

REF

GIMA 23840	I23204
GIMA 23841	I23105
GIMA 23842	I23106
GIMA 23843	I23108



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UK

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M23840-M-Rev.2.06.26

INSTRUCTIONS FOR USE

Product Name:
Sterile Insulin Pen Needles for Single Use

Specification

Needle OD: 0.18mm (34G), 0.20mm (33G), 0.23mm (32G), 0.25mm (31G), 0.3mm (30G), 0.33mm (29G), 0.36mm (28G);
Needle length: 3.5 mm ~ 13 mm;
Example: If the OD of the Sterile Insulin Pen Needles for Single Use is 0.18 mm, the needle length is 4 mm, it will be marked as 0.18 x 4 mm;

Product Structure:

Schematic representation of the Sterile Insulin Pen Needles for Single Use:

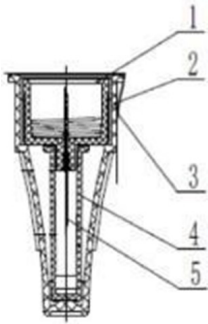


Figure 1. Sterile Insulin pen needles for Single Use
1. Needle hub
2. Hub sheath
3. Sealed paper
4. Needle protective cover
5. Needle tube

Intended purpose:

The Sterile Insulin Pen Needles for Single Use is intended for medical purpose to use with pen injector devices for the subcutaneous injection of insulin. It can only be used once and shall be disposed of as medical waste after use.

Intended users:

At home or medical institution, used by the doctors or patients to inject insulin.

Contraindications:

- 1. Patients who are told by a doctor that they are not suitable for taking drugs by injection.
- 2. Inflammation, tumors, and traumatic ulceration were found in the injection site.
- 3. Severe bleeding, coagulation tendency, platelet, or coagulation factor is significantly reduced or anticoagulant therapy with heparin, dicoumarin.
- 4. Injection during tetanus attack and rabies spasm may induce paroxysmal spasm.
- 5. Epilepsy convulsions, psychiatric patients, and uncooperative patients need to be injected under guardianship.

Cautions and Warning:

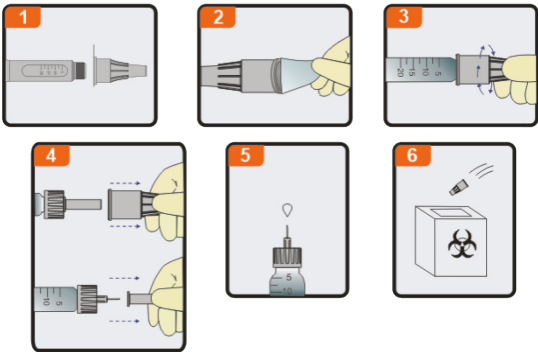
- 1. Please check the product packaging before use. Do not use if the package is damaged.
- 2. Pay attention to check for any foreign substances and impurities in the primary package, or whether the needle cap is detached, if notice any, do not use the product.
- 3. This product is for single use only and should not be reused. Reusing it may cause infection.
- 4. Use it immediately after opening the primary package and disposed of it as medical waste after use.
- 5. Use the product before the expiry date marked on the label. The shelf life of the product is 5 years. Do not use it if it has exceeded its shelf life.
- 6. This product is strictly prohibited from secondary sterilization.
- 7. The injection site should not be kneaded by hand.
- 8. During operation, the user should take care to avoid accidental needlestick injuries.
- 9. Before use, ensure the needle tip is not damaged or has any burrs. If any are present, do not use the product.
- 10. Store this product in a cool, dry, clean, and well-ventilated environment, away from corrosive gases.

Potential complications:

- 1. Pain;
- 2. Injection site bleeding;
- 3. Redness;

How to use:

- 1. Prepare the insulin pen syringe per its instructions.
- 2. Tear off the sealed paper in the hub sheath and the needle protective cover vertically.
- 3. Connect the insulin pen needle to your insulin pen and tighten it in a clockwise direction.
- 4. Remove the hub sheath and protective cover from the needle vertically.
- 5. Expel any air from the pen, then proceed with the injection.
- 6. After injection, discard the insulin pen needle in the nearest sharps collector or according to your site’s policy.



Sterilization:

EO Sterilization.

Shelf life:

5 years.

Signs and Symbols Used on Labels:

Symbol	Description	Symbol	Description	Symbol	Description
	Imported by		Lot number		Date of manufacture
	Use-by date		Sterilized using ethylene oxide		Caution: read instructions (warnings) carefully
	Disposable device, do not re-use		Don't use if package is damaged		Medical Device
	Do not resterilize		Authorized representative in the European Union		Manufacturer
	CE marking of conformity, and Notified Body Code		Consult instructions for use		Unique device identifier
	Keep away from sunlight		Keep in a cool, dry place		Single sterile barrier system
	Fragile, handle with care		UK Responsible Person		Product code

Storage conditions:

The product should be stored in a dry room with excellent ventilation and without caustic gases.

Transportation conditions:

The product shall be protected from hook, heavy pressure and rain during transportation.

Note: If any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies