OLMESARTAN medoxomil + AMLODIPINE besilate

TN2501I

ALZOR CCB®

20mg / 5mg Film Coated Tablet
20mg / 10mg Film Coated Tablet
40mg / 5mg Film Coated Tablet
40mg / 10mg Film Coated Tablet
ANGIOTENSIN II RECEPTOR BLOCKER/
CALCIUM CHANNEL BLOCKER/
ANTIHYPERTENSIVE

FORMULATION

Each film coated tablet contains:
Olmesartan medoxomil USP……20mg
Amlodipine (as besilate) BP……5mg
Each film coated tablet contains:
Olmesartan medoxomil USP……20mg
Amlodipine (as besilate) BP……10mg
Each film coated tablet contains:
Olmesartan medoxomil USP……40mg
Amlodipine (as besilate) BP……5mg
Each film coated tablet contains:
Olmesartan medoxomil USP……40mg
Amlodipine (as besilate) BP……10mg

DESCRIPTION:

20mg/ 5mg-White to off-white coloured, circular, biconvex, film coated tablets, plain on both sides.
20mg/ 10mg-Light orange to orange coloured, circular, biconvex, film coated tablets, plain on both sides.
40mg/ 5mg-Light blue to blue coloured, circular, biconvex, film coated tablets, plain on both sides.
40mg/ 10mg- White to off-white coloured, circular, biconvex, film coated tablets, plain on both sides.

MECHANISM OF ACTION

Combination of two antihypertensive drugs: a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker), Amlodipine besilate, and an angiotensin II receptor blocker, Olmesartan medoxomil. The Amlodipine component inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle, and the Olmesartan medoxomil component blocks the vasoconstrictor effects of angiotensin II.

Amlodipine. Amlodipine besilate binds to both dihydropyridine and nonhydropyridine binding sites. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. Negative inotropic effects can be detected *in vitro* but such effects have not been seen in intact animals at therapeutic doses. Serum calcium concentration is not affected by Amlodipine. Within the physiologic pH range, Amlodipine is an ionized compound (pKa=8.6), and its kinetic interaction with the calcium channel receptor is characterized by a gradual rate of association and dissociation with the receptor binding site, resulting in a gradual onset of effect.

Amlodipine is a peripheral arterial vasodilator that acts directly on vascular smooth muscle to cause a reduction in peripheral vascular resistance and reduction in blood pressure.

Olmesartan medoxomil. Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation and renal reabsorption of sodium. Olmesartan blocks the vasoconstrictor effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in vascular smooth muscle. Its action is, therefore, independent of the pathways for angiotensin II synthesis.

An AT2 receptor is found also in many tissues, but this receptor is not known to be associated with cardiovascular homeostasis. Olmesartan has more than a 12,500-fold greater affinity for the AT_1 receptor than for the AT_2 receptor.

Blockade of the renin-angiotensin system with ACE inhibitors, which inhibit the biosynthesis of angiotensin II from angiotensin I, is a mechanism of many drugs used to treat hypertension. ACE inhibitors also inhibit the degradation of bradykinin, a reaction also catalyzed by ACE. Because Olmesartan does not inhibit ACE (kininase II), it does not affect the response to bradykinin. Whether this difference has clinical relevance is not yet known.

Blockade of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on renin secretion, but the resulting increased plasma renin activity and circulating angiotensin II levels do not overcome the effect of Olmesartan on blood pressure.

PHARMACODYNAMICS

Amlodipine. Following administration of therapeutic doses to patients with hypertension, Amlodipine produces vasodilation resulting in a reduction of supine and standing blood pressures. These decreases in blood pressure are not accompanied by a significant change in heart rate or plasma catecholamine levels with chronic dosing.

With chronic once daily oral administration, antihypertensive effectiveness is maintained for at least 24 hours. Plasma concentrations correlate with effect in both young and elderly patients. The magnitude of reduction in blood pressure with Amlodipine is also correlated with the height of pretreatment elevation; thus, individuals with moderate hypertension (diastolic pressure 105 -114 mmHg) had about a 50% greater response than patients with mild hypertension (diastolic pressure 90-104 mmHg).

In hypertensive patients with normal renal function, therapeutic doses of Amlodipine resulted in a decrease in renal vascular resistance and an increase in glomerular filtration rate and effective renal plasma flow without change in filtration fraction or proteinuria.

Amlodipine does not change sinoatrial nodal function or atrioventricular conduction in intact animals or man.

Olmesartan medoxomil. Olmesartan medoxomil doses of 2.5 mg to 40 mg inhibit the pressor effects of angiotensin I infusion. The duration of the inhibitory effect was related to dose, with doses of Olmesartan medoxomil >40 mg giving >90% inhibition at 24 hours.

Plasma concentrations of angiotensin I and angiotensin II and plasma renin activity (PRA) increase after single and repeated administration of Olmesartan medoxomil. Repeated administration of up to 80 mg Olmesartan medoxomil had minimal influence on aldosterone levels and no effect on serum potassium.

PHARMACOKINETICS

The pharmacokinetics of Amlodipine besilate and Olmesartan medoxomil are equivalent to the pharmacokinetics of Amlodipine besilate and Olmesartan medoxomil when administered separately. The bioavailability of both components is well below 100%, but neither component is affected by food. The effective half-lives of Amlodipine (45±11 hours) and Olmesartan (7±1 hours) result in a 2- to 3- fold accumulation for Amlodipine and negligible accumulation for Olmesartan with once-daily dosing.

Amlodipine. After oral administration of therapeutic doses of Amlodipine, absorption produces peak plasma concentrations between 6 and 12 hours. Absolute bioavailability is estimated as between 64% and 90%.

Olmesartan medoxomil. Olmesartan medoxomil is rapidly and completely bioactivated by ester hydrolysis to Olmesartan during absorption from the gastrointestinal tract. The absolute bioavailability of Olmesartan medoxomil is approximately 26%. After oral administration, the peak plasma concentration (C_{max}) of Olmesartan is reached after 1 to 2 hours. Food does not affect the bioavailability of Olmesartan medoxomil.

DISTRIBUTION

Amlodipine. *Ex vivo* studies have shown that approximately 93% of the circulating drug is bound to plasma proteins in hypertensive patients. Steady-state plasma levels of Amlodipine are reached after 7 to 8 days of consecutive daily dosing.

Olmesartan medoxomil. The volume of distribution of Olmesartan is approximately 17 L. Olmesartan is highly bound to plasma proteins (99%) and does not penetrate red blood cells. The protein binding is constant at plasma Olmesartan concentrations well above the range achieved with recommended doses.

METABOLISM AND EXCRETION

Amlodipine. Amlodipine is extensively (about 90%) converted to inactive metabolites via hepatic metabolism. Elimination from the plasma is biphasic with a terminal elimination half-life of about 30 to 50 hours. Ten percent of the parent compound and 60% of the metabolites are excreted in the urine.

Olmesartan medoxomil. Following the rapid and complete conversion of Olmesartan medoxomil to Olmesartan during absorption, there is virtually no further metabolism of Olmesartan. Total plasma clearance of Olmesartan is 1.3 L/h; with a renal clearance of 0.6 L/h. Approximately 35% to 50% of the absorbed dose is recovered in urine while the remainder is eliminated in feces via the bile.

Olmesartan appears to be eliminated in a biphasic manner with a terminal elimination half-life of approximately 13 hours. Olmesartan shows linear pharmacokinetics following single oral doses of up to 320 mg and multiple oral doses of up to 80 mg. Steady-state levels of Olmesartan are achieved within 3 to 5 days and no accumulation in plasma occurs with once-daily dosing.

