Olumiant® (baricitinib) PRESCRIBING INFORMATION

United Kingdom (Great Britain)

Refer to Summary of Product Characteristics (SmPC) for full prescribing information

Presentation: each film coated tablet contains baricitinib equivalent to 2 mg in the 2 mg tablet and 4 mg in the 4 mg tablet. **Uses:** Rheumatoid arthritis (RA) 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). Baricitinib may be used as monotherapy or in combination with methotrexate. Atopic dermatitis (AD) Treatment of moderate to severe atopic dermatitis in patients 2 years of age and older who are candidates for systemic therapy. Baricitinib may be used with or without topical corticosteroids. Alopecia areata (AA) Treatment of severe alopecia areata in adult patients. Juvenile idiopathic arthritis (JIA) Treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs: Polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive [RF+] or negative [RF-], extended oligoarticular), enthesitis related arthritis, and Juvenile psoriatic arthritis. Baricitinib may be used as monotherapy or in combination with methotrexate. **Dosage and administration:** Treatment should be initiated by physicians experienced in the diagnosis and treatment of the conditions for which Baricitinib is indicated. Posology *Adults:* The recommended dose of baricitinib is 4 mg once daily. A dose of 2 mg once daily is recommended for patients at higher risk of venous thromboembolism (VTE), major adverse cardiovascular events (MACE) and malignancy, for patients aged ≥65 years and for patients with a history of chronic or recurrent infections. A dose of 4 mg once daily may be considered for patients who do not achieve adequate control of disease activity with 2 mg once daily dose. A dose of 2 mg once daily should be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. *Children ≥2 years of age and adolescents AD, and JIA:* The recommended dose of baricitinib is 4 mg once daily for patients weighing 30 kg or more. For patients weighing 10 kg to less than 30 kg, the recommended dose is 2 mg once daily. *AD:* A reduction to half the dose should be considered for patients who have achieved sustained control of disease activity with the recommended dose and are eligible for dose tapering. *AD:* consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 8 weeks of treatment. *AA:* once a stable response has been achieved, it is recommended to continue treatment for at least several months, in order to avoid relapse. The benefit-risk of treatment should be re-assessed at regular intervals on an individual basis. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 36 weeks of treatment. *JIA:* Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 12 weeks of treatment. Treatment initiation: Treatment should not be initiated in patients with an absolute lymphocyte count (ALC) less than 0.5 x 10^9 cells/L, an absolute neutrophil count (ANC) less than 1 x 10^9 cells/L, or who have a haemoglobin value less than 8 g/dL. Treatment may be initiated once values have improved above these limits. **Special Populations:** Renal impairment: The recommended dose is 2 mg once daily in adult patients with creatinine clearance between 30 and 60 mL/min. In paediatric patients with creatinine clearance between 30 and 60 mL/min, the recommended dose of baricitinib should be reduced by half. Baricitinib is not recommended for use in patients with creatinine clearance <30 mL/min. Hepatic impairment: No dose adjustment is required in patients with mild or moderate hepatic impairment. Baricitinib is not recommended for use in patients with severe hepatic impairment. Co-administration with OAT3 inhibitors: The recommended dose is 2 mg once daily in adult patients taking strong Organic Anion Transporter 3 (OAT3) inhibitors, such as probenecid. In paediatric patients taking strong OAT3 inhibitors, the recommended dose of baricitinib should be reduced by half. (consult SmPC for full information on Interaction with other medicinal products and other forms of interaction). Elderly: Clinical experience in patients aged ≥75 years is very limited. Paediatric population (less than 2 years): The safety and efficacy of baricitinib in children less than 2 years have not yet been established. The safety and efficacy of baricitinib in children less than 18 years of age with AA have not yet been established. **Method of administration:** Oral use: Once daily with or without food and may be taken at any time of the day. Alternative administration: paediatric patients who are unable to swallow whole tablets, it may be considered to disperse the tablets in water. Only water should be used to disperse the tablet. Only the number of tablets needed for the dose should be dispersed. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. Pregnancy: Women of childbearing potential have to use effective contraception during and for at least 1 week after treatment. If a patient becomes pregnant while taking baricitinib the parents should be informed of the potential risk to the foetus. **Warnings and special precautions:** Refer to SmPC for full details.

