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To whom it may concern:

Availability of Aspire Pharma's Products

Aspire Pharma fully understand that when undertaking a switch, availability of the products concerned is essential. If patients cannot get their medicines it can lead to loss of confidence or inconvenience to everyone concerned: Medicines Management teams, GPs, pharmacists and patients.

As part of Aspire Pharma's commitment to work in partnership with the NHS, to ensure that there are no stock issues experienced, we have ensured that all of the mainline wholesalers listed below carry stocks of Neditol® (tolterodine) XL, Gatalin® (galantamine) XL, Repinex® (ropinirole) XL and Biquelle® (quetiapine) XL as standard. This means that pharmacies can obtain the products on a daily delivery.

- Alliance/Unichem
- AAH
- Mawdsley Brooks
- Phoenix

We also hold large volumes of product at our warehouse at all times. If you have a requirement for a local wholesaler not listed above to supply Aspire Pharma's products, we will be happy to arrange this.

In addition to the normal level of stocks that the above wholesalers hold, if Aspire Pharma are made aware of an intention to switch to our products, as part of our service, we will contact all the local wholesalers and arrange for them to order in extra stocks to ensure that no issues are incurred by the patients.

Yours faithfully

Graham Fraser Pye
Managing Director

NEDITOL XL (Tolterodine) Capsules Prescribing Information (please refer to the full SmPC before prescribing)

Indications: Neditol XL is indicated in symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome. **Contraindications:** Neditol XL is contraindicated in patients with a hypersensitivity to the active substance or to any of the excipients, urinary retention, uncontrolled narrow angle glaucoma, myasthenia gravis, severe ulcerative colitis or toxic megacolon. **Special warnings and precautions for use:** Neditol XL should be used with caution in patients with significant bladder outlet obstruction at risk of urinary retention, gastrointestinal obstructive disorders, renal impairment, hepatic disease, autonomic neuropathy, hiatus hernia and patients at risk of decrease gastrointestinal motility. Neditol XL should be used with caution in patients with risk factors for QT prolongation including; congenital or documented acquired QT prolongation, electrolyte disturbances such as hypokalaemia, hypomagnesaemia and hypocalcaemia, bradycardia, relevant pre-existing cardiac diseases and concomitant administration of drugs known to prolong QT-interval including Class IA and Class III anti-arrhythmics. As with all treatments for symptoms of urgency and urge incontinence, organic reasons for urge and frequency should be considered before treatment. This product contains lactose and sodium. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of galactose intolerance, lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Concomitant treatment with potent CYP3A4 inhibitors, such as macrolide antibiotics, antifungal agents and antiproteases is not recommended. Concomitant treatment with other drugs that possess antimuscarinic properties may result in more pronounced therapeutic effect and side effects. Conversely, the therapeutic effect of tolterodine may be reduced in concomitant administration of muscarinic cholinergic receptor agonist. The effect of prokinetics like metoclopramide and cisapride may be decreased by tolterodine. Neditol XL is not recommended during pregnancy and should be avoided during lactation. The ability to drive and use machines may be negatively affected by Neditol XL. The product is not recommended for children. **Side effects:** Due to the pharmacological effect of tolterodine it may cause mild to moderate antimuscarinic effects like dryness of the mouth (very common, ≥1/10), dyspepsia and dry eyes. Common (≥1/100 to <1/10) side effects include sinusitis, dizziness, somnolence, headache, dry eyes, abnormal vision (including abnormal accommodation), dyspepsia, constipation, abdominal pain, flatulence, diarrhoea, dysuria, fatigue and peripheral oedema. Uncommon (≥1/1000 to <1/100) side effects include hypersensitivity not otherwise specified, nervousness, paraesthesia, memory impairment, vertigo, palpitations, cardiac failure, arrhythmia, urinary retention and chest pain. Side effects of a not known frequency include anaphylactoid reactions, confusion, hallucinations, disorientation, tachycardia, flushing, gastroesophageal reflux, vomiting, angioedema and dry skin. Cases of aggravation of symptoms of dementia have been reported after tolterodine therapy was initiated in patients taking cholinesterase inhibitors for treatment of dementia. **Dosage and method of use**: Capsules should be taken once daily with or without food and must be swallowed whole. The effect of the treatment should be re-evaluated after 2-3 months. The usual dose is 4mg, except in patients with impaired liver or kidney function, whose recommended dose is 2mg. In case of troublesome side effects the dose may be reduced from 4mg to 2mg. **MA number:** PL 17277/0271-0272 **Cost** £12.89 for 4mg 28x pack, £11.60 for 2mg 28x pack. **MAH:** Pharmathen S.A. 6 Dervenakion Str. 15351 Pallini Attiki Greece. **Distributor:** Aspire Pharma Ltd, Bellamy House, Winton Road, Petersfield, Hampshire, GU32 3HA. **Legal category:** POM. **Date last reviewed:** October 2015. **Version number:** 1010083024 v 4.0.

