

**COMPOSITION:****XIGA-Met XR 5/500 Tablet:**

Each film coated tablet contains:

Dapagliflozin Propanediol monohydrate equivalent to
Dapagliflozin 5 mg.
Metformin HCl (as extended release) 500 mg.

Product Specs.: Innovator**XIGA-Met XR 10/500 Tablet:**

Each film coated tablet contains:

Dapagliflozin Propanediol monohydrate equivalent to
Dapagliflozin 10 mg.
Metformin HCl (as extended release) 500 mg.

Product Specs.: Innovator**XIGA-Met XR 5/1000 Tablet:**

Each film coated tablet contains:

Dapagliflozin Propanediol monohydrate equivalent to
Dapagliflozin 5 mg.
Metformin HCl (as extended release) 1000 mg.

Product Specs.: Innovator**XIGA-Met XR 10/1000 Tablet:**

Each film coated tablet contains:

Dapagliflozin Propanediol monohydrate equivalent to
Dapagliflozin 10 mg.
Metformin HCl (as extended release) 1000 mg.

Product Specs.: Innovator**DESCRIPTION:**

XIGA-Met XR (dapagliflozin and metformin HCl extended-release) tablets contain two oral anti-hyperglycemic medications used in the management of type 2 diabetes: Dapagliflozin and Metformin hydrochloride.

Dapagliflozin:

Dapagliflozin is described chemically as D-glucitol, 1,5-anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-, (1S)-, compounded with (2S)-1,2-propanediol, hydrate (1.1:1). The empirical formula is C₂₁H₂₅ClO₆•C₃H₈O₂•H₂O and the formula weight is 502.98.

Metformin hydrochloride:

Metformin hydrochloride (N,N-dimethylimidodicarbonimidic diamide hydrochloride) is a white to off-white crystalline compound with a molecular formula of C₄H₁₁N₅•HCl and a molecular weight of 165.63. Metformin hydrochloride is freely soluble in water, slightly soluble in alcohol, and is practically insoluble in acetone, ether, and chloroform. The pKa of metformin is 12.4. The pH of a 1% aqueous solution of metformin hydrochloride is 6.68.

CLINICAL PHARMACOLOGY:**Mechanism of Action:**

XIGA-Met XR combines two anti-hyperglycaemic medicinal products with different and complementary mechanisms of action to improve glycaemic control in patients with type 2 diabetes:

Dapagliflozin, a SGLT2 inhibitor, and metformin hydrochloride, a member of the biguanide class. Sodium-glucose cotransporter 2 (SGLT2), expressed in the proximal renal tubules, is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. Dapagliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, dapagliflozin reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Metformin hydrochloride improves glucose tolerance in patients with type 2 diabetes, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Metformin does not produce hypoglycemia in either patients with type 2 diabetes or in healthy subjects, except in unusual circumstances, and does not cause hyperinsulinemia. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and day-long plasma insulin response may actually decrease.

Pharmacodynamics:**Dapagliflozin:**

Dapagliflozin Increases in the amount of glucose excreted in the urine were observed in healthy subjects and in subjects with type 2 diabetes mellitus following the administration of dapagliflozin. The pharmacodynamics of 5 mg dapagliflozin twice daily and 10 mg dapagliflozin once daily were compared in healthy subjects. The steady-state inhibition of renal glucose reabsorption and the amount of urinary glucose excretion over a 24-hour period was the same for both dosing regimens. In clinical studies, use of metformin was associated with either a stable body weight or modest weight loss. Clinical efficacy and safety The co-administration of dapagliflozin and metformin has been studied in subjects, with type 2 diabetes, inadequately controlled on diet and exercise alone, and in subjects inadequately controlled on metformin alone or in combination with a DPP-4 inhibitor (sitagliptin), sulphonylurea or insulin.

Pharmacokinetics:

XIGA-Met XR combination tablets are considered to be bioequivalent to co-administration of corresponding doses of dapagliflozin and metformin hydrochloride extended release (GLUCOPHAGE® XR) administered together as individual tablets. The administration of XIGA-Met XR in healthy subjects after a standard meal compared to the fasted state resulted in the same extent of exposure for both dapagliflozin and metformin extended-release. Compared to the fasted state, the standard meal resulted in 35% reduction and a delay of 1 to 2 hours in the peak plasma concentrations of dapagliflozin. This effect of food is not considered to be clinically meaningful. Food has no relevant effect on the pharmacokinetics of metformin when administered as XIGDUO XR combination tablets.

