Urosin®

Tamsulosin Hydrochloride
Sustained Release Capsule

DESCRIPTION

Urosin® is a preparation of tamsulosin hydrochloride. It binds selectively and competitively to postsynaptic alpha$_1$-receptors, in particular to the subtype alpha$_{1A}$, which bring about maximum urinary flow rate by reducing smooth muscle tension in the prostate and urethra, thereby relieving obstruction. It also improves the complex of irritative and obstructive symptoms in which bladder instability and tension of the smooth muscles of the lower urinary tract play an important role.

INDICATIONS

Urosin® is indicated in the treatment of functional symptoms of benign prostatic hyperplasia (BPH).

DOSAGE AND ADMINISTRATION

One capsule daily, to be taken with or without food.

CONTRAINDICATION

Tamsulosin hydrochloride is contraindicated in the patients with a history of orthostatic hypotension; severe hepatic insufficiency. Hypersensitivity to tamsulosin hydrochloride or any other component of the product.

USE IN PREGNANCY AND LACTATION

Not applicable, as tamsulosin hydrochloride is intended for male patients only.

SIDE-EFFECTS

Adverse events were mostly mild and their incidence was generally low. The most commonly reported adverse event was abnormal ejaculation occurring in approximately 2% of patients. Suspected adverse reactions reported with tamsulosin includes;

Nervous system: Dizziness, headache, syncope.
Cardio-vascular system: Palpitations, postural hypotension.
Respiratory system: Rhinitis.
Gastrointestinal: Nausea, vomiting, constipation, diarrhoea.
Dermatological: Rash, pruritus, urticaria, angioedema.
Reproductive system: Abnormal ejaculation, priapism.
General: Asthenia.

DRUG INTERACTIONS

No interactions have been seen when tamsulosin hydrochloride was given concomitantly with atenolol, enalapril, nifedipine or theophylline. Concomitant cimetidine brings about a rise in plasma levels of tamsulosin hydrochloride and furosemide a fall, but as levels remain within the normal range, posology need not be changed.

In vitro, neither diazepam nor propranolol, trichlormethiazide, chlormadinon, amitryptyline, diclofenac, glibenclamide, simvastatin and warfarin change the free fraction of tamsulosin in human plasma. Neither does tamsulosin hydrochloride change the free fractions of diazepam, propranolol, trichlormethiazide and chlormadinon.

No interactions at the level of hepatic metabolism have been seen during in vitro studies with liver microsomal fractions (representative of the cytochrome P450-linked drug metabolising enzyme system), involving amitriptyline, salbutamol, glibenclamide and finasteride. Diclofenac and warfarin, however, may increase the elimination rate of tamsulosin hydrochloride.

OVERDOSAGE

Acute overdose with 5 mg tamsulosin hydrochloride may cause acute hypotension (systolic blood pressure 70 mm Hg). Vomiting and diarrhoea were observed, which were treated with fluid replacement and the patient was able to be discharged the same day. In case of acute hypotension occurring after overdose, cardiovascular support should be given. Blood pressure can be restored and heart rate brought back to normal by lying the patient down. If this does not help, then volume expanders, and when necessary, vasopressors could be employed. Renal function should be monitored and general supportive measures applied. Dialysis is unlikely to be of help, as tamsulosin hydrochloride is very highly bound to plasma proteins.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Urosin® Capsule: Box containing 5 strips of 6 capsules each. Each sustained release capsule contains Tamsulosin Hydrochloride USP 0.4 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH

PM01488 V03