

Tell your doctor immediately if you notice any of these symptoms. Do not attempt to treat yourself at home. Delay in treatment can cause serious damage to health or end fatally.

This overview of adverse drug reactions is not complete and it is necessary to familiarise yourselves with other potential adverse reactions the list of which is available from the Patient Information Leaflet (PIL). The PIL is distributed in each package of the medicinal product and it may be also found at https://prehledy.sukl.cz/prehled_leciv.html#/ under the abbreviation PIL if you enter the name of the medicinal product.

Patient's name:

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Physician's name:

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Physician's phone number:

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Physician's phone number outside of office hours:

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Version 4.0. Date of approval: February 2023.

CZ-RNQ-230003; Approved by SÚKL: December 2024



Patient Card RINVOQ[®] ▼ (upadacitinib)

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

Show this card to to a nurse or physician during any medical examination including emergency or dental treatment.

▼ *This medicinal product is under additional monitoring. This will allow for rapid collection of new safety information. Should you experience any of the adverse reactions, please tell your doctor or pharmacist. You can also report it directly via mailing address: Státní ústav pro kontrolu léčiv, Odbor farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.gov.cz or via <https://nezadouciucinky.sukl.cz/>.*

RINVOQ® increases the risks listed below with possible symptoms:

- *Risk of infections including serious infections* (for example tuberculosis (TB), shingles, viral hepatitis),
Fever, sweating, chills, weight loss or cough (possible tuberculosis),
Painful skin rash with blisters (shingles),
Feeling tired or short of breath (pneumonia), abdominal pain, yellowing of the skin and conjunctiva (hepatitis).

- *Risk of heart disease and risk of blood clots in veins or lungs*

Chest pain or tightness, shortness of breath or swollen legs or abdomen.

- *Risk of cancer including skin cancer*

Any change in the skin color, or growth on the skin.

- *Risk of a hole in your bowel*

Unexpected stomach pain.

Vaccination

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.

Before being given any vaccines, talk to your doctor.

Pregnancy and the need of contraception

RINVOQ® must not be taken during pregnancy. Women must use effective contraception even 4 weeks after the last dose. Tell doctor straight away, when woman becomes pregnant or is planning pregnancy.