Absorption: Dapagliflozin Following oral administration of dapagliflozin, the maximum plasma concentration (C_{max}) is usually attained within 2 hours under fasting state. The C_{max} and AUC values increase dose proportionally with increase in dapagliflozin dose in the therapeutic dose range. The absolute oral bioavailability of dapagliflozin following the administration of a 10 mg dose is 78%. Administration of dapagliflozin with a high-fat meal decreases its C_{max} by up to 50% and prolongs T_{max} by approximately 1 hour, but does not alter AUC as compared with the fasted state. These changes are not considered to be clinically meaningful and dapagliflozin can be administered with or without food. Metformin hydrochloride Following a single oral dose of metformin extended-release, C_{max} is achieved with a median value of 7 hours and a range of 4 to 8 hours. The extent of metformin absorption (as measured by AUC) from the metformin extended-release tablet increased by approximately 50% when given with food. There was no effect of food on C_{max} and T_{max} of metformin.

Distribution: Dapagliflozin is approximately 91% protein bound. Protein binding is not altered in patients with renal or hepatic impairment.

Metformin hydrochloride:

Distribution studies with extended-release metformin have not been conducted; however, the apparent volume of distribution (V/F) of metformin following single oral doses of immediate release metformin 850 mg averaged 654 ± 358 L. Metformin is negligibly bound to plasma proteins, in contrast to sulfonylureas, which are more than 90% protein bound. Metformin partitions into erythrocytes.

Metabolism: Dapagliflozin The metabolism of dapagliflozin is primarily mediated by UGT1A9; CYP-mediated metabolism is a minor clearance pathway in humans. Dapagliflozin is extensively metabolized, primarily to yield dapagliflozin 3-O-glucuronide, which is an inactive metabolite. Dapagliflozin 3-O-glucuronide accounted for 61% of a 50 mg [14C]-dapagliflozin dose and is the predominant drug-related component in human plasma. Metformin hydrochloride Intravenous single-dose studies in healthy subjects demonstrate that metformin is excreted unchanged in the urine and does not undergo hepatic metabolism (no metabolites have been identified in humans) or biliary excretion. Metabolism studies with extended-release metformin tablets have not been conducted.

Elimination: Dapagliflozin and related metabolites are primarily eliminated via the renal pathway. Following a single 50 mg dose of [14C]-dapagliflozin, 75% and 21% total radioactivity is excreted in urine and feces, respectively. In urine, less than 2% of the dose is excreted as parent drug. In feces, approximately 15% of the dose is excreted as parent drug. The mean plasma terminal half-life (t_{1/2}) for dapagliflozin is approximately 12.9 hours following a single oral dose of dapagliflozin 10 mg. Metformin hydrochloride renal clearance is approximately 3.5 times greater than creatinine clearance, which indicates that tubular secretion is the major route of metformin elimination.

Following oral administration, approximately 90% of the absorbed drug is eliminated via the renal route within the first 24 hours, with a plasma elimination half-life of approximately 6.2 hours. In blood, the elimination half-life is approximately 17.6 hours, suggesting that the erythrocyte mass may be a compartment of distribution.

SPECIAL POPULATIONS:

Renal impairment: XIGA-Met XR Use of metformin in patients with renal impairment increases the risk for lactic acidosis. Because XIGA-Met XR contains metformin, it is contraindicated in patients with moderate to severe renal impairment No dose adjustment is required in patients with mild renal impairment.

Hepatic impairment: Use of metformin in patients with hepatic impairment has been associated with some cases of lactic acidosis. Because XIGA-Met XR contains metformin, it should generally be avoided in patients with hepatic impairment.

Elderly (≥ 65 years): There is no clinically meaningful increase in exposure based on age alone in subjects up to 70 years old. However, an increased exposure due to age-related decrease in renal function can be expected. There are insufficient data to draw conclusions regarding exposure in patients > 70 years old.

Gender: Based on a population pharmacokinetic analysis, gender does not have a clinically meaningful effect on systemic exposures of dapagliflozin; thus, no dose adjustment is recommended. Metformin hydrochloride Metformin pharmacokinetic parameters did not differ significantly between healthy subjects and patients with type 2 diabetes when analyzed according to gender.

Race: There were no clinically relevant differences in systemic exposures between White, Black or Asian races.

Body weight: Dapagliflozin exposure was found to decrease with increased weight. Consequently, low-weight patients may have somewhat increased exposure and patients with high weight somewhat decreased exposure. However, the differences in exposure were not considered clinically meaningful.

Pediatric population: Pharmacokinetics in the pediatric population have not been studied.

