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Single-dose Tray

Do not substitute needles or any other components in the tray.

All administration components are included.

KYDUETO® is provided in a single-dose tray so that patients can administer the once-weekly subcutaneous injection themselves.

Each premeasured vial contains a single 2-mg dose of KYDUETO.

Each prefilled syringe contains 0.65 mL of diluent.

ONCE-WEEKLY TYPE 2 DIABETES TREATMENT

Kydueto®
(exenatide) Extended-Release
Injectable Suspension

Treatment for: Diabetes Type 2
KYDUETO® (exenatide) is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

ONCE-WEEKLY TYPE 2 DIABETES TREATMENT

Kydueto®
(exenatide) Extended-Release
Injectable Suspension

KYDUETO® (exenatide extended-release for injectable suspension) once-weekly diabetes treatment, type 2 diabetes glycemic control, type 2 diabetes patients, patients with type 2 diabetes”.

Indication and Important Limitations of Use for KYDUETO®

KYDUETO® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

KYDUETO® is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes mellitus, and should be used along with diet and exercise. KYDUETO® is not recommended as the first medication to treat diabetes. KYDUETO® is a long-acting form of the medication in (exenatide) injection so both drugs should not be used together. KYDUETO® is not a substitute for insulin and has not been studied in combination with insulin. KYDUETO® is not for people with type 1 diabetes or people with diabetic ketoacidosis (a condition caused by very high blood sugar). KYDUETO® is not recommended for use in children. It is not known if KYDUETO® is safe and effective in people with a history of pancreatitis or severe kidney problems.

Dosing and Administration

KYDUETO® (exenatide extended-release for injectable suspension) is injected subcutaneously by patients once every 7 days at any time of day, independent of meals, as a fixed dose with no titration required. KYDUETO® must be injected immediately after powder is suspended.

KYDUETO® must not be administered intravenously or intramuscularly.

If desired or necessary, patients can change their day of weekly administration as long as the last dose was administered 3 or more days before.

If patients miss a dose, it should be administered as soon as noticed, provided the next regularly scheduled dose is not 1 or 2 days later. In that case, patients should wait until their next regular dosing day to resume their usual dosing schedule of once every 7 days.

Two doses of KYDUETO® should not be administered less than 3 days apart.

KYDUETO® (exenatide extended-release for injectable suspension) is dispensed in a trade pack (carton) containing 4 single-dose trays.

Each single-dose tray contains 1 vial of exenatide 2 mg, 1 vial connector, 1 prefilled diluent syringe, and 2 custom needles (1 provided as a spare). The minimum salable unit is 1 trade pack (carton), representing a 4-week supply. Trade packs (cartons) should not be opened, nor should a single-dose tray be sold individually.

Inject KYDUETO under the skin (subcutaneously) not into a muscle or vein. You can take the injection in your stomach area (abdomen), your thigh, or the back of your upper arms. Each week you can use the same general area of your body. Just be sure not to inject in the exact same place.

Food and Drug Administration (FDA) approved .Prescription Only (POM)

A Taj Pharma”India Product