

Daplozmet®

(Dapagliflozin + Metformin HCl)



Highnoon

COMPOSITION

Daplozmet 5/850mg Tablet: Each film-coated tablet contains: Dapagliflozin (as Dapagliflozin Propanediol Monohydrate) 5mg Metformin Hydrochloride 850mg

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DESCRIPTION

Dapagliflozin is a sodium-glucose co-transport 2 inhibitor that enhances urinary excretion of glucose by renal glucose reabsorption.

MECHANISM OF ACTION

Daplozmet (Dapagliflozin and Metformin HCl) combines two anti-hyperglycaemic medicinal products with different and complementary mechanisms of action to improve glycaemic control in patients with type 2 diabetes.

Dapagliflozin

Dapagliflozin is a highly potent, selective and reversible inhibitor of SGLT2.SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Despite the presence of hyperglycemia in type 2 diabetes, reabsorption of filtered glucose continues. Dapagliflozin improves both fasting and post-prandial plasma glucose levels by reducing renal glucose reabsorption leading to urinary glucose excretion. Dapagliflozin does not impair normal endogenous glucose production in response to hypoglycemia. Dapagliflozin acts independently of insulin secretion and insulin action. Urinary glucose excretion (glucosuria) induced by dapagliflozin is associated with sodium loss and reduction in weight. Inhibition of glucose and sodium co-transport by dapagliflozin is also associated with mild diuresis and transient natriuresis. Dapagliflozin does not inhibit other glucose transporters important for glucose transport into peripheral tissues and is > 1,400 times more selective for SGLT2 versus SGLT1, the major transporter in the gut responsible for glucose absorption.

Metformin

Metformin is a biguanide with antihyperglycemic effects, which improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycemia. Metformin decreases hepatic glucose production by inhibiting gluconeogenesis, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and day-long plasma insulin response may actually decrease.

PHARMACOKINETICS

Dapagliflozin

Peak plasma concentrations of dapagliflozin occur within 2 to 3 hours after an oral dose, with a bioavailability of about 78%. It is about 91% bound to plasma proteins. Dapagliflozin is extensively metabolized to inactive metabolites via uridine diphosphate glucuronosyltransferase UGT1A9 in the liver and kidney. It has a plasma terminal half-life of about 13 hours; about 75% of the dose is excreted in the urine and 21% in the faeces.

Metformin

Metformin hydrochloride is slowly and incompletely absorbed from the gastrointestinal tract, the absolute bioavailability of a single 500mg dose is reported to be about 50 to 60%, although this is reduced somewhat if taken with food. Protein binding in plasma is negligible. Metformin is excreted unchanged in the urine. The plasma elimination half-life is reported to range from about 2 to 6 hours. Metformin crosses the placenta and is distributed into the breast milk in small amounts.

INDICATIONS AND USAGE

- It is indicated in adults with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control.
- It is indicated to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.
- It is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.
- It is indicated to reduce the risk of sustained estimated GFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.
- It is not recommended for patients with type 1 diabetes mellitus or diabetic ketoacidosis. It may increase the risk of diabetic ketoacidosis in these patients.
- Because of Metformin component, the use of dapagliflozin is limited in Type II Diabetes Mellitus for all indications. It is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. It is not expected to be effective in these populations.

DOSAGE AND ADMINISTRATION

- Take once daily in the morning with food.
- Swallow the tablets whole and never crush, cut, or chew.
- Individualize the starting dose of Dapagliflozin and Metformin HCl combination based upon the patient's current regimen.
- To improve glycaemic control for patients not already taking dapagliflozin, the recommended starting dose for dapagliflozin is 5 mg once daily.
- For indication related to the heart failure and chronic kidney disease, The recommended dose for dapagliflozin is 10mg once daily.
- Dosing may be adjusted based on effectiveness and tolerability while not exceeding the maximum recommended daily dose of 10 mg dapagliflozin and 2000 mg metformin HCl. Patients taking an evening dose of metformin should skip their last dose before starting this combination (Dapagliflozin and Metformin HCl).
- Assess renal function before initiating this combination (Dapagliflozin and Metformin HCl) and periodically thereafter.
- Assess the volume status and if necessary correct the volume depletion prior to initiation of this combination (Dapagliflozin and Metformin HCl).

