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TOGETHER

COMPOUNDED Tirzepatide 10mg/mL—L-Carnitine 25mg/mL

Type 2 diabetes (T2D) and obesity are deep-rooted diseases that have no specific cure so far, but can be kept under control by **proper application of therapy** and treatment, as well as incorporating **lifestyle modifications**. Tirzepatide is a synthetic linear peptide molecule containing 39 amino acids. Tirzepatide is the first agent that functions as a dual agonist for the two main human GLP-1 and GIP incretins, and has impressive glycemic efficacy. Moreover, it is the first effective drug to have demonstrated notable body weight loss in a phase 3 study in patients with T2D. Tirzepatide has significantly better therapeutic efficacy than current drugs such as semaglutide and insulin degludec. [1].

The <u>recommended starting dosage of Tirzepatide</u> is <u>2.5 mg injected subcutaneously (SubQ) once weekly</u>. The 2.5 mg dosage is for treatment initiation and is not intended for glycemic control. After 4 weeks, increase the dosage to 5 mg injected SubQ_once weekly. If additional glycemic control is needed, increase the dosage in 2.5 mg increments after at least 4 weeks on the current dose. The maximum dosage of Tirzepatide is 15 mg injected SubQ once weekly. If a dose is missed, instruct patients to administer Tirzepatide as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day. Inject Tirzepatide SubQ in the abdomen, thigh, or upper arm, and rotate injection sites. Administer Tirzepatide once weekly, any time of day, with or without meals.

The most frequent adverse events with tirzepatide are mild to moderate and transient gastrointestinal events, including nausea (12-18%), diarrhea (12-14%), and vomiting (2-6%) [2]. Tirzepatide delays gastric emptying and has the potential to impact the absorption of concomitantly administered oral medications. Patients using oral hormonal contraceptives are advised to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with Trizepatide. Trizepatide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus [3].

In the event of an overdosage, contact Poison Control for latest recommendations. Appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms. A period of observation and treatment for these symptoms may be necessary [3].

Levocarnitine (L-3-hydroxy-4-N-trimethylaminobutyrate) is synthesized in the liver from the amino acids methionine and lysine. Levocarnitine facilitates long-chain fatty acid transport from the cytosol to the mitochondria, providing substrates for oxidation and subsequent cellular energy production. Levocarnitine can promote the excretion of excess organic or fatty acids in patients with defects in fatty acid metabolism or specific organic acidopathies that bioaccumulate acyl CoA esters. Levocarnitine clears the acyl CoA esters by formation of acylcarnitine which is rapidly excreted. Levocarnitine may cause gastrointestinal symptoms and should be used conservatively in patients with diarrhea. Levocarnitine therapy has been associated with an increased seizure activity. It should be administered with caution to patients with a history of a seizure disorder. Use levocarnitine with caution in hepatic disease since no specific information is available.

References:

- Chavda VP, Ajabiya J, Teli D, Bojarska J, Apostolopoulos V. Tirzepatide, a New Era of Dual-Targeted Treatment for Diabetes and Obesity: A Mini-Review. Molecules. 2022 Jul 5;27(13):4315. doi: 10.3390/molecules27134315. PMID: 35807558; PMCID: PMC9268041.
- Rosenstock J, Wysham C, Frías JP, Kaneko S, Lee CJ, Fernández Landó L, Mao H, Cui X, Karanikas CA, Thieu VT. Efficacy and safety of a novel dual GIP and GLP-1 receptor agonist tirzepatide in patients with type 2 diabetes (SURPASS-1): a double-blind, randomised, phase 3 trial. Lancet. 2021 Jul 10;398(10295):143-155.
- 3. MONJUARO Prescribing information, FDA Access Data
- Carnitor (levocarnitine) injection package insert. Gaithersburg, MD: Sigma Tau Pharmaceuticals; 2015 Apr.

This medication was shipped in a cooler or insulated bag with ice packs to preserve the integrity of the medication during transportation. If you suspect that your medication could have been tampered, or is damaged, or is outside the expected temperature, **DO NOT USE IT** and call the pharmacy to obtain advise.

How to Safely Dispose of Unused or Expired Medicine

The best way to dispose of most types of unused or expired medicines is to mail/drop-off the medications back to the pharmacy. If you cannot get to a drug take-back location promptly and your medicine is on the FDA flush list, your next best option is to immediately flush this potentially dangerous medicine down the toilet. If the medication is not on the flush list, you should follow the instructions below:

- <u>Mix</u> medicines with an unpalatable substance such as dirt, cat litter, or used coffee grounds.
- Place the mixture in a container such a sealed plastic bag
- Throw the container in your household trash
- <u>Scratch out</u> all personal information on the prescription label of your empty pill bottle or empty medicine packaging to make it unreadable, then dispose the container.

CDC INJECTION SAFETY CONSIDERATIONS

- Medications should be drawn up in a designated clean medication preparation area using a new sterile syringe and sterile needle to draw up medications including when obtaining additional doses of medication for the same patient.
- Prepare an injection as close as possible to the time of administration to the patient.
- DO NOT leave the needle inserted into a medication vial septum for multiple uses.
- Vials that are labeled as single-dose or single-use should be used for only a single patient. Enter those vials only once.
- DO NOT combine (pool) leftover contents of single-dose or singleuse vials or store single-dose or single-use vials for later use.
- If a single-dose or single-use vial has been opened or accessed (e.g., needle-punctured) the vial should be discarded according to the time the pharmacy specifies for the opened vial or at the end of the case/procedure for which it is being used, whichever comes first. It should not be stored for future use.
- Medication vials should always be discarded whenever sterility is compromised or questionable.
- Multi-dose vials should be dedicated to a single patient whenever possible
- If a multi-dose has been opened or accessed (e.g., needlepunctured) the vial should be dated and discarded within 28 days unless our pharmacy label specifies a different date for that opened vial.

DOSING CONVERSION <u>ONLY</u> FOR OUR COMPOUNDED TIRZEPATIDE 10MG/ML WITH L-CARNITINE 25MG/ML.

Dosage in mg	Unit Equivalence	Mililiters Equivalence
2.5 mg	25 Units	0.25mL
5 mg	50 Units	0.50mL
7.5 mg	75 Units	0.75mL
10 mg	100 Units	1mL
12.5 mg	125 Units	1.25mL
15 mg	150 Units	1.50mL