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Front

OLMESARTAN MEDOXOMIL + AMLODIPINE

OLMESTAL-A- 25

20 mg/5 mg Film-Coated Tablet
Angiotensin II Receptor Blocker/ Calcium Channel Blocker

FORMULATION:
Each film-coated tablet contains:
Olmesartan Medoxomil .....20 mg
Amlodipine (as besilate) BP.....5 mg

PRODUCT DESCRIPTION:
Yellow colured round shaped plain on both sides film-coated tablet.

PHARMACODYNAMICS:
Mechanism of Action:
Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) is a combination of the angiotensin II receptor antagonist Olmesartan, and the calcium channel blocker Amlodipine. The Amlodipine component of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The Olmesartan medoxomil component blocks the vasoconstrictor effects of angiotensin II.

Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25): Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) is a combination of an angiotensin II receptor antagonist, Olmesartan medoxomil, and a calcium channel blocker, Amlodipine besilate. The combination of these active ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone.
With chronic once daily oral administration, antihypertensive effectiveness is maintained for at least 24 hours.
The antihypertensive effect of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) was similar irrespective of age and gender, and was similar in patients with and without diabetes.
In follow-up studies, the antihypertensive effect of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) was sustained during long-term therapy. When required, addition of a diuretic (hydrochlorothiazide) increased the blood pressure lowering effect of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25).
Olmesartan medoxomil: The Olmesartan medoxomil component of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) is a selective angiotensin II type 1 (AT1) receptor antagonist. Olmesartan medoxomil is rapidly converted to the pharmacologically active metabolite, Olmesartan. Angiotensin II is the primary vasoactive hormone of the renin-angiotensin-aldosterone system, and plays a significant role in the pathophysiology of hypertension. The effects of angiotensin II include vasoconstriction, stimulation of the synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Olmesartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by blocking it's binding to the AT1 receptor in tissues, including vascular smooth muscle and the adrenal gland. The action of Olmesartan is independent of the source or route of synthesis of angiotensin II. The selective antagonism of the angiotensin II (AT1) receptors by Olmesartan results in increases in plasma renin levels and angiotensin I and II concentrations, and some decrease in plasma aldosterone concentrations.
In hypertension, Olmesartan medoxomil causes a dose-dependent, long-lasting reduction in arterial blood pressure. There has been no evidence of first-dose hypotension, of tachyphylaxis during long-term treatment, or of rebound hypertension after abrupt cessation of therapy.
Following once daily administration to patients with hypertension, Olmesartan medoxomil produces an effective and smooth reduction in blood pressure over the 24-hour dose interval. Once daily dosing produced similar decreases in blood pressure as twice daily dosing at the same total daily dose.
With continuous treatment, maximum reductions in blood pressure are achieved by 8 weeks after the initiation of therapy; although, a substantial proportion of the blood pressure lowering effect is already observed after 2 weeks of treatment.
The effect of Olmesartan medoxomil on mortality and morbidity is not yet known.
Amlodipine besilate: The Amlodipine component of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) is a calcium channel blocker that inhibits the transmembrane influx of calcium ions through the potential-dependent L-type channels into the heart and smooth muscle. Experimental data indicate that Amlodipine binds to both dihydropyridine and non-dihydropyridine binding sites. Amlodipine is relatively vessel-selective, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. The antihypertensive effect of Amlodipine derives from a direct relaxant effect on arterial smooth muscle, which leads to a lowering of peripheral resistance and hence, of blood pressure.
In hypertensive patients, Amlodipine causes a dose-dependent, long-lasting reduction in arterial blood pressure. There has been no evidence of first-dose hypotension, of tachyphylaxis during long-term treatment, or of rebound hypertension after abrupt cessation of therapy.
Following administration of therapeutic doses to patients with hypertension, Amlodipine produces an effective reduction in blood pressure in the supine, sitting, and standing positions. Chronic use of Amlodipine is not associated with significant changes in heart rate or plasma catecholamine levels. In hypertensive patients with normal renal function, therapeutic doses of Amlodipine reduce renal vascular resistance and increase glomerular filtration rate and effective renal plasma flow, without changing filtration fraction or proteinuria.
Epidemiological studies have shown that long-term treatment with Amlodipine monotherapy reduces the risk of cardiovascular mortality and morbidity.

