# Suliqua ePI Structured Data

Link to SmPC: [Suliqua, INN - insulin glargine + lixisenatide (europa.eu)](https://www.ema.europa.eu/en/documents/product-information/suliqua-epar-product-information_en.pdf)

Link to FHIR R5 [(4.6.0) resources](http://hl7.org/fhir/2021May/resourcelist.html)

Link to Skilarence template: [gravitate-health/input/fsh/Suliqua-instances-en at master · hl7-eu/gravitate-health (github.com)](https://github.com/hl7-eu/gravitate-health/tree/master/input/fsh/Suliqua-instances-en)

# Bundle

Package leaflet for 100/50 bundle

Package leaflet for 100/30 bundle

# Composition

Package leaflet for 100/50 – Norwegian text

Package leaflet for 100/30 – Norwegian text

# Organization

Market Authorization Holder

sanofi-aventis groupe

54, rue La Boétie

75008 Paris

France

Manufacturer API

Sanofi-Aventis Deutschland GmbH

Brueningstrasse 50

Industriepark Höchst

65926 Frankfurt am Main GERMANY

Manufacturer Batch release

Sanofi-Aventis Deutschland GmbH Brueningstrasse 50

Industriepark Höchst

65926 Frankfurt am Main GERMANY

Regulator

ORG-99999999

European Medicines Agency

Domenico Scarlattilaan 6

1083 HS Amsterdam

The Netherlands

Can reuse the same EMA Organization resource from Skilarence

# Regulated Authorization

EU/1/16/1157/001 100/50 x3 pre-filled pens

EU/1/16/1157/002 100/50 x5 pre-filled pens

EU/1/16/1157/003 100/33 x3 pre-filled pens

EU/1/16/1157/004 100/33 x5 pre-filled pens

EU/1/16/1157/005 100/50 x10 pre-filled pens

EU/1/16/1157/006 100/33 x10 pre-filled pens

# Medicinal product definition

EU/1/16/1157/001 100/50 x3 pre-filled pens

EU/1/16/1157/002 100/50 x5 pre-filled pens

EU/1/16/1157/003 100/33 x3 pre-filled pens

EU/1/16/1157/004 100/33 x5 pre-filled pens

EU/1/16/1157/005 100/50 x10 pre-filled pens

EU/1/16/1157/006 100/33 x10 pre-filled pens

# Packaged product definition

Carton with this many pens:

EU/1/16/1157/001 100/50 x3 pre-filled pens

EU/1/16/1157/002 100/50 x5 pre-filled pens

EU/1/16/1157/003 100/33 x3 pre-filled pens

EU/1/16/1157/004 100/33 x5 pre-filled pens

EU/1/16/1157/005 100/50 x10 pre-filled pens

EU/1/16/1157/006 100/33 x10 pre-filled pens

Pack type and material details

Packs of 3, 5 and 10 pre-filled pens.

Type I colourless glass cartridge with a black plunger (bromobutyl rubber) and a flanged cap (aluminium) with inserted laminated sealing disks (bromobutyl rubber on the medicinal product side and polyisoprene on the outside) containing 3 ml of solution.

Not all pack sizes may be marketed.

Shelf life and storage conditions

24 months.

Shelf-life after first use of the pen: 28 days For in-use pens

Store below 25°C. Do not refrigerate. Do not freeze.

Do not store with attached needle.

Store pen away from direct heat or direct light. The pen cap must be put back on the pen after each injection in order to protect from light.

Not in-use pens

Store in a refrigerator (2°C - 8°C).

Do not freeze or place next to the freezer compartment or a freezer pack. Keep the pre-filled pen in the outer carton in order to protect from light.

# Administrable product definition

Suliqua 100 units/ml + 50 micrograms/ml solution for injection in a pre-filled pen

Suliqua 100 units/ml + 33 micrograms/ml solution for injection in a pre-filled pen

# Manufactured item definition

Suliqua 100 units/ml + 50 micrograms/ml solution for injection in a pre-filled pen

Suliqua 100 units/ml + 33 micrograms/ml solution for injection in a pre-filled pen

# Ingredient

Insulin glargine 100 units/ml 2ZM8CX04RZ

Lixisenatide 50 ug/ml 74O62BB01U

Lixisenatide 33 ug/ml 74O62BB01U

Glycerol 85% PDC6A3C0OX

Methionine AE28F7PNPL

Metacresol GGO4Y809LO

Zinc chloride 86Q357L16B

Concentrated hydrochloric acid QTT17582CB

Sodium hydroxide 55X04QC32I

Water for injections 059QF0KO0R

# Substance

Insulin glargine 100 units/ml 2ZM8CX04RZ

Lixisenatide 74O62BB01U

Glycerol 85% PDC6A3C0OX

Methionine AE28F7PNPL

Metacresol GGO4Y809LO

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Water for injections 059QF0KO0R

# Clinical use issue

Indication #1 - type 2 diabetes

|  |  |  |
| --- | --- | --- |
| TYPE 2 DIABETES MELLITUS | 10067585 | METABOLISM AND NUTRITION DISORDERS |

Contraindication #1 - hypersensitivity

|  |  |  |
| --- | --- | --- |
| DRUG HYPERSENSITIVITY | 10013700 | IMMUNE SYSTEM DISORDERS |

Interactions

Is there a way of getting the Felleskatalogen terms and codes out of your XML? Or do we need to code them?

# Undesirable effects

MeDRA terms

| **System Organ Class** | **Preferred Term** | **Code** | **Frequency** |
| --- | --- | --- | --- |
| GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS | FATIGUE | 10016256 | Common (temporary code = 01) |
| GASTROINTESTINAL DISORDERS | ABDOMINAL PAIN UPPER | 10000087 | Common (temporary code = 01) |
| GASTROINTESTINAL DISORDERS | DYSPEPSIA | 10013946 | Common (temporary code = 01) |
| NERVOUS SYSTEM DISORDERS | HEADACHE | 10019211 | Common (temporary code = 01) |
| SKIN AND SUBCUTANEOUS TISSUE DISORDERS | URTICARIA | 10046735 | Common (temporary code = 01) |
| INFECTIONS AND INFESTATIONS | NASOPHARYNGITIS | 10028810 | Uncommon (temporary code = 02) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | OROPHARYNGEAL PAIN | 10068319 | Uncommon (temporary code = 02) |
| RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS | RHINORRHOEA | 10039101 | Uncommon (temporary code = 02) |
| IMMUNE SYSTEM DISORDERS | HYPERSENSITIVITY | 10020751 | Uncommon (temporary code = 02) |
| GASTROINTESTINAL DISORDERS | DIARRHOEA | 10012735 | Uncommon (temporary code = 02) |
| GASTROINTESTINAL DISORDERS | VOMITING | 10047700 | Uncommon (temporary code = 02) |
| GASTROINTESTINAL DISORDERS | NAUSEA | 10028813 | Uncommon (temporary code = 02) |
| NERVOUS SYSTEM DISORDERS | DIZZINESS | 10013573 | Uncommon (temporary code = 02) |

# Binary

Should we use pictures from the instructions for use? E.g., page 70 of the SmPC.

# Document Reference

I believe this is the resource we will use for the video. But we’ll have to confirm.