

Device & consumable description

Juvapen (Toxin)

The Juvapen (Toxin) is a cordless motorized injection system powered by a lithium battery. The Juvapen (Toxin) is a non-sterile device intended to assist certified practitioners in injecting Botulinum toxins. After attaching the syringe holder (Toxinlink) onto the device, the practitioner simply inserts the dedicated filled 1ml syringe onto the Toxinlink. Once the Juvapen (Toxin) is fully assembled the practitioner presses on the top part of lever or the syringe holder for an accurate dosage delivery in drops or continuous flow mode. The Juvapen (Toxin) is only intended for Botulinum toxin injections.

Syringe holder / Toxinlink

The Toxinlink has been designed to improve syringe handling ergonomics, allowing the user to have greater freedom to operate during injections. The Toxinlink provides low force accurate activation with the lever or strong grip activation directly pressing on the top of the syringe holder. The Toxinlink is only compatible with the 1 ml syringe that is provided. The Toxinlink is compatible exclusively with Juvapen (Toxin).

Advantages of the Juvapen (Toxin)

For the patient:

- Significantly less pain.
- Highly precise injections.
- Reduced side effects.

For the practitioner:

- User-friendly & ergonomic design for more comfort.
- Easy to use & intuitive system.
- Optimized control of the procedure: depth of the injection, homogeneous delivery and precise dosage.
- Accuracy in the dosages.

Precautions and recommendations

Precautions for use: please read the following instructions carefully and follow the proper safety measures in order to perform a successful injection.

- Only a qualified and experienced medical practitioner should use the Juvapen (Toxin)
- The use of the Juvapen (Toxin) and the results thereof are the exclusive responsibility of the practitioner.
- The practitioner is the only one who can evaluate the indications and contraindications relative to the technique to employ, the product to be administered and the appropriate needle to be used.
- In all cases, the medical practitioner shall proceed only after having fully familiarized himself / herself with both the product and its educational material, including their instructions for use.
- Only 1ml syringes that are provided with are recommended by the manufacturer.
- The Juvapen (Toxin) syringe and its holder are for a single patient and single session use. Discard immediately after use into a sharps waste container. Do not use if the package is opened or damaged.

Adverse reactions and contraindications

It is the practitioner's full responsibility to read and follow the Instructions for use in order to avoid any adverse reactions or complaints. Possible side effects and contraindications can result from the use of products in conjunction with the Juvapen (Toxin) (e.g. Botulinum toxin, needle, cannula, etc.). It is the practitioner's full responsibility to check and follow the instructions for use of any products used with the Juvapen (Toxin).

General recommendations

- Keep the Juvapen (Toxin) out of reach of children.
- The equipment cannot be used where there is an inflammable mixture of air, oxygen or nitrogen.
- Store the Juvapen (Toxin) away from heat and direct exposure to sun.
- Keep the Juvapen (Toxin) away from water and chemical products.
- Always check whether the device is functioning properly before use.
- If the Juvapen (Toxin) is damaged, it must be sent back to Juvaplus SA (please refer to the Warranty).
- If the On/Off light turns orange, change the battery.
- The Juvapen (Toxin) turns off automatically, when not in use, after 2 minutes.
- The Toxinlinks are designed for use with the Juvapen (Toxin) exclusively and therefore cannot be used with any other third party device.
- Do not use other batteries other than the ones supplied by Juvaplus SA. Damage of the Juvapen (Toxin) caused by third party batteries voids the warranty.
- Do not sterilize any of the components: Juvapen (Toxin), syringe holder and battery.
- Wearing single-use gloves is highly recommended for the use of the equipment.
- No alteration of this equipment is allowed.
- Dispose of the battery according to your local environmental regulations.
- Do not dispose of the Juvapen (Toxin), but rather, return it to Juvaplus SA.
- Do not use the Juvapen (Toxin) near electronic equipment which emits electromagnetic fields.
- Only use syringes provided by Juvaplus SA.