Baricitinib should only be used if no suitable treatment alternatives are available in patients:

- 65 years of age and older;
- patients with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers);
- patients with malignancy risk factors (e.g. current malignancy or history of malignancy).

Infections Serious and sometimes fatal infections have been reported in patients receiving other JAK inhibitors. Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo. In RA clinical studies, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment should be carefully considered prior to initiating baricitinib in patients with active, chronic or recurrent infections. If an infection develops, the patient should be monitored carefully, and therapy should be temporarily interrupted if the patient is not responding to standard therapy. Treatment should not be resumed until the infection resolves. As there is a higher incidence of infections in the elderly and in the diabetic populations in general, caution should be used when treating the elderly and patients with diabetes. Tuberculosis: Patients should be screened for tuberculosis (TB) before starting therapy. Baricitinib should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of treatment in patients with previously untreated latent TB. Haematological abnormalities: Absolute Neutrophil Count (ANC) <1 x 10^9 cells/L, Absolute Lymphocyte Count (ALC) <0.5 x 10^9 cells/L, and haemoglobin <8 g/dL were reported in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC <1 x 10^9 cells/L, ALC <0.5 x 10^9 cells/L or haemoglobin <8 g/dL observed during routine patient management. The risk of lymphocytosis is increased in elderly patients with RA. Rare cases of lymphoproliferative disorders have been reported. Viral reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies. In RA clinical studies, herpes zoster was reported more commonly in patients ≥65 years of age who had previously been treated with both biologic and synthetic conventional disease-modifying antirheumatic drugs DMARDs. If a patient develops herpes zoster, treatment should be temporarily interrupted until the episode resolves. Vaccination: Use with live, attenuated vaccines during, or immediately prior to, baricitinib therapy is not recommended. Prior to initiating treatment, it is recommended that all patients and particularly paediatric patients, be brought up to date with all immunisations in agreement with current immunisation guidelines. Lipids: Dose dependent increases in blood lipid parameters were reported in paediatric and adult patients treated with baricitinib. Elevations in low density lipoprotein (LDL) cholesterol decreased to pre-treatment levels in response to statin therapy in adults. In both paediatric and adult patients lipid parameters should be assessed approximately 12 weeks following initiation of therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. Hepatic transaminase elevations: Dose dependent increases in blood alanine transaminase (ALT) and aspartate transaminase (AST) activity were reported in patients treated with baricitinib. Increases in ALT and AST to ≥5 and ≥10 x upper limit of normal (ULN) were reported in clinical trials. In RA clinical studies, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy. If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, treatment should be temporarily interrupted until this diagnosis is excluded. Malignancy: Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. Lymphoma and other malignancies have been reported in patients receiving JAK inhibitors, including baricitinib. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Venous thromboembolism: In a retrospective observational study of baricitinib in RA patients, a higher rate of venous thromboembolic events (VTE) was observed compared to patients treated with TNF inhibitors. In patients with cardiovascular or malignancy risk factors baricitinib should only be used if no suitable treatment alternatives are available. In patients with known VTE risk factors other than cardiovascular or malignancy risk factors, baricitinib should be used with caution. Patients should be re-evaluated periodically during baricitinib treatment to assess for changes in VTE risk. Promptly evaluate patients with signs and symptoms of VTE and discontinue baricitinib in patients with suspected VTE, regardless of dose or indication. Major adverse cardiovascular events (MACE): In a retrospective observational study of baricitinib in RA patients, a higher rate of MACE was observed compared to patients treated with TNF inhibitors. In patients over 65 