GERIATRIC

The pharmacokinetic properties of Olmesartan medoxomil and Amlodipine besilate in the elderly are similar to those of the individual components.

Amlodipine. Elderly patients have decreased clearance of Amlodipine with a resulting increase in AUC of approximately 40% to 60%, and a lower initial dose may be required.

Olmesartan medoxomil. The pharmacokinetics of Olmesartan medoxomil was studied in the elderly (≥65 years). Overall, maximum plasma concentrations of Olmesartan were similar in young adults and the elderly. Modest accumulation of Olmesartan was observed in the elderly with repeated dosing; $AUC_{ss\cdot\tau}$ was 33% higher in elderly patients, corresponding to an approximate 30% reduction in CLR.

PEDIATRIC

Amlodipine. Weight-adjusted clearance and volume of distribution were similar to values in adults.

Olmesartan medoxomil. The pharmacokinetics of Olmesartan medoxomil have not been investigated in patients <18 years of age.

GENDER

Population pharmacokinetic analysis indicated that female patients had approximately 15% smaller clearances of Olmesartan than male patients. Gender had no effect on the clearance of Amlodipine.

Olmesartan medoxomil. Minor differences were observed in the pharmacokinetics of Olmesartan medoxomil in women compared to men. AUC and C_{max} were 10% to 15% higher in women than in men.

RENAL INSUFFICIENCY

Amlodipine. The pharmacokinetics of Amlodipine is not significantly influenced by renal impairment. Patients with renal failure may therefore receive the usual initial dose.

Olmesartan medoxomil. In patients with renal insufficiency, serum concentrations of Olmesartan were elevated compared to subjects with normal renal function. After repeated dosing, the AUC was approximately tripled in patients with severe renal impairment (creatinine clearance <20mL/min). The pharmacokinetics of Olmesartan medoxomil in patients undergoing hemodialysis has not been studied.

HEPATIC INSUFFICIENCY

Amlodipine. Patients with hepatic insufficiency have decreased clearance of Amlodipine with a resulting increase in AUC of approximately 40% to 60%.

Olmesartan medoxomil. Increases in $AUC_{0-\infty}$ and C_{max} were observed in patients with moderate hepatic impairment compared to those in matched controls, with an increase in AUC of about 60%.

HEART FAILURE

Amlodipine. Patients with heart failure have decreased clearance of Amlodipine with a resulting increase in AUC of approximately 40% to 60%.

INDICATIONS

Olmesartan medoxomil plus Amlodipine besilate is indicated for the treatment of hypertension, alone or with other antihypertensive agents. This fixed combination drug is indicated as initial therapy in patients likely to need multiple anti-hypertensive agents to achieve their blood pressure goals. Initial therapy is not recommended in patients ≥ 75 years of age or in hepatically impaired patients.

CONTRAINDICATION

Patients with known hypersensitivity to Olmesartan medoxomil, Amlodipine besilate or any of its components.

DOSAGE AND ADMINISTRATION

General Considerations

The side effects of Olmesartan medoxomil are generally rare and apparently independent of dose.
Those of Amlodipine are generally dose-dependent (mostly edema).
Maximum antihypertensive effects are attained within 2 weeks after a change in dose.
Olmesartan medoxomil plus Amlodipine besilate may be taken with or without food.
Olmesartan medoxomil plus Amlodipine besilate may be administered with other antihypertensive agents.
Dosage may be increased after 2 weeks. The maximum recommended dose of Olmesartan medoxomil plus Amlodipine besilate is 40/10 mg.

Replacement Therapy

Olmesartan medoxomil plus Amlodipine besilate may be substituted for its individually titrated components.
When substituting for individual components, the dose of one or both of the components can be increased if blood pressure control has not been satisfactory.

Add-on Therapy for Patients with Hypertension Not Adequately Controlled on Amlodipine or Olmesartan Medoxomil Alone

Olmesartan medoxomil plus Amlodipine besilate may be used as add-on therapy for patients not adequately controlled on Amlodipine or Olmesartan medoxomil.