Body Weight: Dapagliflozin based on a population pharmacokinetic analysis, body weight does not have a clinically meaningful effect on systemic exposures of dapagliflozin; thus, no dose adjustment is recommended.

THERAPEUTIC INDICATIONS:

XIGA-Met XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate.

XIGA-Met XR is not recommended for patients with type 1 diabetes mellitus or diabetic ketoacidosis.

DOSAGE & ADMINISTRATION:

Recommended Dosing: Healthcare providers should individualize the starting dose based on the patient's current treatment.

XIGA-Met XR should be taken once daily in the morning with food with gradual dose escalation to reduce the gastrointestinal (GI) side effects due to metformin. recommended dose is one tablet twice daily. Each tablet contains a fixed dose of dapagliflozin and metformin. XIGA-Met XR tablets must be swallowed whole and never crushed, cut, or chewed. Occasionally, the inactive ingredients of XIGA-Met XR will be eliminated in the feces as a soft, hydrated mass that may resemble the original tablet. 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 XR should skip their last dose before starting XIGA-Met XR. In patients with volume depletion, correcting this condition prior to initiation is recommended.

SPECIAL POPULATIONS:**Renal impairment:**

No dosage adjustment is indicated in patients with mild renal impairment (eGFR of 60 mL/min/1.73 m2 or greater). Assessment of renal function is recommended prior to initiation of XIGDUO XR therapy and periodically thereafter. XIGA-Met XR should not be used in patients with moderate to severe renal impairment.

CONTRAINDICATIONS:

XIGA-Met XR is contraindicated in patients with:

- Moderate to severe renal impairment (e.g., serum creatinine levels ≥1.5 mg/dL for men, ≥1.4 mg/dL for women, or eGFR > 60 mL/min/1.73 m2 or CrCl <60ml/min which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia.
- History of a serious hypersensitivity reaction to dapagliflozin or hypersensitivity to metformin hydrochloride.
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma. Diabetic ketoacidosis should be treated with insulin.

SPECIAL WARNING & PRECAUTIONS:

for use Lactic acidosis: Lactic acidosis is a rare, but serious, metabolic complication that can occur due to metformin accumulation during treatment with XIGA-Met XR; when it occurs, it is fatal in approximately 50% of cases. Lactic acidosis may also occur in association with a number of pathophysiologic conditions, including diabetes mellitus, and whenever there is significant tissue hypoperfusion and hypoxemia. Lactic acidosis is characterized by elevated blood lactate levels (>5 mmol/L), decreased blood pH, electrolyte disturbances with an increased anion gap, and an increased lactate/pyruvate ratio. When metformin is implicated as the cause of lactic acidosis, metformin plasma levels >5µg/mL are generally found. The reported incidence of lactic acidosis in patients receiving metformin hydrochloride is very low (approximately 0.03 cases/1000 patient-years, with approximately 0.015 fatal cases/1000 patient-years). Lactic acidosis should be suspected in any diabetic patient with metabolic acidosis lacking evidence of ketoacidosis (ketonuria and ketonemia). Lactic acidosis is a medical emergency that must be treated in a hospital setting. In a patient with

lactic acidosis who is taking metformin, the drug should be discontinued immediately and general supportive measures promptly instituted. Because metformin hydrochloride is dialyzable (with a clearance of up to 170 mL/min under good hemodynamic conditions), prompt hemodialysis is recommended to correct the acidosis and remove the accumulated metformin.

Hypoxic States: Cardiovascular collapse (shock), acute congestive heart failure, acute myocardial infarction, and other conditions characterized by hypoxemia have been associated with lactic acidosis and may also cause prerenal azotemia. When such events occur in patients the drug should be promptly discontinued.

Use in patient with Renal impairment: Metformin is known to be substantially excreted by the kidney and the risk of metformin accumulation and lactic acidosis increases with the degree of impairment of renal function. Therefore, XIGA-Met XR is contraindicated in patients with moderate to severe renal impairment. Also, dapagliflozin increases serum creatinine and decreases eGFR. Elderly patients and patients with impaired renal function may be more susceptible to these changes. Adverse reactions related to renal function can occur after initiating Before initiation of therapy, and at least annually thereafter, renal function should be assessed and verified as normal or mildly impaired. In patients in whom development of renal impairment is anticipated (e.g., elderly), renal function should be assessed more frequently and discontinued if evidence of moderate to severe renal impairment is present.

