

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

RINVOQ® 15 MG

RINVOQ® 30 MG

RINVOQ® 45 MG

Prolonged-release tablets

The active ingredient and its quantity:

Each RINVOQ 15 MG prolonged-release tablet contains 15 mg upadacitinib (as hemihydrate)

Each RINVOQ 30 MG prolonged-release tablet contains 30 mg upadacitinib (as hemihydrate)

Each RINVOQ 45 MG prolonged-release tablet contains 45 mg upadacitinib (as hemihydrate)

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

In addition to the leaflet, RINVOQ has a 'Patient Safety Information Card'. This card includes important safety information, which you should know before starting and during treatment with RINVOQ, and act accordingly. Read the 'Patient Safety Information Card' and the patient leaflet before starting treatment with the preparation. Keep the card for further information if needed.

1. WHAT IS THE MEDICINE INTENDED FOR?

RINVOQ is indicated for the treatment of:

- Moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs). RINVOQ may be used as monotherapy or in combination with methotrexate.
- Active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more DMARDs. RINVOQ may be used as monotherapy or in combination with methotrexate.
- Axial spondyloarthritis
 - Active non-radiographic axial spondyloarthritis (nr-axSpA) in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).
 - Active ankylosing spondylitis ([AS]; Radiographic Axial Spondyloarthritis) in adult patients who have responded inadequately to conventional therapy.
- Moderate to severe atopic dermatitis in adults and adolescents aged 12 and older who are candidates for systemic treatment.
- Adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.
- Adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response or were intolerant to either conventional therapy or a biologic agent.
- Patients 2 years of age and older with active juvenile psoriatic arthritis (JPsA) who have had an inadequate response or intolerance to one or more TNF blockers.
- Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis (pJIA) who have had an inadequate response or intolerance to one or more TNF blockers.

Therapeutic group: selective immunosuppressants, Janus kinase inhibitors.

RINVOQ works by reducing the activity of an enzyme called 'Janus kinase' in the body, which lowers inflammation.

Rheumatoid arthritis

RINVOQ is used to treat adults with rheumatoid arthritis. Rheumatoid arthritis is a disease that causes inflamed joints. If you have moderate to severe active rheumatoid arthritis, you may first be given other medicines, one of which will usually be methotrexate. If these medicines do not work well enough, you will be given RINVOQ either alone or in combination with methotrexate to treat your rheumatoid arthritis. RINVOQ can help to reduce pain, stiffness and swelling in your joints, reduce tiredness, and it can slow down damage to the bone and cartilage in your joints. These effects can ease your normal daily activities and so improve your quality of life.

Psoriatic arthritis

RINVOQ is used to treat adults with psoriatic arthritis. Psoriatic arthritis is a disease that causes inflamed joints and psoriasis. If you have active psoriatic arthritis, you may first be given other medicines. If these medicines do not work well enough, you will be given RINVOQ either alone or in combination with methotrexate to treat your psoriatic arthritis.

RINVOQ can help to reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, and tiredness, and help to slow damage to the bone and cartilage in your joints. These effects can help you to do normal daily activities and so improve your quality of life.

Axial spondyloarthritis (non-radiographic axial spondyloarthritis and ankylosing spondylitis)

RINVOQ is used to treat adults with axial spondyloarthritis. Axial spondyloarthritis is a disease that primarily causes inflammation in the spine. If you have active axial spondyloarthritis, you may first be given other medicines. If these medicines do not work well enough, you will be given RINVOQ to treat your axial spondyloarthritis.

RINVOQ can help to reduce back pain, stiffness, and inflammation in your spine. These effects can ease your normal daily activities and so improve your quality of life.

Atopic dermatitis

RINVOQ is used to treat adults and adolescents 12 years and older with moderate to severe atopic dermatitis, also known as atopic eczema. RINVOQ may be used with eczema medicines that you apply to the skin or it may be used on its own.

Taking RINVOQ can improve the condition of your skin, and reduce itching and flares. RINVOQ can help improve symptoms of pain, anxiety and depression that people with atopic dermatitis may have. RINVOQ can also help improve your sleep disturbance and overall quality of life.

Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the large bowel. RINVOQ is used to treat adults with ulcerative colitis who did not respond well enough or did not tolerate previous therapy. RINVOQ can help to reduce the signs and symptoms of the disease including bloody stools, abdominal pain and the need to rush to the toilet and the number of times you go to the toilet. These effects can enable your normal daily activities and reduce fatigue.

Juvenile psoriatic arthritis (JPsA)

RINVOQ is used to treat patients 2 years of age and older with juvenile psoriatic arthritis. Juvenile psoriatic arthritis is a disease that causes inflamed joints and psoriasis.

RINVOQ is expected to help reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, and tiredness, and help to slow damage to the bone and cartilage in your joints. These effects can help you to do normal daily activities and so improve your health-related quality of life.

Polyarticular juvenile idiopathic arthritis (pJIA)

RINVOQ is used to treat patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis. Polyarticular juvenile idiopathic arthritis is a disease that causes inflamed joints.

RINVOQ is expected to help reduce pain, stiffness, and swelling in your joints, tiredness, and help to slow damage to the bone and cartilage in your joints. These effects can help your health to do normal daily activities and improve your health-related quality of life.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to upadacitinib or any of the other ingredients contained in the medicine (listed in section 6)
- you have a severe infection (such as pneumonia or bacterial skin infection)
- you have severe liver problems (TB)
- you are pregnant (see section "Pregnancy, breast-feeding and fertility" below)

If you notice any of the following serious side effects, tell a doctor straight away:

- symptoms such as a rash (hives), trouble breathing, or swelling of your lips, tongue or throat, if you are taking RINVOQ had serious allergic reactions. If you have any of these symptoms during treatment with RINVOQ, stop taking RINVOQ and get emergency medical help straight away.
- you have or had in the past cancer, smoke or have smoked in the past, because your doctor will discuss this with you if RINVOQ is appropriate for you.

If you notice any of the following serious side effects, tell a doctor straight away:

- you have had diverticulitis (painful inflammation of small pockets in the lining of your intestines) or have an increased risk of heart attack, stroke or heart problems, or are taking

medication to treat your heart, if you have had recent surgery, or if you are taking RINVOQ to treat your heart, tell your doctor if you have had recent surgery, or if you are taking RINVOQ to treat your heart.

If you notice any of the following serious side effects, tell a doctor straight away:

- you have had a stroke (a lack of blood flow to the brain), or have had a heart attack, stroke or heart problems, or are taking

medication to treat your heart, if you have had recent surgery, or if you are taking RINVOQ to treat your heart.

If you notice any of the following serious side effects, tell a doctor straight away:

- you have had a heart attack, stroke or heart problems, or are taking

medication to treat your heart, if you have had recent surgery, or if you are taking RINVOQ to treat your heart.

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