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BIQUELLE XL (QUETIAPINE) PRICE GUARANTEE

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

The BIQUELLE® XL range will save the NHS 56% on their current costs compared with the current Category C UK Drug Tariff price for quetiapine prolonged-release tablets.[1**]

Product	Category C Drug Tariff Price[1]	BIQUELLE XL Price
Quetiapine prolonged-release tablets 50mg x 60	£67.66	£29.45
Quetiapine prolonged-release tablets 150mg x 60	£113.10	£49.45
Quetiapine prolonged-release tablets 200mg x 60	£113.10	£49.45
Quetiapine prolonged-release tablets 300mg x 60	£170.00	£74.45
Quetiapine prolonged-release tablets 400mg x 60	£226.20	£98.95

I can confirm that the above prices will be held until at least 2019, at which time there is scheduled to be a new PPRS review. ***

If you would like any further information, please do not hesitate to contact Aspire Pharma on 01730 231148.

Yours faithfully

Graham Fraser-Pye
Managing Director.

* Ensuring brand continuity by guaranteeing a single product is dispensed, rather than patients being dispensed a variety of generic products.
** 56% saving on the cost of Category C quetiapine XL in the October 2016 Drug Tariff.
*** No change in price subject to no material change to the products or Category C of the UK Drug Tariff until the 2019 PPRS review.

References: 1) October 2016 UK Drug Tariff.

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

Indications: Biquelle XL is indicated for the treatment of schizophrenia and for the treatment of bipolar disorder by treating moderate to severe manic and major depressive episodes as well as preventing the recurrence of manic and depressed episodes in patients who have previously responded to quetiapine treatment. Biquelle XL is also indicated as an add-on treatment for treatment of major depressive episodes in patients with major depressive disorder (MDD) who have had sub-optimal response to antidepressant monotherapy. **Contraindications:** Biquelle XL is contraindicated in patients with a hypersensitivity to the active substance or to any of the excipients, and concomitant administration of cytochrome P450 3A4 inhibitors (i.e., HIV protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone). **Special warnings and precautions for use:** Biquelle XL should be used with caution in the elderly; patients with known hepatic impairment particularly during initial dosing, cardiovascular disease, cerebrovascular disease, other conditions predisposing to hypotension, history of seizures, family history of QT prolongation, risk factor of stroke, risk of aspiration pneumonia, congenital long QT syndrome, medicinal products known to cause electrolyte imbalance or to increase QT interval; and medicines known to increase QT interval, congestive heart failure, heart hypertrophy, hypokalaemia or hypomagnesaemia; and in combination with other centrally acting medicinal products, alcohol, or with neuroleptics in the elderly. Biquelle XL contains lactose, patients with rare hereditary problems of glucose intolerance, the lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Consult SmPC before prescribing to patients who are pregnant or breast-feeding. This product is not recommended for use in children and adolescents <18 years old. Patients experiencing somnolence may require more frequent contact for a minimum of 2 weeks from onset of somnolence and discontinuation of Biquelle XL may be considered. Patients should be advised not to drive or operate machinery, until individual susceptibility to quetiapine affecting a patient's mental awareness is known. Consult SmPC for patient monitoring requirements. There have been reports of false positive results in enzyme immunoassays for methadone and tricyclic antidepressants in patients who have taken quetiapine. Confirmation of questionable immunoassay screening results by an appropriate chromatographic technique is recommended. In patients receiving a hepatic enzyme inducer, initiation of quetiapine should only occur if the physician considers that the benefits of quetiapine outweigh the risks of removing the hepatic enzyme inducer, and it is important that any change in the inducer is gradual, and if required, replaced with a non-inducer. In patients who develop akathisia on quetiapine, increasing the dose may be detrimental. Consult SmPC for dose reduction/titration or discontinuation requirements when starting or stopping Biquelle XL. Patients should be advised to exercise caution until they are familiar with their medication as it may cause orthostatic hypotension and dizziness. Concomitant use of quetiapine with a strong hepatic enzyme inducer could affect the efficacy of quetiapine. The use of Biquelle XL in pregnancy should only be considered where the benefits outweigh the risks, use during lactation is not recommended as quetiapine is present in breast milk. All possible risk factors for venous thromboembolism should be identified before and during treatment with quetiapine and preventative measures undertaken. Sleep apnoea syndrome has been reported in patients using quetiapine. In patients receiving concomitant central nervous system depressants and who have a history of or are at risk for sleep apnoea, such as those who are overweight/obese or are male, quetiapine should be used with caution. Quetiapine should be used with caution in patients receiving medications having anti-cholinergic (muscarinic) effects. Quetiapine should be used with caution in patients with a current diagnosis or prior history of urinary retention, clinically significant prostatic hypertrophy, intestinal obstruction or related conditions, increased intraocular pressure or narrow angle glaucoma. **Side effects:** Very common (≥1/10) side effects include decreased haemoglobin, elevations in serum triglyceride levels, 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) side effects include 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 (including after abrupt withdrawal), 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 and pyrexia. Serious side effects include neutropenia, thrombocytopenia, hypersensitivity (including allergic skin reactions), Diabetes Mellitus, exacerbation of pre-exisitng Diabetes Mellitus, seizure, tardive dyskinesia, syncope, QT prolongation, elevations in serum aspartate aminotransferase, bradycardia agranulocytosis, venous thromboembolism, pancreatitis, hepatitis, neuroleptic malignant syndrome, hypothermia, elevations in blood creatine phosphokinase, anaphylactic reaction, inappropriate antidiuretic hormone secretion, angioedema, Stevens-Johnson syndrome, rhabdomyolysis, neutropenia, toxic epidermal necrolysis and erythema multiforme. Please see SmPC for full list of side effects and side effects from unlicensed use in children. **Dosage and method of use**: Biquelle XL tablets should be swallowed whole once daily without food. Different dosing schedules exist for each indication and patients should be maintained at the lowest effective dose. For the treatment of schizophrenia and moderate to severe manic episodes in bipolar disorder the starting dose is 300mg, recommended dose 600mg up to 800mg. Treatment for major depressive episodes in bipolar disorder the starting dose is 50mg on day 1, 100mg day 2, 200mg day 3 and 300mg day 4 maintaining at 300mg. For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who have previously responded to quetiapine treatment, patients should continue on the same dose between 300-800mg. As an add on treatment of major depressive episodes in MDD, the starting dose is 50mg on day 1 and 2, and 150mg day 3 and 4, and maintenance between 50-300mg. For posology in special populations and for further dosage information please consult SmPC for further information. **MA number:** PL 35533/0051-55. **Cost:** £29.45 for 50mg x60 pack, £49.45 for 150mg x60 pack, £49.45 for 200mg x60 pack, £74.45 for 300mg x60 pack, £98.95 for 400mg x60 pack. **MAH:** Aspire Pharma Ltd, Unit 4, Rotherbrook Court, Bedford Road, Petersfield, Hampshire, GU32 3QG, UK. **Legal category:** POM. **Date last reviewed:** October 2016. **Version Number:** 1010269093 v 4.0.

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.