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.

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.

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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 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 to HPRA Pharmacovigilance, Website: www.hpra.ie or to AbbVie Pharmacovigilance at +353 1 4287900. By reporting side effects, you can help provide more information on the safety of this medicine.

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Your name:

.....

Consultant's name – who prescribed RINVOQ®:

.....

Consultant's phone number:

.....

The date you started RINVOQ®:

.....

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www.rinvoq.eu

abbvie

Patient Card

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

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

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.

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Risk of infections

RINVOQ® can reduce your body's ability to fight infections and may make an existing infection worse or increase the chance of you getting a new infection – for example tuberculosis (TB), pneumonia, or shingles. Tell your doctor straight away if you notice signs of infection, such as:

- Fever, sweating, chills, weight loss, loss of appetite, swelling in the neck or a cough that will not go away – these may be signs of TB.
- Painful skin rash with blisters – this may be a sign of shingles.
- Shortness of breath, fever and a cough with mucus – these may be signs 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, or just before starting RINVOQ® treatment.

Tell your doctor if you have recently had or plan to have a vaccination – your doctor 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 (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.

- If you are a woman of child-bearing potential, 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®.
- If you are breast-feeding or are planning to breastfeed, talk to your doctor before taking this medicine.

Risk of blood clots in veins or lungs

Blood clots in veins or lungs have been observed with RINVOQ®. Tell your doctor or pharmacist before and during treatment with RINVOQ® if you have had blood clots in the veins of your legs or lungs.

Seek medical attention straight away if you get signs of blood clots in veins or legs, such as a painful swollen leg, shortness of breath, or chest pain.