Patients with Renal Impairment

- It is contraindicated in patients with an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73m², end stage renal disease or on dialysis due to metformin component.
- No dose adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m².
- Initiation of Dapagliflozin is not recommended in patients with eGFR between 30 and 45 mL/min/1.73m². Assess the benefit and risk of continuing therapy if eGFR falls persistently below this level.
 - Dapagliflozin is likely to be ineffective to improve glycaemic control in patients with eGFR below 30 and 45 mL/min/1.73m².
 - Metformin initiation is not recommended for patients with eGFR less than 45 mL/min/1.73m².

Discontinuation for Iodinated Contrast Imaging Procedures

Discontinue this combination (Dapagliflozin and Metformin HCl) at the time of, or prior to, an iodinated contrast imaging procedure in patients with a history of liver disease, alcoholism or heart failure; or in patients who will be administered intra-arterial iodinated contrast. Re-evaluate eGFR 48 hours after the imaging procedure; restart the drug if renal function is stable.

CONTRAINDICATIONS

It is contraindicated in patients with:

- hypersensitivity to the active substances or to any of the excipients. Hypersensitivity included anaphylactic reactions or angioedema or hypersensitivity to metformin.
- any type of acute metabolic acidosis (such as lactic acidosis, diabetic ketoacidosis) with or without coma
- severe renal failure (GFR < 30 mL/min)
- end stage renal disease
- patient on renal dialysis
- acute conditions with the potential to alter renal function such as
 - dehydration
 - severe infection
 - shock
- acute or chronic disease which may cause tissue hypoxia such as
 - cardiac or respiratory failure
 - recent myocardial infarction
 - shock
- hepatic impairment
- acute alcohol intoxication, alcoholism

WARNINGS AND PRECAUTIONS

- Dapagliflozin causes intravascular volume contraction. Dapagliflozin increases diuresis associated with a modest decrease in blood pressure, which may be more pronounced in patients with high blood glucose concentrations. Symptomatic hypotension can occur after initiating dapagliflozin particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73m²), elderly patients, or patients on loop diuretics. Before initiating dapagliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms of hypotension after initiating therapy. It is not recommended for use in patients receiving loop diuretics or who are volume depleted, e.g. due to acute illness. Caution should be exercised in patients for whom a dapagliflozin-induced drop in blood pressure could pose a risk, such as patients with known cardiovascular disease, patients on anti-hypertensive therapy with a history of hypotension or elderly patients. Careful monitoring of volume status (e.g., physical examination, blood pressure measurements, laboratory tests including hematocrit) and electrolytes is recommended for patients receiving it.
- Fatal cases of ketoacidosis have been reported in patients taking dapagliflozin. Dapagliflozin is not indicated for the treatment of patients with type 1 diabetes mellitus. Patients treated with dapagliflozin who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels as ketoacidosis associated with dapagliflozin may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, dapagliflozin should be discontinued, the patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement. Before initiating dapagliflozin, consider factors in the patient history (such as nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness) that may predispose to ketoacidosis including pancreatic insulin deficiency from any cause, caloric restriction and alcohol abuse. In patients treated with dapagliflozin consider monitoring for ketoacidosis and temporarily discontinuing dapagliflozin in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery). Treatment should be interrupted in patients who are hospitalized for major surgical procedures or acute serious medical illnesses. In both cases, treatment with dapagliflozin may be restarted once the patient's condition has stabilized.
- Lactic acidosis, a very rare but serious metabolic complication, most often occurs at acute worsening of renal function or cardiorespiratory illness or sepsis. Metformin accumulation occurs at acute worsening of renal function and increases the risk of lactic acidosis. In case of dehydration (severe diarrhea or vomiting, fever or reduced fluid intake), this combination (Dapagliflozin and Metformin HCl) should be temporarily discontinued and contact with a health care professional is recommended. Medicinal products that can acutely impair renal function (such as antihypertensives, diuretics and NSAIDs) should be initiated with caution in metformin treated patients. Other risk factors for lactic acidosis are excessive alcohol intake, hepatic insufficiency, inadequately controlled diabetes, ketosis, prolonged fasting and any conditions associated with hypoxia, as well as concomitant use of medicinal products that may cause lactic acidosis. Patients and/or care givers should be informed on the risk of lactic acidosis. Lactic acidosis is characterized by acidosis dyspnea, abdominal pain, muscle cramps, asthenia and hypothermia followed by coma. In case of suspected symptoms, the patient should stop taking this combination (Dapagliflozin and Metformin HCl) and seek immediate medical attention. Diagnostic laboratory findings are decreased blood pH (< 7.35), increased plasma lactate levels above 5 mmol/L, and an increased anion gap and lactate/pyruvate ratio.
- There have been reports of serious urinary tract infections including urethritis and pyelonephritis requiring hospitalization in patients receiving SGLT2 inhibitors, including dapagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated.
- Insulin and insulin secretagogues are known to cause hypoglycemia. Dapagliflozin can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when these agents are used in combination with dapagliflozin.
- Dapagliflozin increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections. Monitor and treat appropriately.
- Increases in LDL-C occur with dapagliflozin. Monitor LDL-C and treat per standard of care after initiating dapagliflozin.
- Dapagliflozin should not be used in patients with active bladder cancer (a causal relationship between dapagliflozin and bladder cancer is unlikely). There are insufficient data to determine whether dapagliflozin has an effect on pre-existing bladder tumors.
- Hematocrit increase was observed with dapagliflozin treatment, therefore, caution in patients with already elevated hematocrit is warranted.
- An increase in cases of lower limb amputation (primarily of the toe) has been observed, with another SGLT2 inhibitor. Like for all diabetic patients it is important to counsel patients on routine preventative foot care.
- Patients taking this medicinal product will test positive for glucose in their urine.
- Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and increased risk of lactic acidosis. It should be discontinued prior to, or at the time of, the imaging procedure and not restarted until at least 48 hours after, provided that renal function has been re-evaluated and found to be stable.
- For patients undergo schedule surgery consider temporarily discontinuation of Dapagliflozin for at least 3 days prior to surgery.
- As this medicinal product contains metformin, evaluation should include serum electrolytes and ketones, blood glucose and, if indicated, blood pH, lactate, pyruvate, and metformin levels. If acidosis of either form occurs, treatment must be stopped immediately, and other appropriate corrective measures initiated.

