# BIQUELLE XL (QUETIAPINE) PRICE GUARANTEE

Our mission is to work with the NHS to help achieve their efficiency savings goals by offering high quality branded medicines that provide significant cost savings and continuity for patients. *

The BIQUELLE® XL range could save the NHS up to 56% on their current costs compared with the current Category C UK Drug Tariffs pricing for quetiapine prolonged-release tablets.[1]**

| Product: Quetiapine prolonged-release tablets (pack size 30 and 60) | Category C Drug Tariff Price[1] | BIQUELLE XL Price | |
|---|---|---|---|
| | | Pack size 60 | Pack size 30 |
| 50mg | £67.66 | £29.45 | £14.73 |
| 150mg | £113.10 | £49.45 | £24.73 |
| 200mg | £113.10 | £49.45 | £24.73 |
| 300mg | £170.00 | £74.45 | £37.23 |
| 400mg | £226.20 | £98.95 | £49.48 |
| **600mg** | **The only 600mg prolonged-release quetiapine tablets, priced at: £70.73 per month** | | |

We confirm that the prices will remain unchanged unless there is a material change to Category C of the UK Drug Tariffs or the product in the 2024 PPRS review.

If you would like any further information, please do not hesitate to contact Aspire Pharma on 01730 231148 or info@aspirepharma.co.uk.

Yours faithfully

Graham J Fraser-Pye

Graham Fraser-Pye
Managing Director.

* Ensuring continuity by guaranteeing a single product is dispensed, rather than patients being dispensed a variety of generic products.
** Based on 56% saving when prescribing Biquelle XL 50, 150, 200, 300, 400 and 600mg tablets only, versus the cost of Category C quetiapine XL on the UK Drug Tariffs.
References: 1) September 2021 UK Drug Tariffs.

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**Biquelle XL (Quetiapine) Prolonged-release Tablets Prescribing Information (please refer to the full SmPC before prescribing)**