Hypotension & Volume Depletion: Dapagliflozin causes intravascular volume contraction. Symptomatic hypotension can occur after initiating dapagliflozin [see Adverse Reactions (6.1)], particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics. For patients receiving this medicinal product, in case of intercurrent conditions that may lead to volume depletion, careful monitoring of volume status (e.g. physical examination, blood pressure measurements, laboratory tests including haematocrit) and electrolytes is recommended. Temporary interruption of treatment with this medicinal product is recommended for patients who develop volume depletion until the depletion is corrected.

Impaired hepatic function: Metformin use in patients with impaired hepatic function has been associated with some cases of lactic acidosis.

Therefore, XIGA-Met XR should generally be avoided in patients with hepatic impairment.

SURGICAL PROCEDURES:

Use of XIGA-Met XR should be temporarily suspended for any surgical procedure (except minor procedures not associated with restricted intake of food and fluids) and should not be restarted until the patient's oral intake has resumed and renal function has been evaluated as normal or mildly impaired.

Change in Clinical Status of Patients with Previously Controlled Type 2 Diabetes:

A patient with type 2 diabetes, previously well controlled on XIGA-Met XR, who develops laboratory abnormalities or clinical illness (especially vague and poorly defined illness) should be evaluated promptly for evidence of ketoacidosis or lactic acidosis. 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, it must be stopped immediately and other appropriate corrective measures initiated.

Use with Medications Known to Cause Hypoglycemia:

Dapagliflozin 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 XIGA-Met XR.

Metformin hydrochloride:

Hypoglycemia does not occur in patients receiving metformin alone under usual circumstances of use, but could occur when caloric intake is deficient, when strenuous exercise is not compensated by caloric supplementation, or during concomitant use with other glucose-lowering agents (such as sulfonylureas and insulin) or ethanol. Elderly, debilitated, or malnourished patients, and those with adrenal or pituitary insufficiency or alcohol intoxication are particularly susceptible to hypoglycemic effects. Hypoglycemia may be difficult to recognize in the elderly and in people who are taking beta-adrenergic blocking drugs.

Concomitant Medications Affecting Renal Function or Metformin Disposition Concomitant medication(s):

may affect renal function or result in significant hemodynamic change or may interfere with the disposition of metformin, such as cationic drugs that are eliminated by renal tubular secretion should be used with caution.

Radiologic Studies with Intravascular Iodinated Contrast Materials:

Intravascular contrast studies with iodinated materials can lead to acute alteration of renal function and have been associated with lactic acidosis in patients receiving metformin. Therefore, in patients in whom any such study is planned, XIGA-Met XR should be temporarily discontinued at the time of or prior to the procedure, and withheld for 48 hours subsequent to the procedure and reinstated only after renal function has been re-evaluated and found to be normal or mildly impaired.

Vitamin B₁₂ Concentrations:

In controlled clinical trials of metformin of 29-week duration, a decrease to subnormal levels of previously normal serum vitamin B₁₂ levels, without clinical manifestations, was observed in approximately 7% of patients. This decrease, possibly due to interference with B₁₂ absorption from the B₁₂-intrinsic factor complex is, however, very rarely associated with anemia and appears to be rapidly reversible with discontinuation of metformin or vitamin B₁₂ supplementation. Measurement of hematologic parameters on an annual basis is advised in patients on XIGA-Met XR and any apparent abnormalities should be appropriately investigated and managed. Certain individuals (those with inadequate vitamin B₁₂ or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B₁₂ levels. In these patients, routine serum vitamin B₁₂ measurements at 2- to 3-year intervals may be useful.

Genital Mycotic Infections:

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 appropriate.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C):

Increases in LDL-C occur with dapagliflozin. Monitor LDL-C and treat per standard of care after initiating XIGA-Met XR.

Bladder Cancer:

There are insufficient data to determine whether dapagliflozin has an effect on pre-existing bladder tumors. Consequently, XIGA-Met XR should not be used in patients with active bladder cancer. In patients with prior history of bladder cancer, the benefits of glyemic control versus unknown risks for cancer recurrence with XIGA-Met XR should be considered.

Macrovascular Outcomes:

There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with XIGA-Met XR or any other antidiabetic drug.

DRUG INTERACTIONS:**Positive Urine Glucose Test:****Dapagliflozin:**

Monitoring glyemic 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 glyemic control.

Interference with 1,5-anhydroglucitol (1,5-AG) Assay:**Dapagliflozin:**

Monitoring glyemic control with 1,5-AG assay is not recommended as measurements of 1,5- AG are unreliable in assessing glyemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glyemic control.

