

PATIENT INFORMATION ON UPADACITINIB

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(Brand name: 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 will have to monitor your condition**
- **other precautions you should take while you are taking upadacitinib.**

Please read it carefully and discuss it with your doctor.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as suggested by your rheumatologist.
- It is important to tell your rheumatologist if you have a new serious illness such as a serious infection, cancer or heart failure.
- If you are worried about any side effects, you should contact your rheumatologist as soon as possible.
- If you stop upadacitinib for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- **If you are taking upadacitinib and plan to become pregnant, you must discuss the timing with your rheumatologist**

For more information about RHEUMATOID ARTHRITIS and other inflammatory conditions see Arthritis Australia's 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) inhibitors. 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?

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 or delay your upadacitinib treatment, your disease may get worse. Keep taking your treatment, unless advised by your rheumatologist to stop or unless serious side effects occur (see Side effects).

If you stop upadacitinib for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.

How will you be checked while on upadacitinib?

Medicines like upadacitinib are very expensive and are highly funded by Medicare. Certain conditions must be met to receive it.

- upadacitinib will only be given if your disease is active and if standard treatments have not worked.
- It will only be kept going if it helps your condition. This will be checked around 12 weeks after the start of treatment.
- Blood tests are needed during your treatment to watch for side effects and to decide if the treatment is working.
- How often you have blood tests will depend on what other medicines you are taking and what other illnesses you have. Your rheumatologist will advise on this.



Australian
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upadacitinib
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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. 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.

Upadacitinib cannot be used with other biologic DMARDs or targeted synthetic DMARDs (such as baricitinib and tofacitinib).

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 side effects

Headaches, cough and stomach/ bowel The most common side effects reported are mild upper respiratory tract infections (common cold, sinus infections), nausea, cough, and fever. 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. This can happen more often in patients with an inflammatory condition. Further risk factors including heart disease will be assessed by your doctor.
- Serious infections such as tuberculosis (TB) are seen rarely, and screening for TB is needed before treatment begins.
- Increases in lipid (cholesterol) levels have been noted in some patients when taking upadacitinib and will be checked using blood tests.
- Changes in liver function have been seen. It is recommended to have regular liver function tests.
- Upadacitinib increases the risk of getting shingles. If you get a painful skin rash with blisters inform your doctor immediately. Vaccination for shingles should be discussed with your rheumatologist before starting treatment.
- Upadacitinib may increase the chance of bowel perforation, though this is rare.
- People with rheumatoid arthritis are at increased risk of lymphoma and some other cancers. Medicines that change your immune system like upadacitinib may increase this risk.
- Skin cancers have been reported in people taking upadacitinib and yearly skin checks are recommended.
- 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.

Use with other medicines

Some medicines can affect upadacitinib or may affect how well it works. It is noted to interact with ant-fungal therapy such as ketoconazole and some antibiotics such as rifampicin.

You should tell all your doctors about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

Use with alcohol

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



Vaccines

If you are taking upadacitinib you should not be immunised with 'live' vaccines such as: MMR (measles, mumps and rubella), Varicella vaccines - Zostavax (Chicken pox/Shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin), Japanese Encephalitis or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.

Pneumococcal vaccines and the yearly seasonal flu vaccinations are encouraged.

For more information on vaccination including the COVID-19 vaccination go to the ARA website; www.rheumatology.org.au patients, medication information, vaccinations.

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

Use in pregnancy and when breastfeeding

It is important to discuss with your doctor if you are planning a pregnancy while on upadacitinib. 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 upadacitinib.

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 on the ARA website; 20210806 210802 Pregnancy Prescribing Info new branding.pdf (rheumatology.org.au)

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

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 medicines 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 medicine. 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.

