

Generex Oral-lyn™

DRUG FORMULATION:

Oral Regular Insulin Spray.

ROUTE OF ADMINISTRATION:

Oral (apply the spray onto buccal mucosa).

DOSAGE:

At the beginning, your Physician will advise you on the dose (number of sprays of Generex Oral-lyn™) you should take. It is recommended that you gradually build up (see schedule below) to using Generex Oral-lyn™ 3 times per day (with breakfast, lunch and dinner). When using the product, you will need to self-administer half of the prescribed dose immediately before the meal (no more than 10 minutes prior to each meal) and the second half immediately after the meal (not later than 10 minutes after the meal). The following schedule is recommended when Generex Oral-lyn™ is being used for the first time and you have been taking prandial (mealtime) injectable insulin and basal injectable insulin for your diabetes.

Order of replacing your prandial injectable insulin with Generex Oral-lyn™:

- For the first 4 weeks, begin by replacing the breakfast injectable insulin dose with Generex Oral-lyn™.
- If you are stable after the first 4 weeks, the second daily dose of Generex Oral-lyn™ replacement will be added at supper for the next 4 weeks.
- If you are stable after the second daily supper-time dosing for 4 weeks, the third daily dose of Generex Oral-lyn™ replacement will be added at lunch for the next 4 weeks and onwards.

Use Generex Oral-lyn™ only as prescribed by your Physician.

If you find that your blood sugar level is higher than usual (above 101 mg/dl) in the afternoon or evening before the meal or if your sugar levels rise excessively during product use, you need to call your Physician and he/she will correct this problem with an additional dose of insulin as required.

If you experience a minor episode of low blood sugar, take glucose as a food or liquid. If the episode is more than minor, call your Physician as soon as possible for further advice.

INSTRUCTIONS FOR INITIAL USE:

Drug Storage:

THE CANISTER AND ACTUATOR THAT IS CURRENTLY BEING USED MUST BE KEPT AT ROOM TEMPERATURE AT ALL TIMES.

• ONLY STOCK CANISTERS THAT ARE NOT IN USE ARE TO BE KEPT AT REFRIGERATED CONDITIONS (+2 to +8°C)

Preparation For Initial Use:

When using the canister for the first time, **make sure that it is removed from the refrigerator before use for a period of at least 8 hours (i.e. overnight).**

- After storage at room temperature for the first time (i.e. overnight), the canister should be warmed by **holding the canister in a closed hand for at least 2 minutes.**
- After 2-minute warming in the hand, the canister should **be shaken for at least 1 minute to fully mix content. Shaking should be done with a side to side moderately aggressive motion (approx. 20-25 shakes per 5 seconds), but avoiding an excessively strong and vigorous force.**

Following the shaking process, the canister is placed into the actuator by simply pushing and twisting the canister until it "clicks" into place.

Once the new canister is securely in place, the unit is primed by spraying 2-4 times into the air. (To prime the unit, simply remove cap of mouthpiece and turn away from face. Then depress the canister into the actuator making sure to hold canister down for at least 1 full second. This action will release the canister content into the air as a spray.) **Note that between sprays, whether priming or actual dosing, unit should be shaken using the same technique as described above for 10-15 seconds.** The shaking process during priming and dosing ensures a fully mixed content and allows any frosting present at the actuator head to disappear.



Drug Administration:

1. Once unit has been primed, it is ready for treatment administration.
2. Rinse mouth with luke warm water to wash away any food debris. This is especially critical when administering treatment after a meal.
3. Prior to delivery of the first dose, shake unit for 10-15 seconds using the procedure described above.
4. To deliver your first and subsequent dose, hold the actuator in an upright position. Place the mouthpiece fully into your mouth forming a tight seal with your teeth and lips, as illustrated in figure 1.
5. Aim the nozzle straight forward. Ultimately, a comfortable position needs to be found that will permit repetitive use of the Generex Oral-lyn™ product.
6. Holding the unit firmly in place, depress the top of the metal canister fully down into the actuator with your index finger holding it in place for 1 full second, as illustrated in figure 2. **It is important to suck the product into the oral cavity as the spray is being delivered.** This eliminates any opposing resistance to the velocity of the propellant and minimizes leaking of the spray from the mouth or around the RapidMist™ delivery unit.

7. Remove mouthpiece from between lips, re-establishing mouth seal, swiftly. Hold product in oral cavity for approximately 5 seconds. Hold breath and minimize swallowing during this 5 second holding period to allow for product absorption.

8. Shake the canister-actuator unit for 10-15 seconds as per instructions outlined in "preparation for initial use" before delivering the next dose.

9. Repeat steps 4 to 8 to deliver your next and subsequent doses.

Failure to suck the product in during drug administration may result in a fine mist coming out of your nose, mouth or RapidMist™ delivery unit. Should this occur, the technique just described will have to be closely monitored for the next spray so that the complete dose is administered correctly and effectively. If an actuation fault occurs, you should repeat the dose.

Failure to wait at least 10-15 seconds between sprays can result in the actuator becoming temporarily clogged. If the actuator becomes clogged for any reason, remove the metal canister from the actuator and clean the plastic actuator before continuing your dosing.

The actuator can be cleaned using the following procedure:

- a. Remove the metal canister
 - b. Clean the plastic actuator and cap by rinsing thoroughly in warm running water
 - c. After completely drying the plastic actuator and cap, replace the canister downward into the actuator using a twisting motion
 - d. Replace the cap onto the mouthpiece
- Discard the canister when the canister is empty (i.e. full "dosing" or "firing" cannot be achieved). Be sure to always follow the dosage prescribed by your doctor. You should not stop using the Generex Oral-lyn™ RapidMist™ system without consulting your physician.

Please note: The dispensers should not be interchanged with any other similar dispenser.

WHAT TO DO IF YOU EXPERIENCE ANY SYMPTOMS THAT MAY RELATE TO THE USE OF THE DRUG?

Please note that the symptoms of exposure may include (but not limited): hypoglycemia, headache, pallor, sweating, visual disturbances, hunger, anxiety, tremulousness, palpitations and slurred speech.

GENERAL ADVICE: In all cases of doubt, or when symptoms persist, seek medical attention.

EYE CONTACT: In case of direct contact of canister contents with eye, immediately flush eyes with plenty of water for at least 15 minutes. Consult a physician immediately.

INGESTION: If untoward effects are noted following accidental ingestion of the canister contents, rinse your mouth and drink plenty of water. Do not induce vomiting unless advised by medical personnel. If large quantities of the product are swallowed, call a Physician immediately.

SKIN CONTACT: Should irritation ever occur, wash the exposed area with soap and water, and if condition persists or worsens, consult a Physician immediately.

STORAGE CONDITIONS

Generex Oral-lyn™ should be refrigerated at +2 to 8 °C; when kept under these storage conditions, it can be used until product expiration. The product can be kept at room temperature (+15 to 30°C) for the full duration of time that it is being used by the patient until the canister is empty. NOTE: When product is to be used by patient, let it come to room temperature if previously refrigerated for a period of at least 8 hours (i.e. overnight).

The canisters with the Generex Oral-lyn™ should not be frozen (i.e. should not be kept at temperatures < 0°C).

The canisters with the Generex Oral-lyn™ should not be exposed to direct sunlight or source of heat.

Precautions

Keep away from sources of ignition.

Contents Under Pressure - do not puncture, do not use or store near heat or open flame. The exposure to temperatures over 48°C can cause a breakage.

Keep out of reach of children.

Benta S.A.L.

Dhayeh - Lebanon

Under license from

Generex Biotechnology Corporation

Toronto, Ontario Canada

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists