MAXPEE Tablets (Tamsulosin hydrochloride)

Composition

MAXPEE-0.4
Each tablet contains: Tamsulosin Hydrochloride 0.4 mg (400 mcg) modified release.

Dosage Form

Tablets

Pharmacology

Pharmacodynamics

Mechanism of Action

The symptoms associated with benign prostatic hyperplasia (BPH) are related to bladder outlet obstruction, which is comprised of two underlying components: static and dynamic. The static component is related to an increase in the prostate size caused, in part, by a proliferation of smooth muscle cells in the prostatic stroma. However, the severity of BPH symptoms and the degree of urethral obstruction do not correlate well with the size of the prostate. The dynamic component is a function of an increase in smooth muscle tone in the prostate and bladder neck leading to constriction of the bladder outlet. Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha$_1$-adrenoceptors, which are abundant in the prostate, prostatic Tablets, prostatic urethra and bladder neck. Blockade of these adreno-receptors can cause smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in the symptoms of BPH.

Tamsulosin hydrochloride, an alpha$_1$-adrenoreceptor blocking agent, exhibits selectivity for alpha$_1$-receptors in the human prostate. At least three discrete alpha1-adrenoceptor subtypes have been identified: alpha$_{1A}$, alpha$_{1B}$ and alpha$_{1D}$; their distribution differs between human organs and tissue. Approximately 70% of the alpha1-receptors in the human prostate are of the alpha $_{1A}$ subtype.

Tamsulosin hydrochloride Tablets are not intended for use as an antihypertensive drug.

Pharmacokinetics

Absorption

Absorption of tamsulosin hydrochloride is essentially complete (>90%), following oral administration under fasting conditions. Tamsulosin hydrochloride exhibits linear kinetics following single and multiple dosing, with achievement of steady-state concentrations by the fifth day of once-a-day dosing.

Effect of Food: The time to maximum concentration (T_{max}) is reached by 4-5 hours under fasting conditions and by 6-7 hours when tamsulosin hydrochloride Tablets are administered with food.

Distribution

The mean steady-state apparent volume of distribution of tamsulosin hydrochloride after intravenous administration to 10 healthy male adults was 16 L, which is suggestive of distribution into the extracellular fluids in the body.

Tamsulosin hydrochloride is extensively bound to human plasma proteins (94/99%), primarily $alpha_1$-acid glycoprotein (AAG), with linear binding over a wide concentration range (20 to 600 ng/mL). The results of two-way *in vitro* studies indicate that the binding of tamsulosin hydrochloride to human plasma proteins is not affected by amitriptyline, diclofenac, glyburide, simvastatin plus simvastatin hydroxy acid metabolite, warfarin, diazepam, propranolol, trichlormethiazide or chlormadinone. Likewise, tamsulosin hydrochloride had no effect on the extent of binding of these drugs.

Metabolism

There is no enantiomeric bioconversion from tamsulosin hydrochloride to the S(+) isomer in humans. Tamsulosin hydrochloride is extensively metabolized by cytochrome (CY) P450 enzymes in the liver and less than 10% of the dose is excreted in the urine unchanged. However, the pharmacokinetic profile of the metabolites in humans has not been established. Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6 as well as via some minor participation of other CYP isoenzymes. Inhibition of hepatic drug-metabolizing enzymes may lead to increased exposure to tamsulosin hydrochloride. The metabolites of tamsulosin hydrochloride undergo extensive conjugation to glucuronide or sulphate prior to renal excretion.

Incubations with human liver microsomes showed no evidence of clinically significant metabolic interactions between tamsulosin hydrochloride and amitriptyline, albuterol (beta agonist), glyburide (glibenclamide) and finasteride (5 alpha-reductase inhibitor for treatment of BPH). However, results

of the *in vitro* testing of the tamsulosin hydrochloride interaction with diclofenac and warfarin were equivocal.

