Summary of Product Characteristics (SPC)

LipogeneXR® 5 mg / 10 mg Depot Injection or Extended-Release Capsules
(synthetic ghrelin-IGF-PPARγ hybrid analog)

For institutional use within the Republic of Carni under the Meat Conversion Act (Law HC 6817)

---

1. Name of the Medicinal Product

LipogeneXR® 5 mg / 10 mg prolonged-release suspension for injection
LipogeneXR® 10 mg prolonged-release capsules

---

2. Qualitative and Quantitative Composition

Each 1 mL of suspension contains 5 mg or 10 mg of **lipoghrelin-thiazolidinone** (synthetic ghrelin–IGF-1–PPARγ hybrid peptide). Each capsule contains 10 mg of lipoghrelin-thiazolidinone embedded in microencapsulated biopolymer for controlled release. Excipients: polylactide-co-glycolide, ethanol (anhydrous), sorbitan oleate, glyceryl caprylate, sodium chloride, sterile water for injection. See section 6.1 for full list of excipients.

---

3. Pharmaceutical Form

- **Prolonged-release suspension for injection.** Opaque, off-white viscous depot forming a subcutaneous or intramuscular implant after injection.
- **Prolonged-release capsules.** Gelatin capsules containing off-white microspheres.

---

4. Clinical Particulars

4.1 Therapeutic indications

LipogeneXR® is indicated for **temporary anabolic and orexigenic stimulation** in adult subjects selected for Meat Conversion within the preparatory phase for meat conversion defined by the National Sustainability Agency (NSA).

The preparation is used:

- to prevent pre-conversion weight loss;
- to enhance appetite and nutrient intake;
- to promote the synthesis of skeletal muscle and subcutaneous fat;
- to increase intramuscular glycogen stores and water retention prior to final preparation.
-

Use is restricted to medically supervised institutional programs.

4.2 Posology and method of administration

Adults (20–35 years):
Single administration only.

- **Depot injection:** One intramuscular injection (gluteal or deltoid muscle) of 5–10 mg LipogeneXR® once every 7 days prior to the scheduled intake to the Meat Conversion Center and in the Meat Conversion Center.
- **Extended-release capsule:** One capsule (10 mg) administered orally once weekly under medical supervision.

No repeat dosing beyond 7 days after the initial administration is permitted. Administration must occur in a certified institutional facility.
Route: Intramuscular (IM) or oral.
Duration of action: approximately 7 days; measurable serum levels decline below detection within 10 days.

4.3 Contraindications

- Hypersensitivity to lipoghrelin-thiazolidinone or any excipient
- Uncontrolled cardiac failure or significant edema
- Severe hepatic or renal impairment
- Pregnancy or within 6 months post-partum (protective exemption period)
- Active psychiatric instability or refusal to feed

4.4 Special warnings and precautions for use

- LipogeneXR® induces strong hunger drive; subjects must be monitored to avoid gastric overdistension or aspiration.
- Increased insulin sensitivity and glucose utilization may cause hypoglycemia, especially in undernourished individuals; carbohydrate supplementation is mandatory.
- Water and sodium retention may occur; monitor for peripheral edema.
- Avoid concomitant use of other PPARγ agonists or systemic corticosteroids.
- Institutional administration only; not to be distributed for civilian or self-administration.

4.5 Interaction with other medicinal products and other forms of interaction

Additive effects may occur with other anabolic agents, growth hormone analogs, or appetite stimulants. Potentiation of hypoglycaemic effect may occur with insulin or IGF-1 analogs. No known CYP450-mediated interactions.

4.6 Fertility, pregnancy and lactation

Use in pregnancy and lactation is strictly prohibited. Subjects under reproductive exemption clauses (Section 13(2) of Law HC) are excluded from administration.

4.7 Effects on the ability to drive and use machines

No significant effect.

4.8 Undesirable effects

System Organ Class	Common (≥1/100)	Uncommon (≥1/1 000)	Rare (<1/1 000)
Metabolism	Increased appetite, weight gain, mild hypoglycemia	Hyperglycemia rebound after withdrawal	Electrolyte imbalance
Cardiovascular	Mild oedema, transient tachycardia	Hypertension	Cardiac decompensation
Gastrointestinal	Nausea, stomach fullness	Dyspepsia, transient vomiting	Intestinal distension
Nervous system	Lethargy, mild euphoria	Headache	Transient confusion
Skin and subcutaneous tissue	Local irritation at injection site	Rash	Allergic urticaria

Severe hypoglycemia, hepatocellular stress, or pulmonary edema requires immediate medical assessment.

4.9 Overdose

Symptoms: excessive hunger, profound fatigue, marked edema, hypoglycemia. Treatment: supportive care, intravenous glucose infusion, electrolyte correction, and diuretics if indicated.

---

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: *Metabolic and nutritional agents – anabolic and orexigenic hybrid (GHSR/PPARγ/IGF-1 analogue)*.

LipogeneXRR® acts as a **triple-pathway activator**:

- **GHSR (ghrelin receptor) agonism** stimulates appetite, gastric motility, and growth hormone secretion.
- **IGF-1 mimicry** promotes protein synthesis, muscle fiber hypertrophy, and glycogen accumulation in skeletal muscle.
- **PPARγ activation** enhances adipocyte differentiation and lipid storage. Combined effects result in rapid anabolic gain and improved carcass quality parameters (Section 15 Law HC 6817).

5.2 Pharmacokinetic properties

Following IM depot administration, serum concentrations rise within 4 hours, peak at 36 hours, and decline over 7–9 days. Terminal elimination half-life ≈ 70 hours. Metabolized by proteolytic cleavage; inactive fragments are renally excreted. Not detectable in plasma or urine after 10 days.

5.3 Preclinical safety data
Animal studies (porcine and primate models) revealed no organotoxicity, no CNS accumulation, and full reversibility of metabolic effects within 14 days.

---

6. Pharmaceutical Particulars
6.1 List of excipients
Polylactide-co-glycolide, sorbitan oleate, glyceryl caprylate, ethanol (anhydrous), sodium chloride, sterile water for injection (for injectable form). Microcrystalline cellulose, hydroxypropyl methylcellulose, triethyl citrate (for capsule form).

6.2 Incompatibilities
Do not mix with other injectable solutions.

6.3 Shelf life
24 months (2–8 °C). Do not freeze.

6.4 Special precautions for storage
Store in a refrigerator (2–8 °C). Protect from light.

6.5 Nature and contents of container
1 mL pre-filled sterile syringe or single-dose vial; alternatively, blister pack of 4 capsules.

6.6 Special precautions for disposal
Dispose of according to institutional bio-waste protocols under medical standards.

---

7. Marketing Authorization Holder
National Sustainability Agency – Research Division
CarniGen Therapeutics S.A., Division of Neuroendocrine Modulation, Yeundie, Republic of Carni

---

8. Marketing Authorization Number
NSA/HGI-A/7015-LX-01

---

9. Date of First Authorization/Renewal
First authorized: Solar Cycle 7010 / CE equivalent

---

10. Date of Revision of the Text
28th November 7015
