UK Prescribing Information Solifenacin Succinate 1mg/ml Oral Solution

Consult the Summary of Product Characteristics before prescribing.

Indications: Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.

Presentation: Each ml of solution contains 1mg solifenacin succinate (0.76mg solifenacin).

Dosage and administration: Oral solution to be taken with a glass of water and swallowed whole with liquids. It can be taken with or without food but not mixed into food or other medicinal products. The 5ml graduated oral syringe should be used to measure the correct dose.
Adults, including the elderly:
The recommended dose is 5mg (5ml) solifenacin succinate once daily. If needed, the dose may be increased to 10mg (10ml) solifenacin succinate once daily.
Renal impairment: No dose adjustment in mild to moderate renal impairment. Patients with severe renal impairment (creatinine clearance ≤ 30ml/min) should be treated with caution and receive no more than 5mg (5ml) once daily.
Hepatic impairment: No dose adjustment is necessary for patients with mild hepatic impairment. Patients with moderate hepatic impairment (Child-Pugh score of 7 to 9) should be treated with caution and receive no more than 5mg (5ml) once daily.
Potent inhibitors of cytochrome P450 3A4: Maximum dose should be limited to 5 mg (5 ml) when treated simultaneously with ketoconazole or therapeutic doses of other potent CYP3A4-inhibitors.

Contraindications: patients with urinary retention, severe gastro-intestinal conditions, myasthenia gravis or narrow-angle glaucoma, and patients at risk for these conditions. Patients hypersensitive to the active substance or excipients, undergoing haemodialysis, severe hepatic impairment, severe renal impairment or moderate hepatic impairment and who are on treatment with a potent CYP3A4 inhibitor, e.g. ketoconazole

Warnings and precautions: Other causes of frequent urination should be assessed before starting treatment. Do not prescribe to patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (contains excipient: liquid maltitol).

Use with caution in patients with: clinically significant bladder outflow obstruction at risk of urinary retention; gastrointestinal obstructive disorders; risk of decreased gastrointestinal motility; severe renal impairment; moderate hepatic impairment; concomitant use of a potent CYP3A4 inhibitor, (e.g. ketoconazole); hiatus hernia/gastro-oesophageal reflux and/or concurrently taking medicinal products (e.g. bisphosphonates) that can cause or exacerbate oesophagitis, autonomic neuropathy, QT prolongation and Torsade de Pointes have been observed in patients with risk factors, such as pre-existing long QT syndrome and hypokalaemia. Safety and efficacy have not yet been established in patients with a neurogenic cause for detrusor overactivity. Angioedema with airway obstruction has been reported. If angioedema occurs, discontinue treatment and undertake appropriate treatment/measures. Anaphylactic reaction has been reported. If anaphylactic reactions occur, discontinue treatment and undertake appropriate treatment/measures. Maximum effect of treatment can be determined after 4 weeks at the earliest. Contains excipient Sodium Benzoate; may increase jaundice (yellowing of skin and eyes) in pre-term and full-term jaundiced neonates.

Interactions: Concomitant medication with anticholinergic properties may result in more pronounced therapeutic effects and undesirable effects**.** An interval of approximately one week

should be allowed after stopping treatment, before commencing other anticholinergic therapy. Can reduce the effect of medicinal products that stimulate motility of the gastro-intestinal tract e.g. metoclopramide and cisapride. Maximum dose should be restricted to 5 mg, when used simultaneously with ketoconazole or other potent CYP3A4 inhibitors. Simultaneous treatment with potent CYP3A4 inhibitors is contra-indicated in severe renal or moderate hepatic impairment. Pharmacokinetic interactions are possible with CYP3A4 substrates with higher affinity (e.g. verapamil, diltiazem) and CYP3A4 inducers (e.g. rifampicin, phenytoin, carbamazepine).

Fertility, pregnancy and lactation: *Pregnancy:* No clinical data are available. Potential risk for humans is unknown. Caution should be exercised. *Breast feeding*: No data on the excretion of solifenacin in human milk are available therefore use should be avoided. *Fertility*: No clinical data are available. Preferable to avoid use in patients planning pregnancy.

Undesirable effects: *Very Common:* Dry mouth. *Common:* Blurred vision, Constipation, Nausea, Dyspepsia, Abdominal pain. *Uncommon:* Urinary tract infection, Cystitis, Somnolence, Dysgeusia, Dry eyes, Nasal dryness, Gastro-oesophageal reflux diseases, Dry throat, Dry skin, Difficulty in micturition, Fatigue, Peripheral oedema. *Rare:* Dizziness*, Headache*, Colonic obstruction, Faecal impaction, Vomiting*, Pruritus*, Rash*, Urinary retention. *Very rare:* Hallucinations*, Confusional state*, Erythema multiforme*, Urticaria*, Angioedema*. *Not known (currently unable to be estimated):* Anaphylactic reaction*, Decreased appetite*, Hyperkalaemia*, Delirium*, Glaucoma*, Torsade de Pointes*, QT prolongation*, Atrial fibrillation*, Palpitations*, Tachycardia*, Dysphonia*, Ileus*, Abdominal discomfort*, Liver disorder*, Liver function test abnormal*, Exfoliative dermatitis*, Muscular weakness*, Renal impairment*.

*observed post-marketing

Adverse reactions: Prescribers should consult the Summary of Product Characteristics in relation to adverse reactions.
Presentation and basic NHS price (excl.VAT): 150ml bottle, £27.62
MA Number: PL 40496/0004
Legal category: POM
PI last revised: December 2020 BLL-002-001
Full prescribing information is available from the Marketing Authorisation Holder:
Brill Pharma Ltd., 6 Sovereign Park, Laporte Way, Luton. Beds LU4 8EL, UK

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 Brill Pharma Ltd on Tel: 0044 (0) 1582 545505 or email: info@brillpharma.co.uk or write to:
Brill Pharma Ltd, 6 Sovereign Park, Laporte Way, Luton, Beds LU4 8EL, UK