

Risk of blood clots in veins or lungs

Blood clots in veins or lungs have been observed with RINVOQ®. Tell your doctor straight away if you experience signs of blood clots in your veins (deep vein thrombosis) or lungs (pulmonary embolism), such as leg pain or tenderness, redness or discolouration in the leg or arm, swelling of the leg or arm, shortness of breath or chest pain.

Risk of cancers

RINVOQ® may potentially increase your risk of developing cancers particularly skin cancer.

Let your doctor know if you notice any change in the appearance of an area on your skin, or notice any new growth on your skin.

If you are at risk of developing bowel perforations, tell your doctor straight away if you experience unexplained or unexpected stomach pain.

Show this card to any healthcare professional involved in your medical care – for example, your dentist or an emergency doctor.

Speak to your doctor if you have any questions or concerns.

Your name:

Specialist's name – who prescribed RINVOQ®:

Specialist's phone number:

The date you started RINVOQ®:

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▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

Patient Card

Keep this card with you (or caregiver) all the time

**Safety Information about RINVOQ®
(upadacitinib) for patients**

- This card contains important safety information you should be aware of – before and during treatment with RINVOQ®.
- Read the Consumer Medicines Information for more information.

Risk of infections

RINVOQ® can reduce your body's ability to fight infections, may make an infection you already have worse, or make it more likely for you to get a new infection – for example tuberculosis (TB), shingles, eczema herpeticum or viral hepatitis. Tell your doctor straight away if you notice signs of infection, such as:

- Fever, sweating, chills, weight loss, or a cough that won't go away – these may be signs of TB.
- Painful skin rash with blisters – this may be a sign of shingles or eczema herpeticum in patients with atopic dermatitis.
- Feeling tired or short of breath – this may be a sign of pneumonia.

Tell your doctor if:

- you have been recently diagnosed with TB or you have ever had TB.
- you have recently been in close contact with someone who has TB.

Vaccines used to help prevent infections

Live vaccines should not be given during RINVOQ® treatment, or just before starting RINVOQ® treatment.

Before being given any vaccines, talk to your doctor – they will know which vaccines you should **not** be given before or during treatment with RINVOQ®.

Risk of heart disease

Treatment with RINVOQ® was associated with increases in cholesterol. Your doctor will check your cholesterol levels while you are taking RINVOQ®.

Tell your doctor straight away if you notice symptoms

such as chest pain or tightness since this may be a symptom of heart disease.

Contraception, pregnancy, and breastfeeding

RINVOQ® should not be taken during pregnancy. Females should use effective contraception while taking RINVOQ® and for at least 4 weeks after your last dose. Talk to your doctor about effective contraception.

- Tell your doctor straight away if you wish to become pregnant, or if you become pregnant.
- Do not breastfeed while using RINVOQ®.