Excretion

On administration of the radiolabelled dose of tamsulosin hydrochloride to 4 healthy volunteers, 97% of the administered radioactivity was recovered, with urine (76%) representing the primary route of excretion compared to faeces (21%) over 168 hours. Because of absorption rate-controlled pharmacokinetics with tamsulosin hydrochloride modified-release Tablets, the apparent half-life of tamsulosin hydrochloride is approximately 9-13 hours in healthy volunteers and 14-15 hours in the target population. Tamsulosin hydrochloride undergoes restrictive clearance in humans, with a relatively low systemic clearance (2.88 L/h).

Pharmacokinetics in Special Populations

Pediatric Use: Tamsulosin hydrochloride Tablets are not indicated for use in paediatric populations.

Geriatric Use: Cross-study comparison of Tamsulosin hydrochloride Tablets overall exposure (AUC) and half-life indicates that the pharmacokinetic disposition of tamsulosin hydrochloride may be slightly prolonged in geriatric males compared to young, healthy male volunteers. Intrinsic clearance is independent of tamsulosin hydrochloride binding to AAG, but diminishes with age, resulting in a 40% overall higher exposure (AUC) in subjects of age 55 to 75 years compared to subjects of age 20 to 32 years.

Renal Impairment: The pharmacokinetics of tamsulosin hydrochloride have been compared in 6 subjects with mild-moderate (30≤ CLcr 2) or moderate-severe (10≤ CLcr 2) renal impairment and 6 normal subjects (CLcr >90 mL/min/1.73 m^2). While a change in the overall plasma concentration of tamsulosin hydrochloride was observed as the result of altered binding to AAG, the unbound (active) concentration of tamsulosin hydrochloride, as well as the intrinsic clearance, remained relatively constant. Therefore, patients with renal impairment do not require an adjustment in tamsulosin hydrochloride Tablets dosing. However, patients with end-stage renal disease (CLcr 2) have not been studied.

Hepatic Impairment: The pharmacokinetics of tamsulosin hydrochloride have been compared in 8 subjects with moderate hepatic impairment (Child-Pugh's classification: Grades A and B) and 8 normal subjects. While a change in the overall plasma concentration of tamsulosin hydrochloride was observed as the result of altered binding to AAG, the unbound (active) concentration of tamsulosin hydrochloride does not change significantly, with only a modest (32%) change in intrinsic clearance

of unbound tamsulosin hydrochloride. Therefore, patients with moderate hepatic impairment do not require an adjustment in tamsulosin hydrochloride Tablets dosage. Tamsulosin hydrochloride has not been studied in patients with severe hepatic impairment.

Indications

MAXPEE Tablets are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

MAXPEE Tablets are not indicated for the treatment of hypertension.

Dosage and Administration

- 0.4 mg once daily with or without food, at the same time every day. The Tablets should be swallowed whole and should not be crunched or chewed..
- For patients who fail to respond to 0.4 mg after 2-4 weeks of dosing, the dose can be increased to 0.8 mg once daily.
- If the drug administration is interrupted or discontinued for a few days due to any reason, therapy should be started again with the same dose.
- If the patient is receiving 0.8 mg once daily and the drug administration is interrupted or discontinued for few days due to any reason, therapy should be started again at 0.4 mg once daily.

Contraindications

MAXPEE Tablets are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of the formulation. Reactions have included skin rash, urticaria, pruritus, angioedema and respiratory symptoms.

Warnings and Precautions

General

Orthostasis

The signs and symptoms of orthostasis (postural hypotension, dizziness and vertigo) were detected more frequently in tamsulosin hydrochloride Tablets-treated patients than in placebo recipients. As with other alpha-adrenergic blocking agents there is a potential risk of syncope. Patients beginning

treatment with tamsulosin hydrochloride Tablets should be cautioned to avoid situations where injury could result should syncope occur.

Priapism

Rarely (probably less than 1 in 50,000 patients), tamsulosin hydrochloride, like other alpha1 antagonists, has been associated with priapism (persistent painful penile erection unrelated to sexual activity). Because this condition can lead to permanent impotence if not properly treated, patients must be advised about the seriousness of the condition.

