MOUNJARO

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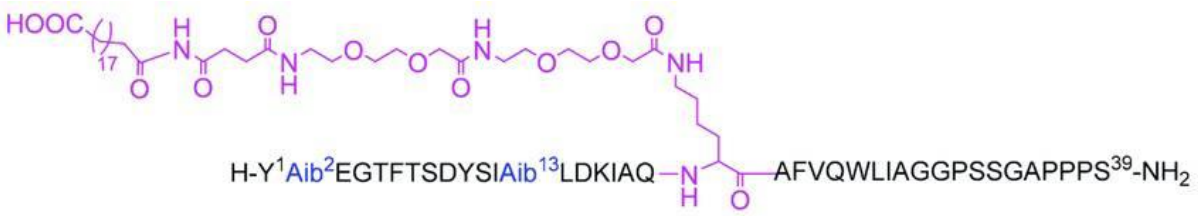
MOUNJARO™ is a diabetes drug used with diet and exercise to manage adults those type 2 diabetes with unsatisfactorily controlled. Patients who can't take metformin, another diabetes drug, can utilise Mounjaro alone. It can be added to other diabetes medications as a "add-on." Tirzepatide is the active ingredient of Mounjaro.is an stimulator of the glucagon-like peptide-1 (GLP-1) receptor and a glucose-dependent insulinotropic polypeptide (GIP) receptor.

DESCRIPTION MOUNJARO (Tirzepatide, a once-weekly GIP receptor and GLP-1 receptor stimulator, is a subcutaneous drug.IIt is a peptide that has been changed by 39 amino acids using the GIP sequence. A C-terminal amide bonding, two non-coded amino acids (aminoisobutyric acid, Aib) at positions 2 and 13, and a Lys residue at position 20 that is connected to 1,20-eicosanedioic acid by a linker are all present in tierzepatide. The empirical formula is C225H348N48O68, and the molecular weight is 4813.53 Da. Formulation for :arrangement.



MOUNJARO is a sterilised without colour to slightly yellow, transparent, and preservative-free subcutaneous fluid. A 0.5 mL solution of tirzepatide at doses of 2.5, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg is included in each singledose pen, along with the following list of ingredients: Water for an injection, a solution containing sodium phosphate dibasic heptahydrate (0.7 mg), and the chemical sodium chloride (4.1 mg) are added. It's possible that solutions of sodium hydroxide or hydrochloric acid were added to alter the pH. .MOUNJARO's pH ranges from 6.5 to 7.5.

Mechanism of Action Tirzepatide is an agonist of both GLP-1 and GIP receptors. It is an altered 39-amino acid peptides that has a C20 fatty diacid component that increases half-life and allows albumin engagement. The primary targets for natural GIP and GLP-1, the GIP and GLP-1 receptors in the body are specifically bound to and activated by tirzepatide. In a glucose-dependent way, tirzepatide reduce glucagon levels and elevate the release of insulin throughout the .first and second phases.

Pharmacodynamics Tirzepatide Tirzepatide decreases consumption of food, fat mass, and the amount of glucose that is present in the blood after meals and while fasting in people with type 2 diabetes. Phases One and Two of Insulin Secretion.

Pharmacokinetics

The pharmacokinetics of tirzepatide The tirzepatide dynamics are the same in healthy people and patients with type 2 diabetes mellitus. Steadystate levels in the blood were reached after four weeks of weekly tirzepatide treatment. Tirazepatide absorption increases in a dose-.proportionate manner.

Absorption Tirzepatide takes 8 to 72 hours to reach its maximal concentration in the blood after underneath the skin medication. After subcutaneous delivery, tirzepatide has an 80% mean complete absorption. Tirzepatide used subcutaneously in the abdomen, thigh, or upper arm .produced a almost the same response.

Distribution After tirzepatide is used subcutaneously to person with type 2 diabetes, the mean apparent steady-state volume of distribution is roughly 10.3 L. Tirzepatide has a 99% binding .strength to plasma albumin.

Elimination Tirzepatide has a metabolic half-life of roughly five days with an estimated .community means removal of 0.061 L/h, making once-weekly dosing possible.

Metabolism Tirzepatide is fractured down by amide hydrolysis, beta-oxidation of the C20 fatty acid component, and proteolytic breakdown of the peptide core. Removal the Urine and stools are the basic style that tirzepatide compounds are removal from the body. There is not proof of intact .tirzepatide in faeces or urine.

INDICATIONS AND USAGE MOUNJARO™

is recommended for persons with type 2 diabetes as a supplement to eating habits and physical activity to enhance glycemic management. Restrictions on Use.

•has never been investigated in individuals with a prior pancreatitis diagnosis.

. • is not recommended for usage in those suffering from type 1 diabetes.

