Besavar XL 10mg Tablets (Alfuzosin hydrochloride) Prescribing Information. Prescribers should consult the SmPC before prescribing.

Presentation: Each Besavar XL sustained release tablet contains 10mg of alfuzosin hydrochloride.

Indication: Treatment of the functional symptoms of benign prostatic hypertrophy (BPH), acute urinary retention (AUR) related to BPH in patients ≥65 years.

Dosage and administration:. BPH: 10mg once daily after a meal. AUR: In patients 65 years and older, 10mg once daily after a meal to be taken from the first day of catheterisation. The treatment should be administered for 3-4 days (2-3 days during catheterisation and 1 day after its removal). In this indication no benefit has been established in patients under 65 years of age or if treatment is extended beyond 4 days.
Method of Administration: Besavar XL should be administered once daily after a meal. The tablets should be swallowed whole and not crunched, crushed, chewed, grinded or pounded to powder to avoid inappropriate release and absorption of the medicine and therefore possible early adverse reactions

Special Populations: Paediatric population: Efficacy has not been demonstrated in children aged 2-16, therefore not indicated for use in this group.

Fertility, pregnancy and lactation: Not applicable.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. Contraindicated in patients with history of orthostatic hypotension and/or hepatic insufficiency. In combination with other alpha-1 receptor blockers and with potent CYP3A4 inhibitors.

Special warnings and precautions: Intraoperative Floppy Iris Syndrome: Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients on or previously treated with alpha-1 blockers. Although the risk of this event with alfuzosin appears very low, ophthalmic surgeons should be informed in advance of cataract surgery of current or past use of alpha-1-blockers, as IFIS may lead to increased procedural complications. Cardiac disorders: Alfuzosin should be used with caution in patients with acute cardiac failure. In coronary patients, the specific treatment for coronary insufficiency should be continued. If angina pectoris reappears or worsens Besavar XL should be discontinued. QTc prolongation: Patients with congenital QTc prolongation, with a known history of acquired QTc prolongation or who are taking drugs known to increase the QTc interval should be evaluated before and during the administration of alfuzosin. Priapism: Prolonged erections and priapism have been reported with alpha-1 blockers including alfuzosin. Priapism requires immediate medical assistance. Hypotension: Care should be taken when alfuzosin is administered to patients who have had a pronounced hypotensive response to another alpha 1-blocker and in patients with pre-existing risk factors (such as underlying cardiac diseases and/or concomitant treatment with anti-hypertensive medication). In patients receiving antihypertensive medications or nitrates, postural hypotension with or without symptoms (dizziness, fatigue, sweating) may develop within a few hours following administration.
These effects are transient, occur at the beginning of treatment and do not usually prevent the continuation of treatment. Blood pressure should be monitored regularly, especially at the beginning of treatment. The risk of developing hypotension and related adverse reactions may be greater in elderly patients. Severe renal impairment (creatinine clearance < 30ml/min): Besavar XL should not be administered.
Tablets contain hydrogenated castor oil which may cause stomach upset and diarrhoea.

Drug interactions: Combinations contra-indicated: Alpha-1-receptor blockers. Concomitant use not recommended: Potent CYP3A4 inhibitors such as itraconazole, ketoconazole, protease inhibitors, clarithromycin, telithromycin and nefazodone. Alfuzosin should not be used concomitantly with CYP3A4 inhibitors that are known to increase the QTc interval (e.g. itraconazole and clarithromycin) and temporary interruption of alfuzosin treatment is recommended if treatment with such medicinal products is initiated.
Combinations to be taken into account: Antihypertensive drugs and nitrates. Anaesthetics: The administration of general anaesthetics to patients receiving Besavar XL could cause profound hypotension. It is recommended that the tablets be withdrawn 24 hours before surgery.

Effects on ability to drive/use machines: No data available. Patients should take into account adverse reactions such as vertigo, dizziness and asthenia (at the beginning of treatment).

Undesirable effects: Tachycardia; aggravation or recurrence of angina pectoris in patients with pre-existing coronary artery disease; atrial fibrillation; intraoperative floppy iris syndrome; asthenia; nausea; abdominal pain; hepatocellular injury; cholestatic liver disease; faintness/dizziness; headache; syncope; priapism; angioedema; hypotension (postural); neutropenia; thrombocytopenia. Please refer to SmPC for full adverse reaction details.

Pack size and UK list price: Besavar XL 10mg Tablets (PL 17780/0221), pack size: 30, £4.62.

Legal Category: POM.

Marketing Authorisation Holder: Zentiva Pharma UK Limited, 12 New Fetter Lane, London ECA 1JP, UK

Date of preparation: 19 Sep 2023 **Ref:** 000606395

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 Zentiva via email to PV-United-Kingdom@zentiva.com or via phone on 0800 090 2408.