CATIONIC DRUGS:**Metformin hydrochloride:**

Cationic drugs (e.g., amiloride, cimetidine, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems.

A 40% increase in exposure (AUC) of metformin when co administered with cimetidine was observed in normal healthy volunteers. Although such interactions remain theoretical (except for cimetidine), careful patient monitoring and dose adjustment of XIGA-Met XR and/or the interfering drug is recommended in patients who are taking cationic medications that are excreted via the proximal renal tubular secretory system.

USE WITH OTHER DRUGS:**Metformin hydrochloride:**

Some medications can predispose to hyperglycemia and may lead to loss of glyemic control. These medications include the 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 XIGA-Met XR, the patient should be observed closely for loss of glyemic control. When such drugs are withdrawn, the patient should be observed closely for hypoglycemia.

SPECIAL POPULATION:

Pregnancy: There are no data from the use of metformin in pregnant women. A limited amount of data from the use of metformin in pregnant women does not indicate an increased risk of congenital malformations.

Nursing Mothers: Metformin is excreted in human milk in small amounts. A risk to the newborns/infants cannot be excluded. This medicinal product should not be used while breast-feeding.

Pediatric Use: Safety and effectiveness of XIGA-Met XR in pediatric patients under 18 years of age have not been established.

Geriatric Use: No dosage change is recommended based on age.

Patients with Mild Renal Impairment T (eGFR >60- <90ml/min/1.732): The safety profile in patients with mild renal impairment is similar to that in the overall population.

ADVERSE REACTIONS:

Because clinical studies are conducted under widely varying conditions, adverse reaction 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 clinical practice.

Vulvovaginitis, balanitis and related genital infections:

Includes, the vulvovaginal mycotic infection, vaginal infection, balanitis, genital infection fungal, vulvovaginal candidiasis, vulvovaginitis, balanitis candida, genital candidiasis, genital infection, genital infection male, penile infection, vulvitis, vaginitis bacterial, vulval abscess.

Urinary tract infection:

Includes the urinary tract infection, cystitis, Escherichia urinary tract infection, genitourinary tract infection, pyelonephritis, trigonitis, urethritis, kidney infection and prostatitis.

Volume depletion: Includes dehydration, hypovolaemia, hypotension.

Polyuria:

Includes pollakiuria, polyuria, urine output increased.

B₁₂ Deficiency:

Long-term treatment with metformin has been associated with a decrease in vitamin B₁₂ absorption which may very rarely result in clinically significant vitamin B₁₂ deficiency (e.g. megaloblastic anaemia).

Gastrointestinal symptoms:

Such as nausea, vomiting, diarrhoea, abdominal pain and loss of appetite occur most frequently during initiation of therapy and resolve spontaneously in most cases.

Hypersensitivity:

Adverse reaction was identified through post-marketing surveillance with the use of dapagliflozin include rash generalised, rash pruritic, rash macular, rash maculo-papular, rash pustular, rash vesicular, and rash erythematous.

Increased creatinine:

Adverse reactions related to increased creatinine were grouped (e.g. include decreased renal creatinine clearance, renal impairment, increased blood creatinine and decreased glomerular filtration rate). Further evaluation of patients who had renal-related adverse events showed that most had serum creatinine changes of ≤ 0.5 mg/dL from baseline. The increases in creatinine were generally transient during continuous treatment or reversible after discontinuation of treatment.

Parathyroid hormone (PTH):

Small increases in serum PTH levels were observed with increases being larger in subjects with higher baseline PTH concentrations.

Bone mineral density measurements in patients with normal or mildly impaired renal function did not indicate bone loss over a treatment period of two years. Bladder Cancer, Increases in Low-Density Lipoprotein Cholesterol (LDL-C), are also the adverse events.

OVERDOSAGE:

There were no reports of overdose during the clinical development program for dapagliflozin. The removal of dapagliflozin by hemodialysis has not been studied. Overdose of metformin hydrochloride has occurred, including ingestion of amounts >50 grams. Hypoglycemia was reported in approximately 10% of cases, but no causal association with metformin hydrochloride has been established. Lactic acidosis has been reported in approximately 32% of metformin overdose cases. Metformin is dialyzable with a clearance of up to 170 mL/min under good hemodynamic conditions. Therefore, hemodialysis may be useful for removal of accumulated drug from patients in whom metformin overdose is suspected.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

XIGA-Met XR 5/500 Tablet	:	Pack of 2 x 7 tablets.
XIGA-Met XR 10/500 Tablet	:	Pack of 2 x 7 tablets.
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ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔

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