Abbreviated prescribing information of Vesicare

Abbreviated prescribing information of Vesicare® film-coated tablet
Version: 002

Composition:
Solifenacin succinate

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

Dosage:
Adults, including the elderly: The recommended dose is 5 mg solifenacin succinate once daily. If needed, the dose may be increased to 10 mg solifenacin succinate once daily.

Administration:
Swallow whole with liquids, do not crush. It can be taken with or without food.

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

Special warnings and precautions for use:
Other causes of frequent urination (heart failure or renal disease) should be assessed before treatment with Vesicare. If urinary tract infection is present, an appropriate antibacterial therapy should be started.

Vesicare should be used 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 (creatinine clearance ≤ 30 ml/min), and doses should not exceed 5 mg for these patients.
- moderate hepatic impairment (Child-Pugh score of 7 to 9), and doses should not exceed 5 mg for these patients.
- concomitant use of a potent CYP3A4 inhibitor, e.g. ketoconazole.
- hiatus hernia/gastro-oesophageal reflux and/or who are concurrently taking medicinal products (such as 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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Angioedema with airway obstruction has been reported in some patients on solifenacin succinate. If angioedema occurs, solifenacin succinate should be discontinued and appropriate therapy and/or measures should be taken.

Anaphylactic reaction has been reported in some patients treated with solifenacin succinate. In patients who develop anaphylactic reactions, solifenacin succinate should be discontinued and appropriate therapy and/or measures should be taken.

The maximum effect of Vesicare can be determined after 4 weeks at the earliest.

Undesirable effects:

Summary of the safety profile

Due to the pharmacological effect of solifenacin, Vesicare may cause anticholinergic undesirable effects of (in general) mild or moderate severity. The frequency of anticholinergic undesirable effects is dose related.

The most commonly reported adverse reaction with Vesicare was dry mouth. It occurred in 11% of patients treated with 5 mg once daily, in 22% of patients treated with 10 mg once daily and in 4% of placebo-treated patients. The severity of dry mouth was generally mild and did only occasionally lead to discontinuation of treatment. In general, medicinal product compliance was very high (approximately 99%) and approximately 90% of the patients treated with Vesicare completed the full study period of 12 weeks treatment.

List of adverse reactions

Very common ≥1/10; Common ≥1/100, <1/10; Uncommon ≥1/1000, <1/100; Rare ≥ 1/10000, <1/1000; Very rare <1/10,000; Not known (cannot be estimated from the available data).

Infections and infestations: *Uncommon:* Urinary tract infection, Cystitis.
Immune system disorders: *Not known:* Anaphylactic reaction*.
Metabolism and nutrition disorders: *Not known:* Decreased appetite*, Hyperkalaemia*.
Psychiatric disorders: Very rare: Hallucinations*, Confusional state*. *Not known:* Delirium*.
Nervous system disorders: *Uncommon:* Somnolence, Dysgeusia. Rare: Dizziness*, Headache*.
Eye disorders: *Common:* Blurred vision. *Uncommon:* Dry eyes. *Not known:* Glaucoma*.
Cardiac disorders: *Not known:* Torsade de Pointes*, Electrocardiogram QT prolonged*, Atrial fibrillation*, Palpitations*, Tachycardia*.
Respiratory, thoracic and mediastinal disorders: *Uncommon:* Nasal dryness. *Not known:* Dysphonia*.
Gastrointestinal disorders: *Very common:* Dry mouth. *Common:* Constipation, Nausea, Dyspepsia, Abdominal pain. *Uncommon:* Gastro-oesophageal reflux diseases, Dry throat. *Rare:* Colonic obstruction, Faecal impaction, Vomiting*. Not known: Ileus*, Abdominal discomfort*.
Hepatobiliary disorders: *Not known:* Liver disorder*, Liver function test abnormal*.
Skin and subcutaneous tissue disorders: *Uncommon:* Dry skin. *Rare:* Pruritus*, Rash*. *Very rare:* Erythema multiforme*, Urticaria*, Angioedema*. *Not known:* Exfoliative dermatitis*.
Musculoskeletal and connective tissue disorders: *Not known:* Muscular weakness*.
Renal and urinary disorders: *Uncommon:* Difficulty in micturition. *Rare:* Urinary retention. *Not known:* Renal impairment*.
General disorders and administration site conditions: *Uncommon:* Fatigue, Peripheral oedema.
*observed post-marketing

Full prescribing information is available upon request.