WARNINGS and PRECAUTIONS

Fetal/Neonatal Morbidity and Mortality

Olmesartan medoxomil. Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. When pregnancy is detected, Olmesartan medoxomil plus Amlodipine besilate should be discontinued as soon as possible.

During the second and third trimesters of pregnancy, these drugs have been associated with fetal injury that includes hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios has also been reported, presumably resulting from decreased fetal renal function; oligohydramnios in this setting has been associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus have also been reported, although it is not clear whether these occurrences were due to exposure to the drug.

These adverse effects do not appear to have resulted from intrauterine drug exposure that has been limited to the first trimester. Mothers whose embryos and fetuses are exposed to an angiotensin II receptor antagonist only during the first trimester should be so informed. Nonetheless, when patients become pregnant, physicians should have the patient discontinue the use of Amlodipine or Olmesartan medoxomil as soon as possible.

Hypotension in Volume-or Salt-Depleted Patients

Olmesartan medoxomil. Symptomatic hypotension may occur after initiation of treatment with Olmesartan medoxomil. Patients with an activated renin-angiotensin system, such as volume-and/or salt-depleted patients (e.g., those being treated with high doses of diuretics) may be particularly vulnerable. Treatment with Olmesartan medoxomil plus Amlodipine besilate should start under close medical supervision. If hypotension does occur, the patient should be placed in the supine position and, if necessary, given an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

Vasodilation

Amlodipine. Since the vasodilation attributable to Amlodipine in Olmesartan medoxomil plus Amlodipine besilate is gradual in onset, acute hypotension has rarely been reported after oral administration. Nonetheless, caution, as with any other peripheral vasodilator, should be exercised when administering Olmesartan medoxomil plus Amlodipine besilate, particularly in patients with severe aortic stenosis.

Patients with Severe Obstructive Coronary Artery Disease

Patients, particularly those with severe obstructive coronary artery disease, may develop increased frequency, duration, or severity of angina or acute myocardial infarction on starting calcium channel blocker therapy or at the time of dosage increase. The mechanism of this effect has not been elucidated.

Patients with Congestive Heart Failure

Amlodipine. In general, calcium channel blockers should be used with caution in patients with heart failure. Amlodipine (5-10 mg per day) has been studied in a placebo-controlled trial of 1153 patients with NYHA Class III or IV heart failure on stable doses of ACE inhibitor, digoxin, and diuretics. Follow-up was at least 6 months, with a mean of about 14 months. There was no overall adverse effect on survival or cardiac morbidity (as defined by life-threatening arrhythmia, acute myocardial infarction, or hospitalization for worsened heart failure). Amlodipine has been compared to placebo in four 8-12 week studies of patients with NYHA class II/III heart failure, involving a total of 697 patients. In these studies, there was no evidence of worsening of heart failure based on measures of exercise tolerance, NYHA classification, symptoms, or LVEF.

Patients with Impaired Renal Function

Olmesartan medoxomil. Changes in renal function may be anticipated in susceptible individuals treated with Olmesartan medoxomil as a consequence of inhibiting the renin-angiotensin-aldosterone system. In patients whose renal function may depend upon the activity of the renin-angiotensin-aldosterone system (e.g., patients with severe congestive heart failure), treatment with angiotensin converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria or progressive azotemia and (rarely) with acute renal failure and/or death. Similar effects may occur in patients treated with Olmesartan medoxomil plus Amlodipine besilate due to the Olmesartan medoxomil component.

In studies of ACE inhibitors in patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen (BUN) have been reported. There has been no long-term use of Olmesartan medoxomil in patients with unilateral or bilateral renal artery stenosis, but similar effects would be expected with Olmesartan medoxomil plus Amlodipine besilate because of the Olmesartan medoxomil component.

