ARNOZA D

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for Arnoza D [Dapagliflozin and Sacubitril/Valsartan Tablets (5mg + 50mg/5mg+ 100mg/5mg+ 200mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES

MECHANISM OF ACTION: *Dapagliflozin*: Dapagliflozin is a highly potent selective and reversible inhibitor of SGLT2. Inhibition of SGLT2 by dapagliflozin reduces reabsorption of glucose from the glomerular filtrate in the proximal renal tubule with a concomitant reduction in sodium reabsorption leading to urinary excretion of glucose and osmotic diuresis. ***Sacubitril/Valsartan***: Sacubitril and Valsartan contains a neprilysin inhibitor, sacubitril, and an angiotensin receptor blocker, valsartan. The cardiovascular and renal effects of Sacubitril and Valsartan in heart failure patients are attributed to the increased levels of peptides that are degraded by neprilysin, such as natriuretic peptides, by LBQ657, and the simultaneous inhibition of the effects of angiotensin II by valsartan. Valsartan inhibits the effects of angiotensin II by selectively blocking the AT1 receptor, and also inhibits angiotensin II-dependent aldosterone release.

INDICATIONS: It is indicated in patients with heart failure with reduced ejection fraction.

DOSAGE AND ADMINISTRATION: The recommended dose is one tablet twice a day. Each film coated tablet contains a fixed dose of Dapagliflozin and Sacubitril Valsartan. It should be given orally one tablet twice a day with or without meal.

CONTRAINDICATION: It is contraindicated in patients with hypersensitivity to any component of Dapagliflozin, Sacubitril and Valsartan. In patients with a history of angioedema related to previous ACE inhibitor or ARB therapy. With concomitant use of ACE inhibitors. Do not administer within 36 hours of switching from or to an ACE inhibitor. With concomitant use of aliskiren in patients with diabetes. History of a serious hypersensitivity reaction to Dapagliflozin, such as anaphylactic reactions or angioedema. Patients who are being treated for glycemic control without established CVD or multiple CV risk factors with severe renal impairment. It is also contraindicated in patients on dialysis.

WARNINGS & PRECAUTIONS: *Dapagliflozin:* Before initiating, assess volume status and renal function in the elderly, patients with renal impairment or low systolic blood pressure, and in patients on diuretics. Concomitant use of an SGLT2 inhibitor with lithium may decrease serum lithium concentrations. The risk of hypoglycemia may be increased when dapagliflozin is used concomitantly with insulin or insulin secretagogues. Assess patients who present with signs and symptoms of metabolic acidosis for ketoacidosis regardless of blood glucose level. If suspected, discontinue medication. Evaluate for signs and symptoms of urinary tract infections and treat promptly. Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with drug. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. Monitor for Genital Mycotic Infections. Elderly patients may be at a greater risk for volume depletion and are more likely to be treated with diuretics. ***Sacubitril/Valsartan***: Sacubitril and Valsartan can cause fetal harm when administered to a pregnant woman. When pregnancy is detected, consider alternative drug treatment, and discontinue Sacubitril and Valsartan. Sacubitril and Valsartan may cause angioedema. Sacubitril and Valsartan lowers blood pressure and may cause symptomatic hypotension. Through its actions on the RAAS, hyperkalemia may occur with Sacubitril and Valsartan. In patients whose renal function depends upon the activity of the renin-angiotensin-aldosterone system (e.g., patients with severe congestive heart failure), treatment with ACE inhibitors and angiotensin receptor antagonists has been associated with oliguria, progressive azotemia and, rarely, acute renal failure and death. As a consequence of inhibiting the renin-angiotensin-aldosterone system (RAAS), decreases in renal function may be anticipated in susceptible individuals treated with Sacubitril and Valsartan**.**

DRUG INTERACTIONS: *Dapagliflozin:* Topiramate or other carbonic anhydrase inhibitors (e.g., zonisamide, acetazolamide or dichlorphenamide) frequently causes a decrease in serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. 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. Warn patients against excessive alcohol intake while receiving Dapagliflozin and Metformin Hydrochloride Extended-Release Tablet. ***Sacubitril/Valsartan***:

Concomitant use of Sacubitril and Valsartan with an ACE inhibitor is contraindicated because of the increased risk of angioedema. Avoid use of Sacubitril and Valsartan with an ARB, because Sacubitril and Valsartan contains the angiotensin II receptor blocker valsartan. The concomitant use of Sacubitril and Valsartan with aliskiren is contraindicated in patients with diabetes. concomitant use of potassium-sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium. In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, concomitant use of NSAIDs, including COX-2 inhibitors, with Sacubitril and Valsartan may result in worsening of renal function, including possible acute renal failure. Increases in serum lithium concentrations and lithium toxicity have been reported during concomitant administration of lithium with angiotensin II receptor antagonists.

ADVERSE REACTIONS: Hypoglycaemia, vulvovaginitis, balanitis, related genital infections, urinary tract infection, fungal infection, volume depletion, necrotising fasciitis of the perineum (fournier's gangrene), diabetic ketoacidosis (when used in type 2 diabetes mellitus), rash, dysuria polyuria, thirst, vulvovaginal pruritus, pruritus genital, haematocrit, increased creatinine, renal clearance decreased during initial treatment, dyslipidaemia, constipation, dry mouth, nocturia, blood creatinine increased during initial treatment, blood urea increased, weight decreased, angioedema, tubulointerstitial nephritis, serum creatinine increased, orthostasis, renal failure, cough, hypotension, hyperkalaemia, cough, dizziness, abdominal or stomach pain, blurred vision, confusion, difficult breathing, faintness, or lightheadedness when getting up suddenly from a lying or sitting position, irregular heartbeat, nausea or vomiting, nervousness, numbness or tingling in the hands, feet, or lips, sweating, unusual tiredness or weakness, heaviness of the legs, bloody urine, decreased frequency or amount of urine, loss of appetite, lower back or side pain, swelling of the face, fingers, or lower legs, weight gain and large hive-like swelling on the face, eyelids, lips, tongue, throat, hands, legs, feet, or sex organs.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

IN/ARNOZA D 5mg + 50mg/5mg+ 100mg/5mg+ 200mg/JAN-2026/01/ABPI

(Additional information is available on request)