Screening for Prostate Cancer

Prostate cancer and BPH frequently co-exist; therefore, patients should be screened for the presence of prostate cancer prior to treatment with MAXPEE Tablets and at regular intervals afterwards.

Intraoperative Floppy Iris Syndrome

Intraoperative floppy iris syndrome (IFIS) has been observed during cataract surgery in some patients treated with alpha1 blockers, including tamsulosin hydrochloride Tablets.

Most reports were in patients taking the alpha1-blocker when IFIS occurred but in some cases, the alpha1-blocker had been stopped prior to surgery. In most of these cases, the alpha1-blocker had been stopped recently prior to surgery (2-14 days), but in a few cases, IFIS was reported after the patient had been off the $alpha_1$-blocker for a longer period (5 weeks-9 months). IFIS is a variant of small pupil syndrome and is characterized by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions. The patient's ophthalmologist should be prepared for possible modifications to their surgical technique, such as the utilization of iris hooks, iris dilator rings or viscoelastic substances.

IFIS may increase the risk of eye complications during and after the operation. The benefit of stopping alpha1-blocker therapy prior to cataract surgery has not been established. The initiation of therapy with tamsulosin hydrochloride in patients for whom cataract surgery is scheduled is not recommended.

Sulpha Allergy

In patients with sulpha allergy, allergic reaction to tamsulosin hydrochloride Tablets has been rarely reported. If a patient reports a serious or life-threatening sulpha allergy, caution is warranted when administering MAXPEE Tablets.

Drug Interactions

Strong and Moderate Inhibitors of CYP3A4 or CYP2D6: Tamsulosin hydrochloride is extensively metabolized, mainly by CYP3A4 and CYP2D6. MAXPEE Tablets should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole). Concomitant treatment with ketoconazole (a strong inhibitor of CYP3A4) resulted in an increase in the C_{max} and AUC of tamsulosin hydrochloride by a factor of 2.2 and 2.8, respectively. In patients known to be CYP2D6 poor metabolizers, MAXPEE Tablets should be used with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), and in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). Concomitant treatment with paroxetine (a strong inhibitor of CYP2D6) resulted in an increase in the C_{max} and AUC of tamsulosin hydrochloride by a factor of 1.3 and 1.6, respectively. The effects of co-administration of both a CYP3A4 and a CYP2D6 inhibitor with tamsulosin hydrochloride have not been evaluated. However, there is a potential for significant increase in tamsulosin hydrochloride exposure when MAXPEE Tablets 0.4 mg is co-administered with a combination of both CYP3A4 and CYP2D6 inhibitors.

Other Alpha-Adrenergic Blocking Agents

The pharmacokinetic and pharmacodynamic interactions between tamsulosin hydrochloride and other alpha-adrenergic blocking agents have not been determined. However, interactions may be expected and MAXPEE Tablets should not be used in combination with other alpha-adrenergic blocking agents.

Cimetidine

The effect of cimetidine at the highest recommended dose (400 mg every 6 hours for 6 days) on the pharmacokinetics of a single tamsulosin hydrochloride 0.4 mg dose was investigated in 10 healthy volunteers (age range 21 to 38 years). Treatment with cimetidine resulted in a significant decrease (26%) in the clearance of tamsulosin hydrochloride, which resulted in a moderate increase in the

tamsulosin hydrochloride AUC (44%). Therefore, MAXPEE Tablets should be used with caution in combination with cimetidine.

Warfarin

A definitive drug-drug interaction study between tamsulosin hydrochloride and warfarin was not conducted. Results from limited *in vitro* and *in vivo* studies are inconclusive. Caution should be exercised with concomitant administration of warfarin and MAXPEE Tablets.

PDE5 Inhibitors

Caution is advised when alpha-adrenergic blocking agents including MAXPEE Tablets, are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension.