PHARMACOKINETICS:
Amlodipine is well-absorbed after oral doses with peak blood concentrations occurring after 6 to 12 hours. The bioavailability varies but is usually about 60 to 65%. Amlodipine is reported to be about 97.5% bound to plasma proteins. It has a prolonged terminal elimination half-life of 35 to 50 hours and steady-state plasma concentrations are not achieved until after 7 to 8 days of use. Amlodipine is extensively metabolized in the liver; metabolites are mostly excreted in urine together with less than 10% of a dose as unchanged drug. Amlodipine is not removed by dialysis.
Following oral intake of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25), peak plasma concentrations of Olmesartan and Amlodipine are reached at 1.5 hours to 2 hours and 6 to 8 hours, respectively. The rate and extent of absorption of the two active substances from Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) are equivalent to the rate and extent of absorption following intake of the two components as separate tablets. Food does not affect the bioavailability of Olmesartan and Amlodipine from Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25).

Absorption and Distribution:
Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25): The pharmacokinetics of Amlodipine and Olmesartan from Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) are equivalent to the pharmacokinetics of Amlodipine and Olmesartan when administered separately. Food did not affect the pharmacokinetics of Olmesartan or Amlodipine when administered as Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) in healthy subjects.
Olmesartan medoxomil: Olmesartan medoxomil is a prodrug. It is rapidly converted to the pharmacologically active metabolite, Olmesartan, by esterases in the gut mucosa and in portal blood during absorption from the gastrointestinal tract. No intact Olmesartan medoxomil or intact side chain medoxomil moiety have been detected in plasma or excreta. The mean absolute bioavailability of Olmesartan from a tablet formulation was 25.6%.
The mean peak plasma concentration (C_{max}) of Olmesartan is reached within approximately 2 hours after oral dosing with Olmesartan medoxomil, and Olmesartan plasma concentrations increase approximately linearly with increasing single oral doses up to about 80 mg.
Food had minimal effect on the bioavailability of Olmesartan; therefore, Olmesartan medoxomil may be administered with or without food.
No clinically relevant gender-related differences in the pharmacokinetics of Olmesartan have been observed.
Olmesartan is highly bound to plasma protein (99.7%), but the potential for clinically significant protein binding displacement interactions between Olmesartan and other highly bound co-administered active substances is low (as confirmed by the lack of a clinically significant interaction between Olmesartan medoxomil and warfarin). The binding of Olmesartan to blood cells is negligible. The mean volume of distribution after intravenous dosing is low (16 L to 29 L).
Amlodipine besilate: After oral administration of therapeutic doses, Amlodipine is slowly absorbed from the gastrointestinal tract. The absorption of Amlodipine is unaffected by the concomitant intake of food. The absolute bioavailability of the unchanged compound is estimated to be 64% to 80%. Peak plasma levels are reached 6 hours to 12 hours post-dose. The volume of distribution is about 20 L/kg. The pKa of Amlodipine is 8.6. Plasma protein binding in vitro is approximately 98%.

Metabolism and Excretion:
Olmesartan Medoxomil: Total plasma clearance of Olmesartan was typically 1.3 L/h (CV, 19%) and was relatively slow compared to hepatic blood flow (ca 90 L/h). Based on the systemic availability of 25.6%, it can be calculated that absorbed Olmesartan is cleared by both renal excretion and hepatobiliary excretion. The terminal elimination half-life of Olmesartan is between 10 hours and 15 hours after multiple oral dosing. Steady state is reached after the first few doses and no further accumulation is evident after 14 days of repeated dosing. Renal clearance is approximately 0.5 L/h-0.7 L/h and is independent of dose.
Amlodipine Besilate: The plasma elimination half-life (t½) varies from 35 hours to 50 hours. Steady-state plasma levels are reached after 7 to 8 consecutive days. Amlodipine is extensively metabolized to inactive metabolites. About 60% of the administered dose is excreted in the urine, about 10% of which is in the form of unchanged Amlodipine.

