Urginafect 5 mg or 10 mg

Solifenacin Succinate 5 mg or 10 mg
Film-coated tablets

1. Name of the medicinal product

Urginafect 5 mg or 10 mg film-coated tablets

2. Qualitative and quantitative composition

Each film-coated tablet contains 5 mg or 10 mg of Solifenacin Succinate.

Excipient(s) with known effect:
Each film-coated tablet of Urginafect 5 mg contains 81 mg lactose monohydrate.
Urginafect 10 mg contains 76 mg lactose monohydrate.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Urginafect 5 mg: Yellowish white to yellow round biconvex film-coated tablet.
Urginafect 10 mg: Brick red to light brown biconvex film-coated tablet.

4. Clinical particulars

4.1 Therapeutic indications

Urginafect is indicated in adults for symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome.

4.2 Posology and method of administration

Posology
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.

Special Populations

Older people: No dosage adjustment is necessary for older people.

Renal impairment

No dose adjustment is necessary for patients with mild to moderate renal impairment (creatinine clearance > 30 ml/min). Patients with severe renal impairment (creatinine clearance ≤ 30 ml/min) should be treated with caution and receive no more than 5 mg once daily (see section 5.2).

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 5 mg once daily (see section 5.2).

Potent inhibitors of cytochrome P450 3A4
The maximum dose of Urginafect should be limited to 5 mg when treated simultaneously with ketoconazole or therapeutic doses of other potent CYP3A4 inhibitors e.g., ritonavir, nelfinavir, itraconazole (see section 4.5).

Paediatric population
The safety and efficacy of Urginafect in children and adolescents below 18 years have not yet been established. Therefore, Urginafect should not be used in children and adolescents.
Method of administration
Urginafect should be taken orally and should be swallowed whole with liquids. It can be taken with or without food.

5. Storage
Store in temperature not exceeding 30°C in a dry place.