GATALIN XL (Galantamine) Capsules Prescribing Information (please refer to the full SmPC before prescribing)

Indications: Gatalin XL is indicated for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type. **Available Strengths:** Gatalin XL (galantamine) 8, 16 and 24mg x 28 capsules. **Dosage and method of use:** Prior to treatment the diagnosis of Alzheimer type dementia should be adequately confirmed by an experienced physician. Therapy with Gatalin XL should occur under supervision of a physician, and where a suitable carer is available who can regularly monitor medicinal product intake. Gatalin XL should be taken once daily in the morning preferably with food, and swallowed whole with liquid. Adequate fluid intake during treatment should be ensured. The recommended starting dose is 8mg/day for 4 weeks. The initial maintenance dosing is 16mg/day and patients should be maintained on 16mg/day for at least 4 weeks. An increase of the maintenance dose to 24mg/day should be considered on an individual basis after appropriate assessment. In patients not showing an increased response or not tolerating 24mg/day, a dose reduction to 16mg/day should be considered. The tolerance and dosing should be reassessed on a regular basis within the first three months of treatment. Discontinuation should be considered when evidence of a therapeutic effect is no longer present or the patient does not tolerate treatment. There is no rebound effect after abrupt discontinuation of treatment. If the patient is switching from galantamine instant release to Gatalin XL, it is recommended that the same total daily dose is administered. Patients switching to a once-daily regimen should take their last dose of immediate release tablets/oral solution in the evening, and start Gatalin XL once daily the following morning. **Contraindications:** Gatalin XL is contraindicated in patients with hypersensitivity to galantamine or any of the excipients and is contraindicated in patients that have significant renal and/or hepatic dysfunction/impairment. The use of galantamine is contraindicated in patients with creatinine clearance less than 9ml/min and in patients with severe hepatic impairment (Child-Pugh score greater than 9). Gatalin XL should not be given concomitantly with other cholinomimetics and has the potential to antagonise the effect of anticholinergic medicinal products. Gatalin XL, as a cholinomimetic, is likely to exaggerate succinylcholine-type muscle relaxation during anaesthesia. **Special warnings and cautions for use**: Stevens-Johnson syndrome and acute generalized exanthematous pustulosis have been reported in patients receiving galantamine, and it is recommended that patients be informed about the signs of serious skin reactions, and that galantamine should be discontinued at the first appearance of a skin rash. Caution should be exercised when administering Gatalin XL to patients with cardiovascular diseases. It is not recommended in patients with gastrointestinal obstruction or recovering from gastrointestinal surgery, in patients with urinary outflow obstruction or recovering from bladder surgery, or in patients at increased risk of developing peptic ulcers. Seizures have been reported with galantamine. Gatalin XL should not be used in women who are lactating, and caution should be exercised in women who are pregnant. Gatalin XL has a minor or moderate influence on the ability to drive and use machines. Gatalin XL is not recommended in children. **Side effects:** For the full list of side effects consult the SmPC for Gatalin XL. 'Very Common' 'Common' and 'Serious' side effects are included in the prescribing information. Very common (≥1/10) side effects include vomiting and nausea. Common (≥1/100 to <1/10) side effects include decreased appetite, hallucination, depression, syncope, dizziness, tremor, headache, somnolence, lethargy, bradycardia, hypertension, abdominal pain and discomfort, upper abdominal pain, diarrhoea, dyspepsia, stomach discomfort, muscle spasms, fatigue, asthenia, malaise, weight decrease, a risk of falling and laceration. Uncommon Serious (≥1/1000 to <1/100) side effects include hypersensitivity, dehydration, visual and auditory hallucination, hypersomnia, seizures, first degree atrioventricular block, sinus bradycardia and muscular weakness. Rare Serious (≥1/10000 to <1/1000) side effects include hepatitis, Stevens-Johnson Syndrome, Acute generalized exanthematous pustulosis and erythema multiforme. **MA number:** PL 35533/0015-0017. **Cost:** £25.94 for 28x pack of 8mg; £32.45 for 28x pack of 16mg; and £39.90 for 28x pack of 24mg. **MAH:** Aspire Pharma Ltd, Bellamy House, Winton Road, Petersfield, Hampshire, GU32 3HA. **Legal category:** POM. **Date last reviewed:** March 2016. **Version number:** 1010083024 v 4.0.