Pharmacokinetics in Special Populations:
Elderly: Analysis indicated that age is not a significant predictor of Olmesartan clearance. As age is correlated with creatinine clearance, any apparent effects of age on Olmesartan clearance can be explained by changes in creatinine clearance. However, elderly patients have decreased clearance of Amlodipine. In hypertensive patients, the Olmesartan drug concentration in plasma area under the curve (AUC) is increased in elderly patients (65 years to 75 years old) and in very elderly patients (≥ 75 years old) compared with the younger age group. Following oral intake of Amlodipine, the time to peak plasma concentration is comparable in young and in elderly patients. In elderly patients, the clearance of Amlodipine tends to decline, resulting in increases in AUC and in elimination $t_{½}$.
Pediatric: No pharmacokinetic data in pediatric patients (below 18 years old) are available for Olmesartan medoxomil.
Renal Impairment: In renally impaired patients, at steady state the Olmesartan AUC was approximately tripled in patients with severe renal impairment, compared to healthy controls. Changes in Amlodipine plasma concentration are not correlated with the degree of renal impairment. In these patients, Amlodipine may be administered at the normal dosage. Amlodipine is not dialysable.
Hepatic Impairment: Increases in Olmesartan AUC values are higher in hepatically impaired patients than in their corresponding matched healthy controls. Olmesartan mean C_{max} values are similar in hepatically-impaired and healthy subjects. Olmesartan medoxomil has not been evaluated in patients with severe hepatic impairment.
The clearance of Amlodipine is decreased and the $t_{½}$ is prolonged in patients with impaired hepatic function, resulting in an increase in AUC of about 60%.
Olmesartan Pharmacokinetic Interactions:
Drug Interaction with Bile Acid Sequestering Agent Colesevelam: Concomitant administration of 40 mg Olmesartan medoxomil and 3750 mg colesevelam hydrochloride in healthy subjects resulted in 28% reduction in C_{max} and 39% reduction in AUC of Olmesartan. Lesser effects, 4% and 15% reduction in C_{max} and AUC respectively, were observed when Olmesartan medoxomil was administered 4 hours prior to colesevelam hydrochloride.

INDICATION:
Indicated as initial therapy in patients who are likely to need multiple antihypertensive agents to achieve their blood pressure goals.

DOSAGE AND ADMINISTRATION:
Adult: The recommended dosage of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) (1 tablet per day). Olmesartan medoxomil / Amlodipine (Olmestal-A-25) may be administered in patients whose blood pressure is not adequately controlled by 20 mg Olmesartan medoxomil or 5 mg Amlodipine alone.
The dosage can be increased after 1 to 2 weeks of therapy to a maximum, dose of one 10/40 mg tablet once daily as needed to control blood pressure. The aforementioned dosages for administration are not recommended in patients older than 75 years or with hepatic impairment. Or as prescribed by the physician.

CONTRAINDICATIONS:
Hypersensitivity to the active substances, to dihydropyridine derivatives or to any of the excipients.
Second and third trimesters of pregnancy.
Severe hepatic insufficiency and biliary obstruction.
Due to the component, Amlodipine, it is also contraindicated in patients with:
-Severe hypotension.
- Shock (including cardiogenic shock).
- Obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis).
- Haemodynamically unstable heart failure after acute myocardial infarction.

WARNING:
Fetal Toxicity
- When pregnancy is detected discontinue use as soon as possible.
- Drugs that act directly on the renin-angiotensin aldosterone system can cause injury and death to the developing fetus.

