



Urief®

Silodosin **TABLET 4 mg**

HIGH affinity to the α_{1A} - adrenergic receptor¹

SELECTIVE α_{1A} blocker¹

Indications¹ : Bladder outlet obstruction associated
with benign prostatic hyperplasia

(BPH)

ABBREVIATION INFORMATION

COMPOSITION Each of Urief® contain Silodosin 4 mg. **INDICATIONS** Bladder outlet obstruction associated with benign prostatic hyperplasia **DOSAGE AND ADMINISTRATION** The adult dosage for oral use is 4 mg of silodosin twice daily after breakfast and evening meals. The dosage may be reduced according to the patient's conditions **CONTRAINDICATIONS** Patients with known hypersensitivity to any of the components of Urief® **PRECAUTIONS** 1. **Careful Administration** (Urief® should be administered with care in patients with orthostatic hypotension, impaired hepatic function, impaired renal function and patients treated with phosphodiesterase-5 inhibitors 2. **Important Precautions** (1) Abnormal ejaculation (e.g., retrograde ejaculation) have been reported. (2) Orthostatic hypotension may occur. (3) Effects on ability to drive and operate machine (4) Prior to treatment with Urief®, the patient should be asked whether they are taking any hypotensive drugs and, in the event that any hypotensive drug are used, closely monitoring changes in blood pressure while using Urief®. (5) Treatment with Urief® does not eliminate the cause of the disease, but gives symptomatic relief. 3. **Drug Interactions** Silodosin is metabolized mainly by cytochrome P450 3A4 (CYP3A4), UDP-glucuronosyltransferases (UGTs), alcohol dehydrogenase (ADH), and aldehyde dehydrogenase (ALDH). Coadministration with potent inhibitors of CYP3A4 activity blocks the metabolism of silodosin. This may result in elevated plasma drug concentrations. Precautions for coadministration with the following drugs: Hypotensive agents, Azole antifungal agents: Itraconazole, Phosphodiesterase-5 inhibitors: Sildenafil citrate, Vardenafil hydrochloride hydrate 4. **Adverse Reactions** Adverse reactions of silodosin (capsule) were reported in 44.8% of a total of 873 patients with lower urinary tract symptoms in a clinical study conducted up to the time of approval. The most common adverse reactions included 17.2% abnormal ejaculation (e.g., retrograde ejaculation), 5.7% thirst, 4.0% diarrhea, 3.6% dizziness on standing up. Abnormal laboratory data were reported in 21.7% of a total of 853 patients. The most common events included patients who are increased in triglycerides, CRP, ALT (GPT), AST, and γ -GTP. It should be noted that, in the phase III double-blind comparative study, abnormal ejaculation (e.g., retrograde ejaculation) was reported in 22.3% of 175 patients. Clinically significant adverse reactions 1) Syncope, unconsciousness (Incidence unknown) 2) Impaired hepatic function, jaundice (Both incidence unknown) 5. **Use in the Elderly** If hepatic or renal function is reduced, the elderly should be treated while carefully monitoring the condition of the patient, such as start administration at a low dose (2 mg/dose). 6. **Use during Pregnancy and Lactation** Not applicable as silodosin is intended for male patients only. 7. **Other Precautions** It has been reported that intraoperative floppy iris syndrome (IFIS) attributable to α_1 -blocking effect **PHARMACOLOGY Mechanism of Action** By blocking the sympathetic nervous system, which mediates the α_{1A} -adrenoceptor subtype which is distributed in lower urinary tract tissue (prostate, urethra, and trigone of bladder), silodosin reduces smooth muscle tone of lower urinary tract tissue and inhibits increases in urethral pressure, thereby improving lower urinary tract symptoms associated with benign prostatic hyperplasia. **PACKAGING** 30 tablets (blister sheets in aluminium pouch: 10 tablets x 3)

Reference

1. Urief® package insert

Further information is available on request
โปรดอ่านรายละเอียดเพิ่มเติมในเอกสารกำกับยา

ใบอนุญาตโฆษณาเลขที่ ขต. 16/2561