Accessories

Battery cap Lithium 6V /170 mAh

The Juvapen (Toxin) must be used with a certified battery IEC60086-4 only

Toxinlink

Toxinlink: Plastic PC Makrolon 2458

Cleaning

After each use, the Juvapen (Toxin) must be cleaned with an adequate cleaning agent before re-using it. Do not immerse the device or its components in water. We recommend using an appropriate cleaning product in accordance with your local regulation.

Handling conditions

It is recommended to store and transport the Juvapen (Toxin) in its original packaging.

Operating conditions 0 - 2000 m

Temperature: 15 °C to 30 °C

Humidity: 60% RH AT 30 °C non-condensing

Transport conditions

Temperature: -20 °C to 40 °C

Humidity: 60% RH AT 30 °C non-condensing

Storage conditions

Temperature: -20 °C to 40 °C

Humidity: 60% RH AT 30 °C non-condensing

Assembly and use

Please refer to the assembly instructions drawings attached.

1. The battery is inserted by screwing it into the Juvapen (Toxin) (do not touch the keyboard while screwing).
2. Unpack the syringe and fill it with toxin in the desirable volume.
3. Break the plunger rod at the chosen volume of toxin.
4. Remove all air bubbles that might have accumulated in the syringe.
5. Connect the Toxinlink with the Juvapen (Toxin) until you hear the Click that indicates the proper attachment with the device.
6. To attach the syringe to the Toxinlink, rotate the syringe onto the bayonet mount. It is properly attached when it is aligned with the device and you feel a firm click.
7. Turn on the device by pressing the button (bottom green light indicates the device is switched on)
8. Attach the needle to the syringe and remove its protection.
9. Select the continuous flow mode, indicated by an orange triangle and orange light.
10. Remove the air from the syringe and prime the needle by pressing on the activation lever, keep on pressing until it removes all the air.
11. Select the desirable dosage by choosing the correct volume (blue led indicates the selected dosage in milliliter).
12. The injection can be performed by pressing the Toxinlink lever and the Juvapen (Toxin) will execute the dosage option.
13. Replace the needle protection.
14. Rotate the syringe from the syringe holder in order to remove it and then discard the syringe and the needle.
15. Select the rewind mode (indicated by an upside down orange arrow and orange light) – If you have completely injected the contents of the syringe, Juvapen will automatically go into Rewind mode.
16. Press Toxinlink lever once to rewind the lead screw to its original position.

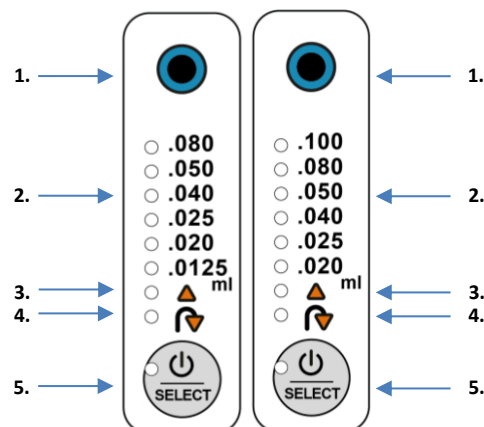
The Device Control Buttons and Control Lights

1. Activation Button – activated by pressing the syringe holder/ Toxinlink lever.
2. Dosage in ml and blue light indicator for each
3. Continuous flow and orange light indicator
4. Rewind mode and orange light indicator
5. Device ON/OFF button, Select button, and status light indicator.

Status Light Color	Continuous or Flashing	Indication	Recommended action
Green	Continuous	Ready to use	Normal use of the device
Orange	Continuous	Warning: End of battery life	Consider changing battery
Orange	Flashing	Piston to its end-point <i>Occlusion of the needle</i>	Juvapen will automatically go into Rewind mode. Press Toxinlink lever once to return the lead screw to its original position. <i>Change the needle</i>
Red	Flashing	Defective Sensor	Contact Juvaplus
Red	Continuous	End of battery life	Change the battery

Model 0.0125-0.080

Model 0.020-0.100



Warranty

The warranty period for the Juvapen (Toxin) is 24 months from the date of purchase.