years of age, patients who are current or past long-time smokers, and patients with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors, baricitinib should only be used if no suitable treatment alternatives are available. Laboratory monitoring: Please refer to the SmPC for laboratory measures and monitoring guidance. Immunosuppressive medicinal products: Combination with biological DMARDs, biological immunomodulators or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. In RA and JIA, data concerning use of baricitinib with potent immunosuppressive medicinal products other than methotrexate (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations. In AD and AA, combination with ciclosporin or other potent immunosuppressants has not been studied and is not recommended. Hypersensitivity: In post-marketing experience, cases of hypersensitivity associated with baricitinib administration have been reported. If any serious allergic or anaphylactic reaction occurs, treatment should be discontinued immediately. Diverticulitis: Cases of diverticulitis and gastrointestinal perforation have been reported in clinical trials and from post-marketing sources. Baricitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medicinal products associated with an increased risk of diverticulitis: nonsteroidal anti-inflammatory drugs, corticosteroids, and opioids. Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of diverticulitis or gastrointestinal perforation. Hypoglycaemia in patients treated for diabetes: There have been reports of hypoglycaemia following initiation of JAK inhibitors, including baricitinib, in patients receiving medication for diabetes. Dose adjustment of anti-diabetic medication may be necessary in the event that hypoglycaemia occurs. **Interactions:** Please refer to the SmPC for full information on interaction with immunosuppressive medicinal products, potential for other medicinal products to affect the pharmacokinetics of baricitinib, and potential for baricitinib to affect the pharmacokinetics of other medicinal products. **Fertility, pregnancy, and lactation:** Pregnancy: There are no adequate data from the use of baricitinib in pregnant women. Studies in animals have shown reproductive toxicity. Baricitinib was teratogenic in rats and rabbits. Baricitinib is contraindicated during pregnancy. Breast-feeding: It is unknown whether baricitinib/metabolites are excreted in human milk. Baricitinib should not be used during breast feeding A decision must be made whether to discontinue breast-feeding or to discontinue therapy. Fertility: The effect of baricitinib on human fertility has not been evaluated. Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis. **Effects on ability to drive and use machines:** Baricitinib has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** Summary of the safety profile: The most commonly reported adverse reactions with baricitinib are increased LDL cholesterol (26.0 %), upper respiratory tract infections (16.9 %), headache (5.2 %), herpes simplex (3.2 %), and urinary tract infections (2.9 %). Serious pneumonia and serious herpes zoster occurred uncommonly in patients with RA. *Very common (≥1/10):* Upper respiratory tract infection, Hypercholesterolaemia, *Common (≥1/100 to <1/10):* Herpes zoster, Herpes simplex, Gastroenteritis, Urinary tract infections, Pneumonia, Folliculitis, Thrombocytosis >600 x 10^9 cells/L, Headache, Nausea, Abdominal pain, ALT increased ≥3 x ULN, Rash, Acne, Creatine phosphokinase increased >5 x ULN. *Uncommon (≥1/1,000 to <1/100):* Neutropaenia <1 x 10^9 cells/L, swelling of the face, Urticaria, Hypertriglyceridaemia, Deep Vein Thrombosis, Pulmonary embolism, Diverticulitis, AST increased ≥3 x ULN, Weight increased. In paediatric patients in the placebo-controlled double-blind randomised withdrawal period of the juvenile idiopathic arthritis clinical trial (n=82); headache, common (11 %); neutropenia <1 000 cells/mm^3, common (2.4 %, one patient); pulmonary embolism, common (1.2 %, one patient). *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at http://www.medicines.org.uk/emc/.* **Legal Category** POM. **Marketing Authorisation Numbers (or Product Licence Numbers) and Holder** PLGB 14895/0255 PLGB 14895/0256, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK only)** £805.56 per pack of 28 x 2 mg film-coated tablets, £805.56 per pack of 28 x 4 mg film-coated tablets, **Date of Preparation or Last Review** July 2024 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Great Britain):** + 44-(0) 1256 315000, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk

PP-BA-GB-1985 July 2024

Adverse events and product complaints should be reported.
Reporting forms and information can be found at
UK: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events and product complaints should also be reported to Lilly: please call Lilly **UK** on **01256 315 000**.

Olumiant® (baricitinib) PRESCRIBING INFORMATION — Ireland and United Kingdom (Northern Ireland)

Refer to Summary of Product Characteristics (SmPC) for full prescribing information

Presentation: each film coated tablet contains baricitinib equivalent to 2 mg in the 2 mg tablet and 4 mg in the 4 mg tablet. **Uses:** Rheumatoid arthritis (RA) 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). Baricitinib may be used as monotherapy or in combination with methotrexate. Atopic dermatitis (AD) Treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy. Alopecia areata (AA) Treatment of severe alopecia areata in adult patients. Juvenile idiopathic arthritis (JIA) Treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs: Polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive [RF+] or negative [RF-], extended oligoarticular), enthesitis related arthritis, and Juvenile psoriatic arthritis. Baricitinib may be used as monotherapy or in combination with methotrexate. **Dosage and administration:** Treatment should be initiated by physicians experienced in the diagnosis and treatment of the conditions for which Baricitinib is indicated. Posology: *RA, adult AD and AA.* The recommended dose of baricitinib is 4 mg once daily. A dose of 2 mg once daily is recommended for patients at higher risk of venous thromboembolism (VTE), major adverse cardiovascular events (MACE) and malignancy, for patients aged ≥ 65 years and for patients with a history of chronic or recurrent infections. A dose of 4 mg once daily may be considered for patients who do not achieve adequate control of disease activity with 2 mg once daily dose. A dose of 2 mg once daily should be considered for patients who have achieved sustained control of disease activity with 4 mg once daily and are eligible for dose tapering. *Paediatric AD* (2 years to < 18 years of age): 4 mg once daily for patients weighing 30 kg or more or 2 mg once daily for patients weighing 10 kg to less than 30 kg. A reduction to half the dose should be considered for patients who have achieved sustained control of disease activity with the recommended dose and are eligible for dose tapering. AD: Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 8 weeks of treatment. Baricitinib may be used with or without topical corticosteroids. AA: Once a stable response has been achieved, it is recommended to continue treatment for at least several months, in order to avoid relapse. The benefit-risk of treatment should be re-assessed at regular intervals on an individual basis. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 36 weeks of treatment. *Juvenile idiopathic arthritis (JIA)* (from 2 to less than 18 years of age): The recommended dose of baricitinib is 4 mg once daily for patients weighing 30 kg or more. For patients weighing 10 kg to less than 30 kg, the recommended dose is 2 mg once daily. Consideration should be given to discontinuing treatment in patients who show no evidence of therapeutic benefit after 12 weeks of treatment. Treatment initiation: Treatment should not be initiated in patients with an absolute lymphocyte count (ALC) less than 0.5 x 10^9 cells/L, an absolute neutrophil count (ANC) less than 1 x 10^9 cells/L, or who have a haemoglobin value less than 8 g/dL. Treatment may be initiated once values have improved above these limits. **Special Populations:** Renal impairment: The recommended dose is 2 mg once daily in adult patients with creatinine clearance between 30 and 60 mL/min. In paediatric patients with creatinine clearance between 30 and 60 mL/min, the recommended dose of baricitinib should be reduced by half. Baricitinib is not recommended for use in patients with creatinine clearance < 30 mL/min. Hepatic impairment: No dose adjustment is required in patients with mild or moderate hepatic impairment. Baricitinib is not recommended for use in patients with severe hepatic impairment. Co-administration with OAT3 inhibitors: The recommended dose is 2 mg once daily in adult patients taking strong Organic Anion Transporter 3 (OAT3) inhibitors, such as probenecid. In paediatric patients taking strong OAT3 inhibitors, the recommended dose of baricitinib should be reduced by half. (consult SmPC for full information on Interaction with other medicinal products and other forms of interaction). Elderly: Clinical experience in patients aged ≥ 75 years is very limited. Paediatric population (less than 2 years): The safety and efficacy of baricitinib in children less than 2 years have not yet been established. The safety and efficacy of baricitinib in children less than 18 years of age with AA has not yet been established. **Method of administration:** Oral use: Once daily with or without food and may be taken at any time of the day. Alternative administration for children: for paediatric patients who are unable to swallow whole tablets, it may be considered to disperse the tablets in water. Only water should be used to disperse the tablet. Only the number of tablets needed for the dose should be dispersed. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients listed in the SmPC. Pregnancy: Women of childbearing potential have to use effective contraception during and for at least 1 week after treatment. If a patient becomes pregnant while taking baricitinib the parents should be informed of the potential risk to the foetus. **Warnings and special precautions:** Refer to SmPC for full details.