- Dapagliflozin or metformin have no or negligible influence on the ability to drive and use machines. Patients should be alerted to the risk of hypoglycemia when this medicinal product is used in combination with other glucose-lowering medicinal products known to cause hypoglycemia.
- Cases of metformin-associated lactic acidosis occurred in the setting of acute congestive heart failure (particularly when accompanied by hypoperfusion and hypoxemia). Cardiovascular collapse (shock), acute myocardial infarction, sepsis, and other conditions associated with hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur, discontinue the drug.
- Withholding of food and fluids during surgical or other procedures may increase the risk for volume depletion, hypotension and renal impairment. It should be temporarily discontinued while patients have restricted food and fluid intake.
- Cases of metformin-associated lactic acidosis, including fatal cases. These cases had a subtle onset and were accompanied by nonspecific symptoms such as malaise, myalgias, abdominal pain, respiratory distress, or increased somnolence; however, hyperthermia, hypotension and resistant bradyrhythms have occurred with severe acidosis. Metformin-associated lactic acidosis was characterized by elevated blood lactate concentrations (>5 mmol/L), anion gap acidosis (without evidence of ketonuria or ketonemia), and an increased lactate: pyruvate ratio; metformin plasma levels generally >5 mcg/mL. Metformin decreases liver uptake of lactate increasing lactate blood levels which may increase the risk of lactic acidosis, especially in patients at risk. If metformin-associated lactic acidosis is suspected, general supportive measures should be instituted promptly in a hospital setting, along with immediate discontinuation of this combination (Dapagliflozin and Metformin HCl). In (Dapagliflozin and Metformin HCl) treated patients with a diagnosis or strong suspicion of lactic acidosis, prompt hemodialysis is recommended to correct the acidosis and remove accumulated metformin (metformin HCl is dialyzable, with a clearance of up to 170 mL/min under good hemodynamic conditions). Hemodialysis has often resulted in reversal of symptoms and recovery. Educate patients and their families about the symptoms of lactic acidosis and if these symptoms occur instruct them to discontinue the drug.
- Necrotizing fasciitis of premium (Fournier gangrene) a rare but serious and life threatening necrotizing infection requiring urgent surgical intervention have been identified in patients with DM receiving SGLT2 inhibitors including Dapagliflozin. Cesses have been reported both males and females. Serious outcomes have included hospitalization, multiple surgeries and death.