Back

SPECIAL PRECAUTIONS:
Hypotension in volume- or salt-depleted patients with treatment initiation may be anticipated.
Start treatment under close supervision .
Increased angina or myocardial infarction with calcium channel blockers may occur upon dosage initiation or increase.
Impaired renal function:
Patients with Hypovolemia or Sodium Depletion: Symptomatic hypotension may occur in patients who are volume- and/or sodium-depleted by vigorous diuretic therapy, dietary salt restriction, diarrhea, or vomiting, especially after receiving the first dose. Correction of this condition prior to administration of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25), or close medical supervision at the start of treatment, is recommended.
Other Conditions with Stimulation of the Renin-Angiotensin-Aldosterone System: In patients whose vascular tone and renal function depend predominantly on the activity of the renin-angiotensin-aldosterone system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis), treatment with other medicinal products that affect this system, such as angiotensin II receptor antagonists, has been associated with acute hypotension, azotemia, oliguria, or rarely, acute renal failure.
Renovascular Hypertension: There is an increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a single functioning kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system.
Sprue-Like Enteropathy: Severe, chronic diarrhea with substantial weight loss has been reported in patients taking Olmesartan medoxomil months to years after drug initiation. Intestinal biopsies of patients often demonstrated villous atrophy. If a patient develops these symptoms during treatment with Olmesartan medoxomil, exclude other etiologies. Consider discontinuation of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) in cases where no other etiology is identified.
Renal Impairment and Kidney Transplantation: Changes in renal function may be anticipated in susceptible individuals. There is no experience of the administration of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) in patients with a recent kidney transplant or in patients with end-stage renal impairment (i.e. creatinine clearance <12 mL/min).
Hepatic Impairment: Since Amlodipine is extensively metabolized by the liver, exposure to Olmesartan medoxomil and Amlodipine is increased in patients with hepatic impairment. Care should be taken when Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) is administered in patients with mild to moderate hepatic impairment. Use of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) in patients with severe hepatic impairment is not recommended.
Severe Obstructive Coronary Disease: As with all vasodilators, special caution is indicated in patients suffering from aortic or mitral valve stenosis, or obstructive hypertrophic cardiomyopathy.

PREGNANCY AND LACTATION:
Use in Pregnancy: Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) can cause fetal harm when administered to a pregnant woman. As a precaution, Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) must not be used during the first trimester of pregnancy. The patient should change to an appropriate alternative form of medication before a planned pregnancy. If pregnancy occurs during therapy, Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) must be discontinued as soon as possible. There is no experience of the use of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) in pregnant women.
Olmesartan medoxomil is contraindicated in the second and third trimesters of pregnancy. During the second and third trimesters of pregnancy, substances that act on the renin-angiotensin system may cause damage (hypotension, impairment of renal function, oliguria and/or anuria, oligohydramnios, cranial hypoplasia, intrauterine growth retardation) and death in fetuses and neonates. Cases of pulmonary hypoplasia, facial anomalies and contractions of limbs were also reported. Animal experimental studies with Olmesartan medoxomil have shown furthermore that renal damage may occur in the late fetal and neonatal phase.
Data on a limited number of exposed pregnancies do not indicate that Amlodipine or other calcium receptor antagonists have a harmful effect on the health of the fetus. However, there may be a risk of prolonged delivery.
If Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) is used during pregnancy, or if the patient becomes pregnant while taking Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25), the patient should be apprised of the potential hazard to a fetus. Should exposure to Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) occurred from the second trimester forward, ultrasound examinations of the renal function and of the skull are recommended. Newborns exposed to angiotensin II antagonists in utero must be closely monitored for the occurrence of hypotension, oliguria, and hyperkalemia.
Use in Lactation: It is not known whether the Olmesartan medoxomil or Amlodipine components of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) are excreted in human milk, but Olmesartan is secreted at low concentration in the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug.

DRUG INTERACTIONS:
Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25): The blood pressure lowering effect of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) can be increased by concomitant use of other antihypertensive medicinal products (e.g. alpha blockers, diuretics).
No drug interaction studies have been conducted with Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) and other drugs; although, studies have been conducted with the individual Olmesartan medoxomil and Amlodipine components of Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25), described as follows.
Olmesartan Medoxomil: *Use with Lithium:* Increases in serum lithium concentrations and lithium toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists, including Olmesartan. Monitor serum lithium levels during concomitant use.
Dual Blockade of the Renin-Angiotensin System (RAS): Dual blockade of the RAS with angiotensin receptor antagonists, ACE inhibitors or aliskiren is associated with increased risks of hypotension, hyperkalemia and changes in renal function (including acute renal failure) compared to monotherapy. Monitor blood pressure, renal function and electrolytes in patients on Olmesartan and other agents that affect the RAS.
Use with Aliskiren: Do not co-administer aliskiren with Olmesartan medoxomil in patients with diabetes because dual use is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy.
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs): NSAIDs and ARBs may act synergistically by decreasing glomerular filtration. The concomitant use of NSAIDs and ARBs may increase the risk of worsening renal function.
Additionally, the antihypertensive effect of ARBs, including Olmesartan, may be attenuated by NSAIDs, including selective COX-2 inhibitors.
Use with Colesevelam Hydrochloride: Concurrent administration of bile acid sequestering agent colesevelam hydrochloride reduces the systemic exposure and peak plasma concentration of Olmesartan. Administration of Olmesartan at least 4 hours prior to colesevelam hydrochloride decreased the drug interaction effect.
Amlodipine Besilate: Concomitant Use Requiring Caution: *CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, ritonavir):* A study in elderly patients showed that diltiazem inhibits the metabolism of Amlodipine, probably via CYP3A4, since plasma concentrations of Amlodipine increased by approximately 50% and its effect was therefore increased. The possibility that more potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, ritonavir) may increase the plasma concentration of Amlodipine to a greater extent than diltiazem cannot be excluded.
CYP3A4 inducers [e.g. anticonvulsants (such as carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone), rifampicin, Hypericum perforatum]: Concomitant administration of CYP3A4 may decrease the plasma concentration of Amlodipine. Clinical monitoring is indicated, with possible adjustment of Amlodipine dosage during treatment with the CYP3A4 inducer and after its withdrawal.
Simvastatin: Co-administration of multiple doses of 10 mg of Amlodipine with 80 mg simvastatin resulted in a 77% increase in exposure to simvastatin compared to simvastatin alone. Limit the dose of simvastatin to 20 mg daily in patients on Amlodipine.