Patients with Hepatic Impairment

Amlodipine. Since Amlodipine is extensively metabolized by the liver and the plasma elimination half-life (t1/2) is 56 hours in patients with severely impaired hepatic function, caution should be exercised when administering Olmesartan medoxomil plus Amlodipine besilate to patients with severe hepatic impairment.

Laboratory Tests

There was a greater decrease in hemoglobin and hematocrit in the combination product compared to either component. Other laboratory changes can usually be attributed to either monotherapy component.

Amlodipine, hepatic enzyme elevations have been reported.

Olmesartan medoxomil, increased blood creatinine levels and hyperkalemia have been reported.

DRUG INTERACTIONS

The pharmacokinetics of Olmesartan medoxomil and Amlodipine besilate are not altered when the drugs are co-administered.

No drug interaction studies have been conducted with Olmesartan medoxomil plus Amlodipine besilate and other drugs, although studies have been conducted with the individual Olmesartan medoxomil and Amlodipine besilate components of Olmesartan medoxomil plus Amlodipine besilate, as described below, and no significant drug interactions have been observed.

In vitro data indicate that Amlodipine has no effect on the human plasma protein binding of digoxin, phenytoin, warfarin, and indomethacin.

Effect of Other Agents on Amlodipine

Cimetidine: Co-administration of Amlodipine with cimetidine did not alter the pharmacokinetics of Amlodipine.

Grapefruit juice: Co-administration of 240 mL of grapefruit juice with a single oral dose of Amlodipine 10 mg in 20 healthy volunteers had no significant effect on the pharmacokinetics of Amlodipine.

Maalox® (antacid): Co-administration of the antacid Maalox® with a single dose of Amlodipine had no significant effect on the pharmacokinetics of Amlodipine.

Sildenafil: A single 100 mg dose of sildenafil in subjects with essential hypertension had no effect on the pharmacokinetic parameters of Amlodipine. When Amlodipine and sildenafil were used in combination, each agent independently exerted its own blood pressure lowering effect.

Effect of Amlodipine on Other Agents

Atorvastatin: Co-administration of multiple 10 mg doses of Amlodipine with 80 mg of atorvastatin resulted in no significant change in the steady state pharmacokinetic parameters of atorvastatin.

Digoxin: Co-administration of Amlodipine with digoxin did not change serum digoxin levels or digoxin renal clearance in normal volunteers.

Ethanol (alcohol): Single and multiple 10 mg doses of Amlodipine had no significant effect on the pharmacokinetics of ethanol.

Warfarin: Co-administration of Amlodipine with warfarin did not change the warfarin prothrombin response time.

Amlodipine has been safely administered with thiazide diuretics, beta-blockers, angiotensin-converting enzyme inhibitors, long-acting nitrates, sublingual nitroglycerin, digoxin, warfarin, non-steroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic drugs.

Drug Interactions with Olmesartan Medoxomil

No significant drug interactions were reported in studies in which Olmesartan medoxomil was co-administered with digoxin or warfarin in healthy volunteers.

The bioavailability of Olmesartan medoxomil was not significantly altered by the co-administration of antacids [Al(OH)3/Mg(OH)2].

Olmesartan medoxomil is not metabolized by the cytochrome P450 system and has no effects on P450 enzymes; thus, interactions with drugs that inhibit, induce, or are metabolized by those enzymes are not expected.

USE IN SPECIFIC POPULATIONS

Pregnancy

Olmesartan medoxomil. Pregnancy Categories C (first trimester) and D (second and third trimesters). [See Warnings and Precautions]

Amlodipine. No evidence of teratogenicity or other embryo/fetal toxicity. Amlodipine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether the Amlodipine or Olmesartan medoxomil components of Olmesartan medoxomil plus Amlodipine besilate tablet 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, taking into account the importance of the drug to the mother.

Pediatric Use

The safety and effectiveness of Olmesartan medoxomil plus Amlodipine besilate in pediatric patients have not been established.

Amlodipine. The effect of Amlodipine on blood pressure in patients less than 6 years of age is not known.

Olmesartan medoxomil. Safety and effectiveness of Olmesartan medoxomil in pediatric patients have not been established.

Geriatric Use

Amlodipine. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Elderly patients have decreased clearance of Amlodipine with a resulting increase of AUC of approximately 40% to 60%, and a lower initial dose may be required.

Olmesartan medoxomil. No overall differences in effectiveness or safety were observed between elderly patients and younger patients.

Hepatic Impairment

There are no studies of Olmesartan medoxomil plus Amlodipine besilate in patients with hepatic insufficiency, but both Amlodipine and Olmesartan medoxomil show moderate increases in exposure in patients with hepatic impairment.

Use caution when administering Olmesartan medoxomil plus Amlodipine besilate to patients with severe hepatic impairment.

Renal Impairment

There are no studies of Olmesartan medoxomil plus Amlodipine besilate in patients with renal impairment.

Amlodipine. The pharmacokinetics of Amlodipine is not significantly influenced by renal impairment. Patients with renal failure may therefore receive the usual initial dose.

Olmesartan medoxomil. Patients with renal insufficiency have elevated serum concentrations of Olmesartan compared with patients with normal renal function. After repeated dosing, AUC was approximately tripled in patients with severe renal impairment (creatinine clearance <20mL/min). No initial dosage adjustment is recommended for patients with moderate to marked renal impairment (creatinine clearance <40 mL/min).

OVERDOSAGE

There is no information on overdosage with Olmesartan medoxomil plus Amlodipine besilate in humans.

Amlodipine. Overdosage might be expected to cause excessive peripheral vasodilation with marked hypotension and possibly a reflex tachycardia. In humans, experience with intentional overdosage of Amlodipine is limited.

If massive overdose should occur, active cardiac and respiratory monitoring should be instituted. Frequent blood pressure measurements are essential. Should hypotension occur, cardiovascular support including elevation of the extremities and the judicious administration of fluids should be initiated. If hypotension remains unresponsive to these conservative measures, administration of vasopressors (such as phenylephrine) should be considered with attention to circulating volume and urine output. Intravenous calcium gluconate may help to reverse the effects of calcium entry blockade. As Amlodipine is highly protein bound, hemodialysis is not likely to be of benefit.

Olmesartan medoxomil. Limited data are available related to overdosage in humans. The most likely manifestations of overdosage would be hypotension and tachycardia; bradycardia could be encountered if parasympathetic (vagal) stimulation occurs. If symptomatic hypotension should occur, supportive treatment should be initiated. The dialyzability of Olmesartan is unknown.

ADVERSE EFFECTS

Edema is a known, dose-dependent adverse effect of Amlodipine but not of Olmesartan medoxomil.

Adverse reaction includes hypotension, orthostatic hypotension, rash, pruritus, palpitation, urinary frequency, and nocturia.

Amlodipine. The most common side effects were headache, edema, gynecomastia, jaundice and hepatic enzyme elevations (mostly consistent with cholestasis or hepatitis)

Olmesartan medoxomil. The overall frequency of adverse events was not dose-related. Events were generally mild, transient, and without relationship to the dose of Olmesartan medoxomil. These are :

Body as a Whole: dizziness, asthenia, angioedema

Gastrointestinal: vomiting

Musculoskeletal: rhabdomyolysis

Urogenital System: acute renal failure

Skin and Appendages: alopecia, pruritus, urticaria

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 shall appear.

STORE AT TEMPERATURES NOT EXCEEDING 30° C.

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AVAILABILITY

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Registration No.: 20mg /10mg - DR-XY47912
Registration No.: 40mg /5mg - DR-XY47986
Registration No.: 40mg /10mg - DR-XY47989

Date of Revision of Package Insert : 0

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