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REPINEX XL (Ropinirole) Prolonged-Release Tablets (please refer to the full SmPC before prescribing)

Indications: Repinex XL is indicated in the initial treatment of Parkinson's disease as a monotherapy or in combination with levodopa, over the course of the disease, when the effect of levodopa wears off or becomes inconsistent and fluctuations in the therapeutic effect occur. **Available strengths:** Repinex XL (ropinirole) 2, 4, and 8mg x 28 tablets. **Dosage and method of use**: Tablets should be taken once daily, at a similar time each day, with or without food, and must be swallowed whole. The starting dose is 2mg once daily for the first week, which should be increased to 4mg once daily from the second week of treatment. Patients should be maintained on the lowest dose that achieves symptomatic control and the maximum daily dose is 24mg. **Contraindications:** Repinex XL is contraindicated in patients with a hypersensitivity to the active substance or to any of the excipients, severe renal impairment (creatinine clearance <30 ml/min) without regular haemodialysis and hepatic impairment. **Special warnings and precautions for use:** Repinex XL should be used with caution in patients as ropinirole is associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Patients must be informed sudden sleep onset can occur during the day and advised to exercise caution while driving or operating machines during treatment. Patients who have experienced somnolence and/or an episode of sudden sleep onset must refrain from driving or operating machines. Repinex XL should be avoided in patients with major psychiatric or psychotic disorders, or a history of these disorders. Patients should be regularly monitored for the development of impulse control disorders, including symptoms of pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating. If patients' experience rapid gastrointestinal transit, there may be risk of incomplete release of medication and of medication residue being passed in the stool. Blood pressure monitoring is recommended, particularly at the start of Repinex XL treatment, in patients with severe cardiovascular disease (in particular coronary insufficiency) owing to the risk of hypotension. Symptoms suggestive of neuroleptic malignant syndrome have been reported with abrupt withdrawal of dopaminergic therapy, therefore, it is recommended to taper treatment. Repinex XL 2mg contains lactose and should not be used in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Repinex XL 4mg contains sunset yellow (E110), and may cause allergic reactions in patients with sensitivity to sunset yellow. Concomitant treatment with neuroleptics and other centrally active dopamine antagonists, such as sulpiride or metoclopramide, should be avoided. If hormone replacement therapy is stopped or introduced during treatment with ropinirole it may be necessary to adjust the ropinirole dose, in accordance with clinical response. In patients treated with medicinal products known to inhibit CYP1A2, e.g., ciprofloxacin, enoxacin or fluvoxamine, the Repinex XL dose may need to be adjusted when these concomitant medicines are introduced or withdrawn. Smoking is known to induce CYP1A2 metabolism, therefore if patients stop or start smoking during treatment with Repinex XL, adjustment of dose may be required. In patients receiving the combination of vitamin K antagonists and ropinirole, cases of unbalanced international normalized ratio (INR) have been reported, warranting increased clinical and biological surveillance. Repinex XL is not recommended during pregnancy and should not be used during lactation. The product is not recommended for children below 18 years of age. **Side effects:** When Repinex XL is used as a monotherapy, side effects include: Very Common (≥1/10): somnolence, syncope and nausea; Common (≥1/100 to <1/10): dizziness (including vertigo), hallucinations, constipation, vomiting, heartburn, abdominal pain, peripheral oedema and leg oedema; Uncommon (≥1/1,000 to <1/100): sudden onset of sleep, excessive daytime somnolence, psychotic reactions (other than hallucinations) including delirium, delusion, paranoia, postural hypotension and hypotension; Not known (cannot be estimated from the available data): pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating, aggression, hypersensitivity reactions (including urticaria, angioedema, rash, pruritus) and hepatic reactions, mainly increased liver enzymes. When Repinex XL is used as an adjunct therapy, side effects include: Very Common (>1/10): dyskinesia, somnolence and nausea; Common (≥1/100 to <1/10): dizziness (including vertigo), hallucinations, confusion, postural hypotension, hypotension, heartburn, constipation and peripheral oedema; Uncommon (≥1/1,000 to <1/100): sudden onset of sleep, excessive daytime somnolence, psychotic reactions (other than hallucinations) including delirium, delusion, paranoia; Not known (cannot be estimated from the available data): pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating and compulsive eating, aggression hypersensitivity reactions (including urticaria, angioedema, rash, pruritus) and hepatic reactions, mainly increased liver enzymes. **MA number:** PL 35533/0023-0025. **Cost:** £6.20 for 2mg x 28 pack, £12.50 for 4mg x 28 pack, £21.00 for 8mg x 28 pack. **MAH:** Aspire Pharma Limited, Bellamy House, Winton Road, Petersfield, Hampshire, GU32 3HA, United Kingdom. **Legal Category:** POM. **Date last reviewed:** June 2016. **Version number:** 1010112063 V 5.0.

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.

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