Nifedipine, Atenolol, Enalapril

In three studies in hypertensive subjects (age range 47 to 79 years) whose blood pressure was controlled with stable doses of nifedipine, atenolol, or enalapril for at least 3 months, tamsulosin hydrochloride Tablets 0.4 mg for 7 days followed by tamsulosin hydrochloride Tablets 0.8 mg for another 7 days (n=8 per study) resulted in no clinically significant effects on blood pressure and pulse rate compared to placebo (n=4 per study). Therefore, dosage adjustments are not necessary when tamsulosin hydrochloride containing MAXPEE Tablets are administered concomitantly with nifedipine, atenolol or enalapril.

Digoxin and Theophylline

In two studies in healthy volunteers (n=10 per study; age range 19 to 39 years) receiving tamsulosin hydrochloride Tablets 0.4 mg/day for 2 days, followed by tamsulosin hydrochloride Tablets 0.8 mg/day for 5 to 8 days, single intravenous doses of digoxin 0.5 mg or theophylline 5 mg/kg resulted in no change in the pharmacokinetics of digoxin or theophylline. Therefore, dosage adjustments are not necessary when a MAXPEE Tablets is administered concomitantly with digoxin or theophylline.

Furosemide

The pharmacokinetic and pharmacodynamic interaction between tamsulosin hydrochloride 0.8 mg/day (steady-state) and furosemide 20 mg intravenously (single dose) was evaluated in 10 healthy volunteers (age range: 21 to 40 years). MAXPEE Tablets had no effect on the pharmacodynamics (excretion of electrolytes) of furosemide. While furosemide produced an 11-12% reduction in the

tamsulosin hydrochloride C_{max} and AUC, these changes are expected to be clinically insignificant and do not require adjustment of the MAXPEE Tablets dosage.

Information for Patients

Patients should be told about the possible occurrence of symptoms related to postural hypotension such as dizziness and syncope when taking tamsulosin hydrochloride, and they should be cautioned about driving, operating machinery or performing hazardous tasks.

Patients should be advised about the possibility of priapism as a result of treatment with tamsulosin hydrochloride and other similar medications. Patients should be informed that this reaction is extremely rare, but if not brought to immediate medical attention, can lead to permanent erectile dysfunction (impotence).

Prostate cancer and BPH frequently co-exist; therefore, patients should be screened for the presence of prostate cancer prior to treatment with MAXPEE Tablets and at regular intervals afterwards.

Patients considering cataract surgery should be advised to tell their ophthalmologist that they have taken MAXPEE Tablets.

Patients should be advised not to crush or chew the MAXPEE Tablets.

Renal Impairment

Patients with renal impairment do not require any dosage adjustment in tamsulosin hydrochloride dosage. However, patients with end-stage renal disease ($CL_{cr}2$) have not been studied.

Hepatic Impairment

Patients with moderate hepatic impairement do not require any dosage adjustment in tamsulosin hydrochloride dosage. Tamsulosin hydrochloride has not been studied in patients with severe hepatic impairment.

Pregnancy

Pregnancy Category B

MAXPEE Tablets are not indicated for use in women.

Lactation

MAXPEE Tablets are not indicated for use in women.

Paediatric Use

MAXPEE Tablets are not indicated for use in the paediatric population.

Efficacy and positive benefit/risk of tamsulosin hydrochloride was not demonstrated in two studies conducted in patients 2 years to 16 years of age with elevated detrusor leak point pressure (>40 cm H_2O) associated with known neurological disorder (e.g., spina bifida). Patients in both studies were treated on a weight-based mg/kg schema (0.025 mg, 0.05 mg, 0.1 mg, 0.2 mg, or 0.4 mg tamsulosin hydrochloride) for the reduction in detrusor leak point pressure below 40 cm H2O. In a randomized, double-blind, placebo-controlled, 14-week, pharmacokinetic, safety and efficacy study in 161 patients, no statistically significant difference in the proportion of responders was observed between groups receiving tamsulosin hydrochloride and placebo. In an open-label, 12-month safety study, 87 patients were treated with tamsulosin hydrochloride. The most frequently reported adverse events (≥5%) from the pooled data of both studies were urinary tract infection, vomiting, pyrexia, headache, nasopharyngitis, cough, pharyngitis, influenza, diarrhea, abdominal pain, and constipation.