**Indications:** Schizophrenia; moderate to severe manic and major depressive episodes in bipolar disorder; prevention of recurrence of manic or depressed episodes in bipolar patients who have previously responded to quetiapine treatment; add-on treatment of major depressive episodes in patients with major depressive disorder (MDD) who have had sub-optimal response to antidepressant monotherapy. **Available strengths:** 50, 150, 200, 300, 400mg (x60 tablets) and 600mg (x30 tablets). **Dosage**: Schizophrenia, moderate to severe manic episodes in bipolar disorder: Administer at least one hour before meal. 300mg day 1, 600mg day 2; recommended daily dose 600mg; max dose 800mg daily. Major depressive episodes in bipolar disorder: Administer at bedtime. 50mg day 1; 100mg day 2; 200mg day 3, 300mg day 4. Recommended daily dose 300mg; Doses over 300mg at experienced physician's discretion. Preventing recurrence in bipolar disorder: Continue on the same dose between 300-800mg at bedtime. For add-on treatment of major depressive episodes in MDD: Administer prior to bedtime. 50mg (day 1 & 2), 150mg (day 3 & 4), dose may be increased to 300mg/day on individual patient evaluation. Maintain at lowest effective dose. **Administration**: Once daily without food. Swallow tablets whole - do not split, chew, or crush. Patients on quetiapine immediate-release tablets may be switched to quetiapine prolonged-release tablets at equivalent total daily dosage taken once daily. Individual dose adjustments may be necessary. **Contraindications:** Patients with hypersensitivity to active substance or excipients; concomitant use of cytochrome P450 CYP 3A4 inhibitors (e.g., HIV protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin, nefazodone). **Special warnings and precautions for use:** Elderly – use with caution. Rate of titration may need to be slower and daily dose lower. Start on 50mg/day and increase by 50mg/day to effective dose depending on response and tolerability. In elderly with major depressive episodes in MDD, start with 50mg/day on Days 1-3, 100mg/day on Day 4, 150mg/day on Day 8. Based on individual patient, if dose increase to 300mg/day required, this should not be before Day 22. Efficacy and safety not evaluated in bipolar patients over 65 with depressive episodes. Long-term efficacy and safety in MDD patients has been evaluated as monotherapy but not as add-on therapy. Not recommended for use in children and adolescents <18 years old due to lack of data. No dose adjustment necessary in renal impairment. Use with caution if known hepatic impairment – start on 50mg/day and increase by 50mg/day to effective dose, depending on response and tolerability. Closely supervise and monitor patients, especially those at high risk, for worsening, suicidal behaviour/thoughts and unusual changes in behaviour, particularly in early treatment and after dose changes -; assess metabolic parameters at initiation of and regularly throughout treatment; observe for signs and symptoms of hyperglycaemia; diabetic patients and those at risk for diabetes mellitus should be monitored regularly for worsening glucose control; consider dose reduction/ discontinuation if symptoms of tardive dyskinesia – symptoms can worsen or even arise after treatment discontinuation; discontinue if neuroleptic malignant syndrome develops and treat appropriately; if akathisia develops, increasing dose may be detrimental; if somnolence occurs, onset usually within first 3 days of treatment; orthostatic hypotension has been reported, usually during titration – can increase risk of falls, especially in elderly; caution in those with cardiovascular disease, risk factors for VTE, cerebrovascular disease, other conditions predisposing to hypotension, elderly patients with Parkinson's disease/parkinsonism, patients receiving concomitant CNS depressants and those at risk for sleep apnoea (e.g. overweight/male), history of seizures, risk factors for neutropenia, concomitant use of medications with anti-cholinergic (muscarinic) effects, diagnosis or history of urinary retention, prostatic hypertrophy, increased intraocular pressure/narrow angle glaucoma, family history of QT prolongation, risk factors for stroke, risk of aspiration pneumonia, history of alcohol or drug abuse. Caution when used with medicines known to cause electrolyte imbalance or increase QT interval, or with neuroleptics, especially in elderly, those with congenital long QT syndrome, congestive heart failure, heart hypertrophy, hypokalaemia, hypomagnesaemia, or in combination with other centrally acting medicines or alcohol. In patients with suspected cardiomyopathy or myocarditis discontinuation of quetiapine should be considered. Severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) which can be life threatening or fatal have been reported very rarely with quetiapine treatment. SCARs commonly present as a combination of: extensive cutaneous rash or exfoliative dermatitis, fever, lymphadenopathy, and possible eosinophilia. If signs and symptoms suggestive of these severe skin reactions appear, withdraw quetiapine immediately and consider alternative treatment. Constipation and intestinal obstruction have been reported, including fatalities in those at higher risk for obstruction including those taking multiple medicines that decrease intestinal motility and may not report constipation symptoms. Pancreatitis has been reported. Severe neutropenia has been reported, mostly within months of initiation. Discontinue if neutrophil count $<1.0x10^9$/L – monitor neutrophil count and for signs of infection. Consider neutropenia if infection or fever, especially if no predisposing factor. Advise to immediately report signs/symptoms of agranulocytosis/infection, promptly check white blood cell and absolute neutrophil count. Contains lactose; do not use if rare hereditary problems of galactose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption. Do not consume grapefruit juice. Advise not to drive/operate machinery until individual susceptibility to quetiapine affecting a patient's mental alertness is known. False positive results reported in enzyme immunoassays for methadone and tricyclic antidepressants. Recommend confirmation of questionable immunoassay screening results by an appropriate chromatographic technique. Concomitant use with strong hepatic enzyme inducer could affect efficacy. If receiving a hepatic enzyme inducer, only initiate quetiapine if benefits outweigh risks of removing enzyme inducer. Any change in inducer must be gradual and if required, should be replaced with a non-inducer (e.g. sodium valproate). Data in combination with divalproex or lithium in manic episodes limited Not approved for dementia-related psychosis. Advise gradual withdrawal over 1-2 weeks to avoid acute withdrawal symptoms. Only use in pregnancy if benefits justify potential risks. If exposed to antipsychotics in third trimester, monitor newborns carefully for adverse events; lactation – decide whether to discontinue breast-feeding or discontinue quetiapine. **Side effects:** For full list of side effects consult SmPC. 'Very Common', 'Common' and 'Serious' side effects included in this prescribing information. Very common (≥1/10): decreased haemoglobin, elevations in serum triglycerides, elevations in total cholesterol (predominantly LDL), decreases in HDL cholesterol, weight gain, dizziness, somnolence, headache, extrapyramidal symptoms, dry mouth and withdrawal (discontinuation) symptoms. Common (≥1/100 to <1/10): leucopenia, decreased neutrophil count, eosinophils increased, hyperprolactinemia, decreases in total T4, decreases in free T4, decreases in total T3, increases in TSH, increased appetite, increased blood glucose to hyperglycaemic levels, abnormal dreams and nightmares, suicidal ideation and suicidal behaviour, dysarthria, tachycardia, palpitations, blurred vision, orthostatic hypotension, dyspnoea, constipation, dyspepsia, vomiting, elevations in serum alanine aminotransferase, elevations in gamma-GT levels, mild asthenia, peripheral oedema, irritability, pyrexia. Serious uncommon/rare/very rare/not known frequency: neutropenia, thrombocytopenia, anaemia, hypersensitivity (including allergic skin reactions), hyponatraemia, Diabetes Mellitus, exacerbation of pre-existing diabetes, seizure, tardive dyskinesia, syncope, QT prolongation, elevations in serum aspartate aminotransferase, bradycardia, agranulocytosis, metabolic syndrome, venous thromboembolism, pancreatitis, intestinal obstruction/ileus, hepatitis, priapism, neuroleptic malignant syndrome, hypothermia, elevations in blood creatine phosphokinase, anaphylactic reaction, inappropriate antidiuretic hormone secretion, angioedema, Stevens-Johnson syndrome, cardiopathy, myocarditis, stroke, rhabdomyolysis, toxic epidermal necrolysis, erythema multiforme, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), cutaneous vasculitis, drug withdrawal syndrome neonatal.. **MA number:** PL 35533/0051-55. **Cost:** £29.45 for 50mg, £49.45 for 150mg, £49.45 for 200mg, £74.45 for 300mg, £98.95 for 400mg (x60 pack), £70.73 for 600mg (x30 pack). **MAH:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG, UK. **Legal category:** POM. **Date last reviewed:** May 2021. **Version Number:** 1010269093 v 11.0

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Aspire Pharma Ltd on 01730 231148.

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