ADVERSE DRUG REACTIONS:
Most common adverse reactions are edema (11.3%), headache (5.3%) and dizziness (4.5%).
Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25): The overall incidence of adverse events on therapy with Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) was not different from that seen with placebo. Most adverse events were mild.
The most common undesirable effects were dizziness, headache, edema, and fatigue.
Edema: Edema is a known dose-dependent undesirable effect of Amlodipine. The incidence of edema was significantly lower in patients receiving Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25) than in those who received Amlodipine 10 mg alone. Across all treatment groups, the frequency of edema was generally higher in women than in men.
The less common undesirable effects included hypotension, orthostatic hypotension, rash, palpitation, and pollakiuria.
Adverse events previously reported with one of the individual components may be potential adverse events with Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25), even if not observed in clinical trials with this product.
Olmesartan Medoxomil: In clinical trials, treatment with Olmesartan medoxomil was well tolerated, with an incidence of adverse events similar to that seen with placebo. Events were generally mild, transient, and without relationship to the dose of Olmesartan medoxomil. The overall frequency of adverse events was not dose-related. Analysis of gender, age, and race groups demonstrated no differences between Olmesartan medoxomil and placebo-treated patients. Dizziness has been reported commonly (≥1% to <10% incidence) in clinical trials with Olmesartan medoxomil.
In post-launch experience, adverse drug reactions that have been reported very rarely (<0.01% incidence) were peripheral edema, headache, cough, abdominal pain, nausea, vomiting, diarrhea, sprue-like enteropathy, anaphylactic reaction, rash, pruritus, angioedema, acute renal failure, increased hepatic enzymes, increased blood creatinine, hyperkalemia, myalgia and asthenic conditions such as asthenia, fatigue, lethargy, malaise.
Amlodipine Besilate: Most adverse reactions reported during therapy with Amlodipine were of mild or moderate severity. The most common undesirable effects were headache, edema, dizziness, facial flushing, and palpitation.
In post-launch experience, gynecomastia has been infrequently reported as an adverse reaction where a causal relationship is uncertain. In post-marketing experience, jaundice and hepatic enzyme elevations (mostly consistent with cholestasis or hepatitis), in some cases severe enough to require hospitalization, have been reported in association with use of Amlodipine.

OVERDOSE AND TREATMENT:
Symptoms: There is no experience of overdose with Olmesartan medoxomil / Amlodipine besilate (Olmestal-A-25). The most likely effects of Olmesartan medoxomil overdosage are hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurred. Amlodipine overdosage can be expected to lead to excessive peripheral vasodilatation with marked hypotension and possibly a reflex tachycardia. Marked and potentially prolonged systemic hypotension up to and including shock with fatal outcome have been reported.
Treatment: If intake is recent, gastric lavage may be considered. In healthy subjects, the administration of activated charcoal immediately or up to 2 hours after ingestion of Amlodipine has been shown to reduce substantially the absorption of Amlodipine.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA:www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/Alu Blister Pack x 10's (Box of 30's)

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