Summary of Product Characteristics (SPC)

SERELYNE™
(Fluoxetinum lauroxilate)
50 mg prolonged-release capsules

1. NAME OF THE MEDICINAL PRODUCT

Serelyne® 50 mg prolonged-release capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

- **Fluoxetinum lauroxilate** equivalent to **50 mg fluoxetinum base** (active moiety).
- Excipients with known effect: microcrystalline cellulose, lauric acid, hypromellose, and magnesium stearate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Prolonged-release capsule.
Opaque white capsule containing off-white microspheres.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Serelyne® is indicated for:

- **Attenuation of acute stress response** and **emotional stabilization** in pre-conversion according to the Meat Conversion Act.
- Short-term management of **severe anticipatory anxiety** and **psychological hyperreactivity** in psychologically competent individuals.

Serelyne® is not indicated for depressive disorders or psychotic conditions.

4.2 Posology and method of administration

Posology

The recommended dose is **one capsule (50 mg)** taken **once weekly**. Treatment duration should not exceed **two consecutive weeks**, corresponding to the pre-conversion preparatory period.

Method of administration

For oral use. Capsules should be swallowed whole with water. Do not chew or crush. Food does not significantly affect absorption.

4.3 Contraindications

- Known hypersensitivity to fluoxetinum or any of the excipients.
- History of serotonin syndrome.
- Concurrent use with monoamine oxidase inhibitors (MAOIs) or within 14 days of discontinuing MAOI therapy.
- Severe hepatic impairment.

4.4 Special warnings and precautions for use

Serelyne® should be used only under medical supervision within the authorized pre-conversion framework. Clinical monitoring is recommended during the first 2 hours after administration to assess possible serotonergic overstimulation. Due to the long elimination phase of the prodrug, **no additional serotonergic agents** (including herbal supplements) should be administered during the 7-day active period.

Although consciousness and cognition remain preserved, **mild emotional flattening** or **reduced reactivity** may occur and should not be misinterpreted as sedation. No withdrawal syndrome has been observed due to the depot formulation's gradual auto-deactivation.

4.5 Interaction with other medicinal products and other forms of interaction

- Concomitant use with MAOIs is contraindicated (risk of serotonin syndrome).
- Caution with CYP2D6 substrates (e.g., tamoxifen, certain beta-blockers), although clinical interaction is minimal due to the low steady-state concentration of active fluoxetinum.
- Ethanol intake does not potentiate CNS depression.

4.6 Fertility, pregnancy and lactation

Administration is not recommended during pregnancy. In lactating women, Serelyne® should be avoided as small amounts of fluoxetinum and lauric acid derivatives may be excreted in breast milk. No data are available on fertility; animal data did not show teratogenic effects.

4.7 Effects on ability to drive and use machines

Serelyne® has **no sedative properties** and does not impair psychomotor performance. However, mild transient dizziness or altered emotional perception may occur in the first 12 hours after administration.

4.8 Undesirable effects

Common (≥ 1/100, < 1/10):

- Mild nausea, abdominal discomfort
- Headache
- Decreased appetite
- Transient emotional blunting

Uncommon (≥ 1/1,000, < 1/100):

- Sleep disturbances (vivid dreams, insomnia)
- Dry mouth
- Sweating, tremor
- Mild muscle tension

Rare (≥ 1/10,000, < 1/1,000):

- Transient serotonergic agitation
- Hypersensitivity reactions (rash, pruritus)

Very rare (< 1/10,000):

- Seizures in predisposed individuals
- Elevated liver enzymes

No apathy or significant cognitive impairment has been reported in controlled clinical trials.

4.9 Overdose

Due to depot release and lipophilic storage, acute overdose is unlikely. Symptoms may include nausea, agitation, or tachycardia. Treatment is supportive; gastric lavage and activated charcoal may be considered within 2 hours of ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Selective serotonin reuptake inhibitors (SSRIs).
ATC code: N06AB-F (prolonged-release formulation).
Mechanism of action:
Serelyne® selectively inhibits the serotonin transporter (SERT) with high affinity (Ki ≈ 0.4 nM). The lauroxilate prodrug is enzymatically cleaved in adipose tissue, releasing fluoxetinum gradually into systemic circulation, maintaining stable plasma concentrations for 7 days. The pharmacodynamic profile allows suppression of excessive autonomic and affective stress responses without loss of consciousness or motor coordination.

5.2 Pharmacokinetic properties

Parameter	Value / Characteristic
Absorption	90 % bioavailability after oral administration
Distribution	Large Vd (~30 L/kg), extensive adipose storage
Plasma protein binding	~95 %
Metabolism	Hydrolytic cleavage by carboxyesterases → active fluoxetinum → oxidative demethylation by CYP2D6
Elimination half-life	Active fluoxetinum: 36–48 h
Duration of action	~7 days (steady release from adipose stores)
Detectability	Below LC-MS limit (< 1 ng/mL) after 14 days

5.3 Preclinical safety data

Animal studies (rodents and primates) showed no organ toxicity or reproductive effects. Chronic administration resulted in no measurable accumulation after 21 days. No genotoxic or carcinogenic potential observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose, lauric acid, hypromellose, magnesium stearate, titanium dioxide, gelatin.

6.2 Incompatibilities
None known.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store below 30 °C. Protect from moisture.

6.5 Nature and contents of container
Blister packs of 4 capsules.

7. MARKETING AUTHORISATION HOLDER
CarniGen Therapeutics S.A., Division of Neuroendocrine Modulation, Yeundie, Republic of Carni

8. MARKETING AUTHORISATION NUMBER(S)
CARNI/CGT/6891/A764/SERELYNE

9. DATE OF FIRST AUTHORISATION/RENEWAL
First authorisation: 21 March 6891

10. DATE OF REVISION OF THE TEXT
October 6899