

Upadacitinib Patient Information



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UPADACITINIB (oo-pad-a-SIT-i-nib)

Patient Information Leaflet

Brand Name: Rinvoq®

What is Upadacitinib?



Upadacitinib is a medication that belongs to a class of drugs called Janus kinase (JAK) inhibitors. It works by blocking specific enzymes (JAK1) that play an important role in the inflammation process. By inhibiting these enzymes, upadacitinib helps reduce inflammation in the body.

Upadacitinib is a tablet that is taken by mouth. It is a targeted synthetic small molecule, which means it is chemically manufactured rather than being derived from living cells like biologic medications.

What is Upadacitinib used for?

Upadacitinib is approved in Australia for:

- Moderate to severe ulcerative colitis in adults
- Moderate to severe rheumatoid arthritis in adults
- Active psoriatic arthritis in adults
- Active ankylosing spondylitis in adults
- Atopic dermatitis (eczema) in adults and adolescents

For ulcerative colitis, upadacitinib is typically prescribed when other treatments such as corticosteroids, immunomodulators, or biologic therapies have not been effective or have caused significant side effects.

How is Upadacitinib taken?

Upadacitinib comes as an extended-release tablet that you take by mouth.

Standard dosing for ulcerative colitis:

- **Induction phase:** 45mg once daily for 8 weeks
- **Maintenance phase:**
 - 15mg or 30mg once daily (as determined by your doctor)

- The lowest effective dose should be used for maintenance treatment

Upadacitinib tablets should be swallowed whole with water. Do not crush, split, or chew the tablets as this can affect how the medication is released into your body. The tablet can be taken with or without food at any time of the day.

How long does Upadacitinib take to work?

The time to experience benefits from upadacitinib varies between individuals:



- Some patients notice improvement in symptoms within the first 2 weeks
- Many patients see significant improvement by 8 weeks
- Your doctor will typically assess the effectiveness of the induction treatment after 8 weeks

If you haven't experienced significant improvement after 16 weeks of treatment, your doctor may consider adjusting your treatment plan.

How should Upadacitinib be stored?

- Store at room temperature between 15°C and 30°C
- Keep the tablets in the original blister pack to protect from moisture
- Keep out of reach of children
- Do not use after the expiry date printed on the package

What monitoring is required while taking Upadacitinib?

Before starting upadacitinib:

- Complete blood count
- Liver function tests
- Kidney function tests
- Lipid profile (cholesterol levels)
- Tuberculosis (TB) screening (skin test, blood test, and/or chest X-ray)
- Hepatitis B and C testing
- Varicella zoster virus (chickenpox) antibody test (if no history of chickenpox or vaccination)
- Pregnancy test for women of childbearing potential

During treatment:

- Regular blood tests to monitor:
 - Complete blood count
 - Liver function
 - Lipid levels
- Regular monitoring of symptoms and disease activity
- Periodic skin examinations to check for skin cancer
- Blood pressure monitoring

What are the risks associated with Upadacitinib?

Serious risks:

1. **Serious infections:**

- Upadacitinib can reduce your ability to fight infections. This includes:
 - Upper respiratory tract infections
 - Pneumonia
 - Cellulitis (skin infection)
 - Herpes zoster (shingles)
 - Serious infections that may require hospitalisation

2. **Blood clots:**

- There is an increased risk of blood clots in the veins (deep vein thrombosis or DVT) or lungs (pulmonary embolism)
- The risk is higher in patients with risk factors such as older age, obesity, a history of blood clots, or who are taking hormonal contraceptives



3. **Cancer risk:**

- There may be an increased risk of certain cancers, particularly lymphomas and non-melanoma skin cancers
- The risk may be higher in current or past smokers
- Regular skin checks are recommended

4. **Gastrointestinal perforations:**

- Rare cases of holes in the wall of the stomach or intestines have been reported
- The risk is higher if you are also taking non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids

5. **Changes in laboratory test results:**

- Decreased white blood cell count
- Decreased red blood cell count (anaemia)
- Increased liver enzymes
- Increased cholesterol levels

6. **Reactivation of herpes zoster (shingles):**

- Upadacitinib increases the risk of developing shingles
- Consider vaccination against shingles before starting treatment

What are the common side effects of Upadacitinib?

Common side effects (affecting more than 1 in 10 people):

- Upper respiratory tract infections (common cold, sinusitis)
- Nausea
- Acne
- Elevated blood cholesterol levels

Less common side effects (affecting between 1 in 100 and 1 in 10 people):

- Cough

- Fever
- Herpes simplex infections (cold sores)
- Herpes zoster (shingles)
- Stomach pain
- Headache
- Increased weight
- Influenza (flu)
- Fatigue
- Anaemia
- Elevated liver enzymes

Drug interactions:

Upadacitinib can interact with several medications. It is important to tell your doctor about all medications you are taking, including:



- Other immunosuppressants (e.g., azathioprine, 6-mercaptopurine, methotrexate)
- Medications that affect the CYP3A4 enzyme (e.g., ketoconazole, clarithromycin, grapefruit juice)
- Live vaccines
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Birth control pills
- Blood thinners
- Cholesterol-lowering medications

Vaccinations and Upadacitinib

Before starting upadacitinib:

It is strongly recommended to update all vaccinations according to the Australian Immunisation Schedule before starting treatment. This includes:

- Influenza vaccine (yearly flu shot)
- Pneumococcal vaccine
- Shingles vaccine (Shingrix is recommended for adults 50 years and older)
- Hepatitis B vaccine (if you are not immune)
- COVID-19 vaccination as per current guidelines

All vaccinations should ideally be completed at least 2-4 weeks before starting upadacitinib.

During upadacitinib treatment:

- **Live vaccines** should be avoided, including:
 - Measles, mumps, rubella (MMR)
 - Varicella (chickenpox)
 - Zoster (Zostavax - but not Shingrix)
 - Oral typhoid
 - Yellow fever
 - BCG (tuberculosis)
 - Oral polio vaccine

- **Non-live vaccines** are generally considered safe but may be less effective while on upadacitinib:
 - Influenza vaccine (yearly)
 - Pneumococcal vaccine
 - Tetanus booster
 - COVID-19 vaccines
 - Shingrix (non-live shingles vaccine)

Always discuss vaccination plans with your gastroenterologist before receiving any vaccine.

Upadacitinib and Pregnancy

Planning pregnancy:

Upadacitinib must not be used during pregnancy.

- Animal studies have shown that upadacitinib may harm the developing foetus
- Women of childbearing potential should use effective contraception during treatment and for at least 4 weeks after the last dose
- Pregnancy testing is recommended before starting treatment

If pregnancy occurs:



- If you become pregnant while taking upadacitinib, inform your doctor immediately
- Your doctor will likely recommend stopping upadacitinib
- You may be enrolled in a pregnancy registry to monitor outcomes

Breastfeeding:

- Upadacitinib should not be used during breastfeeding
- It is not known whether upadacitinib passes into breast milk
- A decision must be made whether to discontinue breastfeeding or to discontinue upadacitinib

Male fertility:

- It is not known whether upadacitinib affects male fertility
- If you are concerned about the effects on fertility, discuss this with your doctor

Special Precautions

Increased risk in certain populations:

The risk of side effects may be higher if you:

- Are 65 years of age or older
- Have a history of heart disease or stroke
- Are a current or past smoker
- Have diabetes
- Have high blood pressure
- Have high cholesterol

- Have a history of blood clots

Surgery:

If you are planning to have surgery, inform your surgeon that you are taking upadacitinib. Your doctor may recommend temporarily stopping upadacitinib before and after surgery to reduce the risk of infection.

Travel:

- Consider carrying a letter from your doctor explaining your need for upadacitinib when travelling
- If travelling overseas, check if you need additional vaccinations and discuss with your doctor (as some travel vaccines are live vaccines)
- Ensure you have enough medication for your entire trip, plus extra in case of delays

Skin protection:

Due to the increased risk of skin cancers, it is important to practise sun safety:

- Use sunscreen (SPF 30+ or higher)
- Wear protective clothing
- Seek shade when possible
- Have regular skin checks with your doctor

Where can I find more information?



- Speak to your gastroenterologist, IBD nurse, or pharmacist
- Contact the Gastroenterological Society of Australia (GESA): www.gesa.org.au
- Contact Crohn's & Colitis Australia: www.crohnsandcolitis.com.au or 1800 138 029
- Call Medicines Line: 1300 MEDICINE (1300 633 424)

This information leaflet is not intended to replace medical advice. Always consult your healthcare team with specific questions about your treatment.

Last updated: April 2025