ADVERSE REACTIONS

The reported adverse events are. lactic acidosis, hypotension, ketoacidosis, acute kidney injury, uresepsis and pyelonephritis, necrotizing fasciitis of the perineum (Fournier's Gangrene), genital mycotic infections, hypoglycemia, nausea, vomiting, diarrhea, abdominal pain, loss of appetite, rash (rash generalized, rash pruritic, rash macular, rash maculo-papular, rash pustular, rash vesicular, and rash erythematous), back pain, dysuria, polyuria (polyakiuria, polyuria, urine output increased), hematuria increased, impairment of renal functions (increases in serum creatinine, decreases in eGFR, renal failure), dyslipidemia, urinary tract infection (urinary tract infection, cystitis, escherichia urinary tract infection, genitourinary tract infection, pyelonephritis, trigonitis, urethritis, kidney infection, and prostatitis), female genital mycotic infections (vulvovaginal mycotic infection, vaginal infection, vulvovaginal candidiasis, vulvovaginitis, genital infection, genital candidiasis, fungal genital infection, vulvitis, genitourinary tract infection, vulval abscess, and vaginitis bacterial), male genital mycotic infection (balanitis, fungal genital infection, balanitis candida, genital candidiasis, genital infection male, penile infection, balanoposthitis, balanoposthitis infective, genital infection, posthitis), increases in low-density lipoprotein cholesterol (LDL-C), taste disturbance Nasopharyngitis, headache, influenza, cough, pharyngitis increased urination, discomfort with urination, and dizziness.

The additional reported adverse events are; constipation, dry mouth, nocturia, Vulvovaginal pruritus, pruritus genital, blood creatinine increased, blood urea increased, weight decreased, fungal infection, thirst, volume depletion (including dehydration, hypovolemia, orthostatic hypotension, or hypotension), breast cancer, prostate cancer, bladder cancer, osmotic diuresis (reductions in intravascular volume) and hypersensitivity reactions (e.g., angioedema, urticaria, hypersensitivity), vitamin B12 deficiency, hyperhidrosis, liver function disorder, hepatitis, urticaria, erythema, pruritus, dry mouth, thirst, weight reduce, and decrease in serum bicarbonate.

DRUG INTERACTIONS

- Monitoring glycaemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycaemic control.
- Monitoring glycaemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycaemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycaemic control.
- Dapagliflozin product may add the diuretic effect of thiazide and loop diuretics and may increase the risk of dehydration and hypotension.
- Topiramate or other carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide) or dichlorophenamide frequently causes a decrease in serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. Concomitant use of these drugs with this combination (Dapagliflozin and Metformin HCl) may increase the risk for lactic acidosis. Consider more frequent monitoring of these patients.
- Concomitant use of drugs that interfere with common renal tubular transport systems involved in the renal elimination of metformin (e.g., organic cationic transporter-2 [OCT2]/multidrug and toxin extrusion [MATE] inhibitors, such as ranolazine, vandetanib, dolutegravir, and cimetidine) could increase systemic exposure to metformin and may increase the risk for lactic acidosis. Consider the benefits and risks of concomitant use.
- Certain drugs tend to produce hyperglycemia and may lead to loss of glycaemic control. These medications include thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs, and isoniazid. When such drugs are administered to a patient receiving (Dapagliflozin and Metformin HCl), observe the patient closely for loss of blood glucose control. When such drugs are withdrawn from a patient receiving (Dapagliflozin and Metformin HCl), observe the patient closely for hypoglycemia.
- Insulin and insulin secretagogues, such as sulphonylureas, cause hypoglycemia. Therefore, a lower dose of insulin or an insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with dapagliflozin.
- Cationic substances that are eliminated by renal tubular secretion (e.g. cimetidine) may interact with metformin by competing for common renal tubular transport systems. Therefore, close monitoring of glycaemic control, dose adjustment within the recommended posology and changes in diabetic treatment should be considered when cationic medicinal products that are eliminated by renal tubular secretion are co-administered.
- Alcohol intoxication is associated with an increased risk of lactic acidosis, particularly in the case of fasting, malnutrition or hepatic impairment due to the metformin.