Geriatric Use

Of the total number of subjects (1,783) in clinical studies of tamsulosin hydrochloride, 36% were 65 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and the other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Undesirable Effects

Because clinical studies are conducted under widely varying conditions, rates of adverse reactions rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The incidence of treatment-emergent adverse events has been ascertained from six short-term U.S. and European placebo-controlled clinical trials in which daily doses of 0.1 to 0.8 mg tamsulosin hydrochloride were used. These studies evaluated safety in 1,783 patients treated with tamsulosin

hydrochloride and 798 patients administered placebo. Table 1 summarizes the treatment-emergent adverse events that occurred in ≥2% of patients receiving either tamsulosin hydrochloride 0.4 mg or 0.8 mg and at an incidence numerically higher than that in the placebo group during two 13-week U.S. trials conducted in 1,487 men.

Table 1: Treatment-Emergent[1] Adverse Events occurring in ≥2% of Tamsulosin Hydrochloride or Placebo Patients in Two U.S. Short-Term Placebo-Controlled Clinical Studies

Body System/ Adverse Event Class	Tamsulosin Hydrochloride Groups		Placebo
	0.4 mg	0.8 mg	
	n = 502	n = 492	n = 493
Body As Whole Headache	97 (19.3)	104 (21.1%)	99 (20.1%)
Infection[2]	45 (9.0%)	53 (10.8%)	37 (7.5%)
Asthenia	39 (7.8%)	42 (8.5%)	27 (5.5%)
Back pain	35 (7.0%)	41 (8.3%)	27 (5.5%)
Chest pain	20 (4.0%)	20 (4.1%)	18 (3.7%)
Nervous System			

Dizziness	75 (14.9%)	84 (17.1%)	50 (10.1%)
Somnolence	15 (3.0%)	21 (4.3%)	8 (1.6%)
Insomnia	12 (2.4%)	7 (1.4%)	3 (0.6%)
Libido decreased	5 (1.0%)	10 (2.0%)	6 (1.2%)
Respiratory System			
Rhinitis[3]	66 (13.1%)	88 (17.9%)	41 (8.3%)
Pharyngitis	29 (5.8%)	25 (5.1%)	23 (4.7%)
Cough increased	17 (3.4%)	22 (4.5%)	12 (2.4%)
Sinusitis	11 (2.2%)	18 (3.7%)	8 (1.6%)
Digestive System			
Diarrhea	31 (6.2%)	21 (4.3%)	22 (4.5%)
Nausea	13	19	16

	(2.6%)	(3.9%)	(3.2%)
Tooth disorder	6 (1.2%)	10 (2.0%)	7 (1.4%)
Urogenital System			
Abnormal ejaculation	42 (8.4%)	89 (18.1%)	1 (0.25%)
Special Senses			
Blurred vision	1 (0.2%)	10 (2.0%)	2 (0.4%)

[1]

A treatment-emergent adverse event was defined as any event satisfying one of the following criteria:

- The adverse event occurred for the first time after initial dosing with the double-blind study medication.
- The adverse event was present prior to or at the time of initial dosing with the double-blind study medication and subsequently increased in severity during double-blind treatment; or,
- The adverse event was present prior to or at the time of initial dosing with the double-blind study medication, disappeared completely, and then reappeared during double-blind treatment.

[2] Coding preferred terms also include cold, common cold, head cold, flu and flu-like symptoms. [3] Coding preferred terms also include nasal congestion, stuffy nose, runny nose, sinus congestion and hay fever.