Baricitinib should only be used if no suitable treatment alternatives are available in patients: 65 years of age and older; with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors (such as current or past long-time smokers; with malignancy risk factors (e.g. current malignancy or history of malignancy).

Infections: Serious and sometimes fatal infections have been reported in patients receiving other JAK inhibitors. Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo. In RA clinical studies, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. If an infection develops, the patient should be monitored carefully, and therapy should be temporarily interrupted if the patient is not responding to standard therapy. Treatment should not be resumed until the infection resolves. As there is a higher incidence of infections in the elderly and in the diabetic populations in general, caution should be used when treating the elderly and patients with diabetes. Tuberculosis: Patients should be screened for tuberculosis (TB) before starting therapy. Baricitinib should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of treatment in patients with previously untreated latent TB. Haematological abnormalities: Absolute Neutrophil Count (ANC) < 1 x 10^9 cells/L, Absolute Lymphocyte Count (ALC) < 0.5 x 10^9 cells/L, and haemoglobin < 8 g/dL were reported in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1 x 10^9 cells/L, ALC < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management. The risk of lymphocytosis is increased in elderly patients with RA. Rare cases of lymphoproliferative disorders have been reported. Viral reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies. In RA clinical studies, herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and synthetic conventional DMARDs. If a patient develops herpes zoster, treatment should be temporarily interrupted until the episode resolves. Vaccination: Use with live, attenuated vaccines during, or immediately prior to, baricitinib therapy is not recommended. Prior to initiating treatment, it is recommended that all patients and particularly paediatric patients, be brought up to date with all immunisations in agreement with current immunisation guidelines. Lipids: Dose dependent increases in blood lipid parameters were reported in paediatric and adult patients treated with baricitinib. Elevations in low density lipoprotein (LDL) cholesterol decreased to pre-treatment levels in response to statin therapy in adults. In Paediatric and adult patients, lipid parameters should be assessed approximately 12 weeks following initiation of therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. Hepatic transaminase elevations: Dose dependent increases in blood alanine transaminase (ALT) and aspartate transaminase (AST) activity were reported in patients treated with baricitinib. Increases in ALT and AST to ≥ 5 and ≥ 10 x upper limit of normal (ULN) were reported in clinical trials. In RA clinical studies, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy. If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, treatment should be temporarily interrupted until this diagnosis is excluded. Malignancy: Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. Lymphoma and other malignancies have been reported in patients receiving JAK inhibitors, including baricitinib. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer. Venous thromboembolism: In a retrospective observational study of baricitinib in RA patients, a higher rate of venous thromboembolic events (VTE) was observed compared to patients treated with TNF inhibitors. In patients with cardiovascular or malignancy risk factors baricitinib should only be used if no suitable treatment alternatives are available. In patients with known VTE risk factors other than cardiovascular or malignancy risk factors, baricitinib should be used with caution. Patients should be re-evaluated periodically during baricitinib treatment to assess for changes in VTE risk. Promptly evaluate patients with signs and symptoms of VTE and discontinue baricitinib in patients with suspected VTE, regardless of dose or indication. Major adverse cardiovascular events (MACE): In a retrospective observational study of baricitinib in RA patients, a higher rate of MACE was observed compared to patients treated with TNF inhibitors. In patients over 65 years of age, patients who are current or past long-time smokers, and patients with history of atherosclerotic cardiovascular disease or other cardiovascular risk factors, baricitinib should only be used if no suitable treatment alternatives are available. Laboratory monitoring: Please refer to the SmPC for laboratory measures and monitoring guidance. Immunosuppressive medicinal products: Combination with biological DMARDs, biological immunomodulators or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. In RA and JIA, data concerning use of baricitinib with potent immunosuppressive medicinal products