- Intravascular administration of iodinated contrast agents may lead to contrast induced nephropathy, resulting in metformin accumulation and increased risk of lactic acidosis.
- Glucocorticoids (given by systemic and local routes), beta-2 agonists, and diuretics have intrinsic hyperglycemic activity. The patient should be informed and more frequent blood glucose monitoring performed, especially at the beginning of treatment with such medicinal products. If necessary, the dose of the glucose- lowering medicinal product should be adjusted during therapy with the other medicinal product and on its discontinuation.
- Some medicinal products can adversely affect renal function which may increase the risk of lactic acidosis, e.g. NSAIDs, including selective cyclo-oxygenase (COX) II inhibitors, ACE inhibitors, angiotensin II receptor antagonists and diuretics, especially loop diuretics. When starting or using such products in combination with metformin, close monitoring of renal function is necessary.

USE IN SPECIFIC POPULATIONS

Pregnancy

Dapagliflozin is not recommended during the second and third trimesters of pregnancy. There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy. Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, preclampsia, spontaneous abortions, preterm delivery, still birth and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia related morbidity. A limited amount of data from the use of metformin in pregnant women does not indicate an increased risk of congenital malformations. When the patient plans to become pregnant, and during pregnancy, it is recommended that diabetes is not treated with this medicinal product, but insulin be used to maintain blood glucose levels as close to normal as possible, to reduce the risk of malformations of the fetus associated with abnormal blood glucose levels.

Lactation

It is unknown whether this medicinal product or dapagliflozin (and/or its metabolites) are excreted in human milk. There is no information regarding the presence of dapagliflozin in human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed infants, advise women that use of dapagliflozin is not recommended while breastfeeding. Metformin is excreted in human milk in small amounts. A risk to the newborns / infants cannot be excluded. It should not be used while breast feeding.

Pediatric Use

Safety and effectiveness of (Dapagliflozin and Metformin HCl) in pediatric patients under 18 years of age have not been established.

Geriatric Use

Elderly (> 65 years)

Because metformin is eliminated in part by the kidney, and because elderly patients are more likely to have decreased renal function, this medicinal product should be used with caution as age increases. Elderly patients are more likely to have impaired renal function, and/or to be treated with anti-hypertensive medicinal products that may cause changes in renal function such as angiotensin-converting enzyme inhibitors (ACE-I) and angiotensin II type 1 receptor blockers (ARB). Monitoring of renal function is necessary to aid in prevention of metformin-associated lactic acidosis, particularly in elderly patients. Risk of volume depletion with dapagliflozin should also be taken into account. Due to the limited therapeutic experience with dapagliflozin in patients 75 years and older, initiation of therapy in this population is not recommended.

Renal Impairment

Metformin-associated lactic acidosis cases primarily occurred in patients with significant renal impairment. The risk of metformin accumulation and metformin-associated lactic acidosis increases with the severity of renal impairment because metformin is substantially excreted by the kidney. Clinical recommendations based upon the patient's renal function include;

- Before initiating the drug, obtain an estimated glomerular filtration rate (eGFR).
- It is contraindicated in patients with an eGFR less than 30 mL/min/1.73m²
- Obtain an eGFR at least annually in all patients taking this combination (Dapagliflozin and Metformin HCl). In patients at increased risk for the development of renal impairment (e.g., the elderly), renal function should be assessed more frequently.
- Use of Dapagliflozin is not recommended when eGFR is less than 45 mL/min/1.73m² and is contraindicated in patients with severe renal impairment (eGFR less than 30 mL/min/1.73m²) or ESRD.

Metformin is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment. It is contraindicated in severe renal impairment, patients with an estimated glomerular filtration rate (eGFR) below 30 mL/min/1.73m².

Hepatic Impairment

Patients with hepatic impairment have developed with cases of metformin associated lactic acidosis. This may be due to impaired lactate clearance resulting in higher lactate blood levels. Therefore, avoid use of this combination (Dapagliflozin and Metformin HCl) in patients with clinical or laboratory evidence of hepatic disease.

OVERDOSAGE

In the event of an overdose, employ reasonable supportive measures, as dictated by the patient's clinical status. The removal of dapagliflozin by hemodialysis has not been studied. High overdose or concomitant risks of metformin may lead to lactic acidosis. Lactic acidosis is a medical emergency and must be treated in hospital.

DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION

Daplozmet 5/850mg Tablets: Alu. Alu. Blister Pack of 2 x 7's.

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ڈیپلوزمیٹ®

(ڈیپاگلیفلوزن + میٹ فارمین ہائیڈروکلورائیڈ)

خوراک و ہدایات:

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