Signs and Symptoms of Orthostasis

In the two U.S. studies, symptomatic postural hypotension was reported by 0.2% of patients (1 of 502) in the 0.4 mg group, 0.4% of patients (2 of 492) in the 0.8 mg group, and by no patients in the placebo group. Syncope was reported by 0.2% of patients (1 of 502) in the 0.4 mg group, 0.4% of patients (2 of 492) in the 0.8 mg group, and 0.6% of patients (3 of 493) in the placebo group. Dizziness was reported by 15% of patients (75 of 502) in the 0.4 mg group, 17% of patients (84 of 492) in the 0.8 mg group, and 10% of patients (50 of 493) in the placebo group. Vertigo was reported by 0.6% of patients (3 of 502) in the 0.4 mg group, 1% of patients (5 of 492) in the 0.8 mg group, and by 0.6% of patients (3 of 493) in the placebo group.

Multiple testing for orthostatic hypotension was conducted in a number of studies. Such a test was considered positive if it met one or more of the following criteria: (1) a decrease in systolic blood pressure of ≥20 mmHg upon standing from the supine position during the orthostatic tests; (2) a decrease in diastolic blood pressure ≥10 mmHg upon standing, with the standing diastolic blood pressure

Following the first dose of double-blind medication in Study 1, a positive orthostatic test result at 4 hours post-dose was observed in 7% of patients (37 of 498) who received tamsulosin hydrochloride 0.4 mg once daily and in 3% of the patients (8 of 253) who received placebo. At 8 hours post-dose, a positive orthostatic test result was observed for 6% of the patients (31 of 498) who received tamsulosin hydrochloride 0.4 mg once daily and 4% (9 of 250) who received placebo (Note: Patients in the 0.8 mg group received 0.4 mg once daily for the first week of Study 1).
In Studies 1 and 2, at least one positive orthostatic test result was observed during the course of these studies for 81 of the 502 patients (16%) in the tamsulosin hydrochloride 0.4 mg once-daily group, 92 of the 491 patients (19%) in the tamsulosin hydrochloride 0.8 mg once-daily group, and 54 of the 493 patients (11%) in the placebo group.

Because orthostasis was detected more frequently in tamsulosin hydrochloride treated patients than in placebo recipients, there is a potential risk of syncope.

Abnormal Ejaculation

Abnormal ejaculation includes ejaculation failure, ejaculation disorder, retrograde ejaculation and ejaculation decrease. As shown in Table 1, in the US studies, abnormal ejaculation was associated with tamsulosin hydrochloride administration and was dose-related. Withdrawal from these clinical

studies of tamsulosin hydrochloride because of abnormal ejaculation was also dose-dependent, with 8 of 492 patients (1.6%) in the 0.8 mg group and no patients in the 0.4 mg or placebo groups discontinuing treatment due to abnormal ejaculation.

Laboratory Tests

No laboratory test interactions with tamsulosin hydrochloride are known. Treatment with tamsulosin hydrochloride for up to 12 months had no significant effect on the prostate-specific antigen (PSA).

Post marketing Experience

The following adverse reactions have been identified during post-approval use of tamsulosin hydrochloride Tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Decisions to include these reactions in the labelling are typically based on one or more of the following factors:

(1) Seriousness of the reaction; (2) frequency of reporting; or (3) strength of causal connection to tamsulosin hydrochloride.

Allergic-type reactions such as skin rash, urticaria, pruritus, angioedema, and respiratory symptoms have been reported, with a positive re-challenge in some cases. Priapism has been reported rarely. Infrequent reports of dyspnoea, palpitations, hypotension, atrial fibrillation, arrhythmia, tachycardia, skin desquamation, including reports of Stevens-Johnson syndrome, constipation, and vomiting have been received during the postmarketing period.

During cataract surgery, a variant of small-pupil syndrome known as Intraoperative floppy iris syndrome (IFIS) has been reported in association with alpha$_1$-blocker therapy.

Overdosage

Should an overdose of tamsulosin hydrochloride lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Laboratory data indicate that tamsulosin hydrochloride is 94-99% protein-bound; therefore, dialysis is unlikely to be of benefit.

Storage and Handling Instructions

Store in a cool dry place.

Packaging Information

MAXPEE-0.4: Alu Alu pack of 10 Tablets

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