery

If you require surgery for any reason, treatment with upadacitinib should be stopped one week before surgery. It will be restarted again after the operation at a time agreed by your surgeon and rheumatologist (usually when the wound is healed).

Cancer

- People with rheumatoid arthritis are at increased risk of lymphoma and some other cancers. It is not known if upadacitinib increases this risk.
- Skin cancers have been reported in people taking upadacitinib and yearly skin checks are recommended.

Use in pregnancy and breastfeeding

Pre-pregnancy planning should be discussed with your treating doctor.

- Upadacitinib should not be used during pregnancy. Women of childbearing potential should use effective birth control both during treatment and for 4 weeks after final dose of Rinvoq.
- Do not breastfeed if you are taking upadacitinib as it is uncertain how much of the drug might be excreted in breastmilk.

More detailed information is available at https://rheumatology.org.au/gps/documents/ARAPregnancyPrescribingGuidanceupdateApr19.pdf

How to store Upadacitinib

Store upadacitinib in a cool, dry place, away from direct heat and light (e.g. not in the bathroom)

Keep all medicines out of reach of children.

Disposal

If your doctor tells you to stop taking your medicine, or if the expiry date has passed, return any unused upadacitinib tablets to your pharmacy.

Do not dispose of upadacitinib tablets via wastewater or household waste.

Questions?	How to help us help you
If you have any questions or concerns write them down and discuss them with your doctor.	Sign up to the ARAD project now!
Your doctor's contact details	The Australian Rheumatology Association collects information on how well these drugs work and how often they cause problems.
	The best way to get this information is from you!
	Contact us in any of the following ways:
	Email: **ARAD@monash.edu**

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any potential side effects.	**Telephone: 03 9508 3424** Visit our website: www.ARAD.org.au