

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 patient information leaflet for more information.

Risk of infections

RINVOQ® may make an existing infection worse or increase the chance of you getting a new infection – for example tuberculosis (TB), shingles 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.
- Feeling tired or short of breath – this may be a sign of pneumonia.

Vaccines used to help prevent infections

Live vaccines (for example influenza vaccine by nasal spray, varicella, measles/mumps/rubella) should not be given during 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 a hole in your bowel

RINVOQ may increase your risk of a hole in your bowel especially if you have Crohn's disease. Tell your doctor straight away if you have unexplained or unexpected stomach pain.

Risk of heart disease

Treatment with RINVOQ® was associated with increases in cholesterol (blood fat). 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 breast-feeding

RINVOQ® must not be taken during pregnancy.

- Use effective contraception while taking RINVOQ® – and for 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 breast-feed while using RINVOQ®.

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 get signs of blood clots in veins or lungs, such as a painful swollen leg, 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.

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

Reporting of side effects. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Patient Information Leaflet. You can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk>.

Your name:

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Consultant's name – who prescribed RINVOQ®:

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Consultant's phone number:

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The date you started RINVOQ®:

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www.gov.uk/mhra

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