DOSAGE AND ADMINISTRATION

Dosage

• beginning dose suggestions for MOUNJARO include (2.5) mg administered via subcutaneous injection once a week. The 2.5 mg dosage is not meant for diabetic .management; rather, it is for the start of the therapy.

• raise the amount taken to 5 mg once a week, underneath the skin injected, following 4 .weeks.

•Following a minimum of 4 weeks on the present amount, if further control of blood sugar is .required, raise the amount being taken in amounts of 2.5 mg.

.•The highest MOUNJARO dosage is one weekly injection of 15 mg under the skin.

• In the event that a dose is missed, advise patients to take MOUNJARO as soon as possible, no more than 4 days (96 hours). Give the following dose on the usual scheduled day and skip the missed one if more than four days had elapsed. Person are able to continue their .normal once-weekly dose regimen in each scenario.

• If essential, the weekly injection day may be adjusted as long as there is a minimum of three days (72 hours) separating the two doses.

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Important Administration Instructions

.•Give MOUNJARO once a week, regardless of food, at any point of day.

.•Under the skin administer MOUNJARO into your upper arm, thigh, or abdomen.

.•Change injectable locations after every dosage.

•Prior to using MOUNJARO, examine it. It ought to look transparent, colourless, or just a .little yellow. If there is visible coloration or particle issue, avoid using MOUNJARO.

•Give MOUNJARO and insulin in distinct injections; do not combine the two. Insulin and MOUNJARO shots can be given in the identical body area, however they shouldn't be .administered next to one another.

CONTRAINDICATIONS

MOUNJARO is contraindicated in patients with:

- Proven extreme sensitivity to tirzepatide or one of the additives in MOUNJARO.

a personal or family history of medullary thyroid cancer (MTC) or in individuals with Many Endocrine Neoplasia syndrome type 2 (MEN 2).

What are the possible side effects of MOUNJARO?

MOUNJARO may cause serious side effects, involving:

• pancreatitis, or disease of the pancreas. If you get intense pain in the abdomen that won't go away, regardless of whether you have vomiting, discontinue using MOUNJARO and give .your doctor a call straight once. Your back might hurt in addition to your stomach.

• low glucose levels, or hypoglycemia. If you combine MOUNJARO with another drug that can depressed your glucose levels, like insulin or a sulfonylurea, your chance of developing low sugar levels may elevated. Low glucose levels manifestations and indicators might involve the following: feeling dizzy or dizziness Vision problems, nervousness, agitation, or alterations in mood ○ perspiring speech impediment, starvation, disorientation or sleepiness, tremors, weaknesses headache Quick heartbeat ○ feeling nervousness.

• severe allergic responses. If you experience one or more of the following signs of a severe allergic reaction, discontinue using MOUNJARO and seek evaluated by a doctor straight away: ○ facial, lip, tongue, or throat swelling ○ difficulty breathing or swallowing ○ severe rash or itching ○ vertigo or dizziness ○ extremely fast heartbeat.

• renal issues, including renal failure. Diarrhoea, nausea, and vomiting may result in dehydration, which can exacerbate renal issues in those who already have them. It is critical .that you drink water to reduce the likelihood of become dehydrated.

• serious digestive issues. Instances of serious stomach issues are being documented in MOUNJARO users. If that you possess persistent or extreme stomach issues, let the doctor .or nurse know.

• alterations in visual. In the event that your vision alters while receiving MOUNJARO .medication, let your doctor know.

• gallbladder problems. Some MOUNJARO users have experienced problems with their gallbladders. Immediately notify your doctor or nurse if you experience any of the following signs of gallbladder issues: ○ discomfort in the upper part of the abdomen fever ○ Jaundice, .or yellowing of the skin or eyes stools the colour of clay.

The most common side effects of MOUNJARO involved:

• nausea

• diarrhea

• decreased appetite

• vomiting

• constipation

• indigestion

• stomach (abdominal) pain

If you experience any side effects that are bothersome or not going away, speak with your .doctor or other medical professional

WARNINGS AND PRECAUTIONS

1-Risk of Thyroid C-Cell Tumors In both sexes of rats: In a 2-year research at clinically significant blood exposures, tirzepatide enhanced the probability of thyroid C-cell tumours (tumours and malignancies) in a quantity- and treatment-dependent manner. Since the significance of tirzepatide-stimulate rodent thyroid C-cell tumours to people has'nt yet been displayed, it's unclear if MOUNJARO stimulate thyroid C-cell tumours, particularly medullary thyroid cancer (MTC), in individuals. Individuals with MEN 2 or those with a personal or family history of MTC not out to use MOUNJARO. People who use MOUNJARO should be informed about the potential dangers for MTC as well as the signs and symptoms (such as a neck bulk, difficulty swallowing, breathing difficulties and chronic hoarseness) associated with thyroid tumours. For individuals receiving MOUNJARO treatment, regular serum calcitonin screening or thyroid ultrasound may not be useful in identifying MTC early. Because of the elevated underlying prevalence of thyroid disorders and a poor diagnostic accuracy for serum calcitonin, this kind of follow-up might elevate the possibility of not needed interventions. People with MTC generally have calcitonin levels >50 ng/L. Extremely increased serum calcitonin levels could suggest MTC. When a mensuration of serum calcitonin manifest an elevate levels, the individual should be estimate too neatly . individual ought to get additional .evaluation if thyroid nodules are discovered during a physical checkup or neck scanning.