other than methotrexate (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations. In AD and AA, combination with ciclosporin or other potent immunosuppressants has not been studied and is not recommended. Hypersensitivity: In post-marketing experience, cases of hypersensitivity associated with baricitinib administration have been reported. If any serious allergic or anaphylactic reaction occurs, treatment should be discontinued immediately. Diverticulitis: Cases of diverticulitis and gastrointestinal perforation have been reported in clinical trials and from post-marketing sources. Baricitinib should be used with caution in patients with diverticular disease and especially in patients chronically treated with concomitant medicinal products associated with an increased risk of diverticulitis: nonsteroidal anti-inflammatory drugs, corticosteroids, and opioids. Patients presenting with new onset abdominal signs and symptoms should be evaluated promptly for early identification of diverticulitis or gastrointestinal perforation. Hypoglycaemia in patients treated for diabetes: There have been reports of hypoglycaemia following initiation of JAK inhibitors, including baricitinib, in patients receiving medication for diabetes. Dose adjustment of anti-diabetic medication may be necessary in the event that hypoglycaemia occurs. **Interactions:** Please refer to the SmPC for full information on interaction with immunosuppressive medicinal products, potential for other medicinal products to affect the pharmacokinetics of baricitinib, and potential for baricitinib to affect the pharmacokinetics of other medicinal products. **Fertility, pregnancy, and lactation:** Pregnancy: There are no adequate data from the use of baricitinib in pregnant women. Studies in animals have shown reproductive toxicity. Baricitinib was teratogenic in rats and rabbits. Baricitinib is contraindicated during pregnancy. Breast-feeding: It is unknown whether baricitinib/metabolites are excreted in human milk. Baricitinib should not be used during breast feeding A decision must be made whether to discontinue breast-feeding or to discontinue therapy. Fertility: The effect of baricitinib on human fertility has not been evaluated. Studies in animals suggest that treatment with baricitinib has the potential to decrease female fertility while on treatment, but there was no effect on male spermatogenesis. **Effects on ability to drive and use machines:** Baricitinib has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** Summary of the safety profile: The most commonly reported adverse reactions with baricitinib are increased LDL cholesterol (26.0 %), upper respiratory tract infections (16.9 %), headache (5.2 %), herpes simplex (3.2 %), and urinary tract infections (2.9 %). Serious pneumonia and serious herpes zoster occurred uncommonly in patients with RA. Very common (≥ 1/10): Upper respiratory tract infection, Hypercholesterolaemia, Common (≥ 1/100 to < 1/10): Herpes zoster, Herpes simplex, Gastroenteritis, Urinary tract infections, Pneumonia, Folliculitis, Thrombocytosis > 600 x 10^9 cells/L, Headache, Nausea, Abdominal pain, ALT increased ≥ 3 x ULN, Rash, Acne, Creatine phosphokinase increased > 5 x ULN. Uncommon (≥ 1/1,000 to < 1/100): Neutropaenia < 1 x 10^9 cells/L, swelling of the face, Urticaria, Hypertriglyceridaemia, Deep Vein Thrombosis, Pulmonary embolism, Diverticulitis, AST increased ≥ 3 x ULN, Weight increased. In paediatric patients in the placebo-controlled double-blind randomised withdrawal period of the juvenile idiopathic arthritis clinical trial (n=82); headache, common (11 %); neutropenia < 1 000 cells/mm^3, common (2.4 %, one patient); pulmonary embolism, common (1.2 %, one patient). *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom (Northern Ireland):*** *https://www. emcmedicines.com/en-GB/northernireland, or* ***Ireland:*** *http://www.medicines.ie/.* **Legal Category:** POM. **Marketing Authorisation Numbers (or Product Licence Numbers) and Holder:** EU/1/16/1170/002, EU/1/16/1170/010, Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands. **Cost (UK (Northern Ireland) only):** £805.56 per pack of 28 x 2 mg film-coated tablets, £805.56 per pack of 28 x 4 mg film-coated tablets. An Irish price is available on request; please see section below for contact information. **Date of Preparation or Last Review:** August 2024 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Northern Ireland):** + 44-(0) 1256 315000, **Ireland:** + 353-(0) 1 661 4377, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk; www.lilly.ie

PP-BA-IE-0111 August 2024

Adverse events and product complaints should be reported. Reporting forms and information can be found at **UK (Northern Ireland): www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store, or **Ireland: www.hpra.ie.**

Adverse events and product complaints should also be reported to Lilly: please call **Lilly UK** on **01256 315 000**, or **Lilly Ireland** on **01 664 0446**.