2-Pancreatitis: Acute pancreatitis, involving fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been seen in individuls treated with GLP-1 receptor agonists. In clinical studies, fourteen cases of acute pancreatitis were proven by ruling in 13 MOUNJARO-treated individuals against 3 cases in 3 comparator-treated individuls. Pancreatitis in the past hasn't been previously investigated among individuals using MOUNJARO. It is unclear if those using MOUNJARO have an increased chance of developing pancreatitis if they have previous experience of the situation. afterwards the setting up MOUNJARO, person need to be carefully monitored for inflammation of pancreas manifestations, which include extrem, continuous epigastric pain that occasionally radiates to back and can be accompanied or not accompanied by vomiting. If inflammaition of pancreas is .detected, stop using MOUNJARO and start treating the condition as needed.

3- Hypoglycemia: with Insulin Secretions or Insulin Concurrent Use Individuals taking MOUNJARO in conjunction with insulin or an insulin secretory substances (like sulfonylurea) might be much liable to low blood sugar, particularly severe low blood sugar levels. Reducing the dosage of insulin or sulfonylurea (or another concurrently used insulin secretory substances) may help minimise the possibility of low blood sugar. Individuals based on these combination drugs should be made aware of the possibility of a low blood .sugar as well as its alarming signs and characteristics.

4- Hypersensitivity Reactions: In clinical research, MOUNJARO has been associated with allergic reactions, including dermatitis and eczema, which have occasionally been serious. Should allergic reactions responses arise, stop using MOUNJARO; treat as soon as possible in accordance with basic medical services; and keep going watching unless complaints and indications subsided. Individuals those had a harsh allergy reaction to tirzepatide or other of the additives in MOUNJARO in the past time shouldn't take it. GLP-1 receptor stimulator had been scientifically linked to allergic response and edoema. It's unknown whether people who have a experience of angioedema or allergic response with a GLP- receptor stimulator are going to be much liable to these issues when using MOUNJARO, thus start care in these .people.

5- Acute Kidney Injury: Digestive issues side effects, such as sicknees, vomiting, and diarrhoea, had been connect to MOUNJARO. These occurrences might end with dehydration, which might cause acute harm to the kidneys if it gets severe. There have been postmarketing observations involving sudden kidney deterioration and exacerbation of chronic renal failure in people taking GLP-1 receptor stimulator; these events can sometimes necessitate hemodialysis. A less of these events had been register in people with no previous history of systemic kidney diseases . many of the events that have been documented include people who had dehydration, nausea, vomiting, or diarrhoea. Prior to .begin or elevate MOUNJAR dosages, do RFT.

6- Severe GIT Disease: The intake of MOUNJARO may have linked to unpleasant digestive responses, some of which may have been serious. Since MOUNJARO hadn't been studied in people have extreme gastroparesis or other GIT disorders, it is'nt suggested in these people..

7- Diabetic Retinopathy: Issues with Patients Who Have Experienced Diabetic Retinopathy in the Past There is a correlation between a brief deterioration of diabetic retinopathy and rapid improvements in controlling blood sugar. Individuals with diabetic retinal edoema, progressive diabetic retinopathy, or non-proliferative diabetic retinopathy necessitating immediate therapy haven't been investigated with MOUNJARO. Diabetes-related retinopathy must be closely watched for individuals who have previous experience .of the condition.

8- Acute Gallbladder Disease: In GLP-1 receptor agonist studies and postmarketing, acute episodes of gallbladder illness, such as cholelithiasis or cholecystitis, have been observed seen. Acute complications of gallbladder disease (cholelithiasis, biliary colic, and cholecystectomy) was reported by 0.6% of the individuals receiving MOUNJARO treatment and 0% of patients receiving a placebo regimen in MOUNJARO placebo-controlled clinical trials. Gallbladder diagnostic procedures and suitable clinical monitoring are recommended if cholelithiasis is suggested.

References

1- U.S. Food and Drug Administration

2- ema.europa.eu/en/medicines/ human/EPAR/ mounjaro

3-http://www.lilly.canada

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