Description du dispositif et du consommable

Juvapen (Toxine)

Le Juvapen (Toxine) est un système d'injection sans fil motorisé, alimenté par une pile au lithium. Le Juvapen (Toxine) est un dispositif non stérile destiné à assister le praticien certifié pour l'injection de toxine Botulique. Après avoir attaché le porte-seringue (Toxinlink) sur le dispositif, le praticien insère simplement la seringue spécifique de 1mL sur le porte-seringue. Une fois le Juvapen (Toxine) correctement assemblé, le praticien appuie sur la partie supérieure du levier du porte-seringue pour délivrer une dose précise en mode goutte ou continu. Le Juvapen (Toxine) est destiné seulement à l'injection de toxine botulique.

Porte-seringue / Toxinlink

Le Toxinlink a été conçu pour améliorer la préhension de la seringue, offrant à l'utilisateur une plus grande liberté d'action pendant l'injection. Le Toxinlink permet d'injecter avec une faible force d'activation grâce au levier ou une force plus élevée en pressant directement sur le porte-seringue. Le Toxinlink est seulement compatible avec la seringue fournie. Le Toxinlink est compatible exclusivement avec le Juvapen (Toxine).

Avantages du Juvapen (Toxine)

Pour le patient:

- Significativement moins de douleur.
- Des injections hautement précises.
- Une réduction des effets secondaires.

Pour le praticien:

- Un design ergonomique et agréable pour davantage de confort.
- Un système intuitif et facile à utiliser.
- Un contrôle optimisé pendant la procédure : profondeur de l'injection, une injection homogène et un dosage précis.
- Une grande précision dans les dosages.

Précautions and recommandations

Précautions d'utilisation: veuillez lire avec attention le mode d'emploi et prendre les mesures de sécurité appropriées pour effectuer une injection avec succès.

- Seul un praticien qualifié et expérimenté doit utiliser le Juvapen (Toxine).
- L'utilisation du Juvapen (Toxine) et les résultats obtenus sont la responsabilité exclusive du praticien.
- Le praticien est le seul à pouvoir évaluer les indications et contre-indications concernant la technique à employer, le produit à être administré et le choix approprié de l'aiguille à utiliser.
- Dans tous les cas, le praticien médical ne doit utiliser le Juvapen (Toxine) qu'après s'être familiarisé avec le dispositif et les supports d'information fournis, y compris son mode d'emploi.
- Seules les seringues de 1mL fournies sont recommandées par le fabricant.
- La seringue du Juvapen (Toxine) et son porte-seringue sont à utiliser pour un patient unique. En disposer immédiatement après utilisation dans une poubelle destinée à cet effet. A ne pas utiliser si l'emballage est ouvert ou endommagé.

Effets indésirables et contre-indications

Il est de l'entière responsabilité du praticien de lire et suivre le mode d'emploi afin d'éviter des effets indésirables ou plaintes. Des effets secondaires peuvent apparaître suite à l'utilisation conjointe de produits (toxine Botulique, seringue, canule, etc.) avec le Juvapen (Toxine). Il est de l'entière responsabilité du praticien de vérifier et suivre les instructions d'utilisation des produits utilisés avec le Juvapen (Toxine).

Recommandations générales

- Garder le Juvapen (Toxine) hors de portée des enfants.
- Le dispositif ne peut être utilisé en présence de mélange inflammable d'air, oxygène ou nitrogène.
- Conserver le Juvapen (Toxine) à l'abri de la chaleur et d'une exposition directe au soleil.
- Garder le Juvapen (Toxine) éloigné de l'eau ou de produit chimique.
- Toujours vérifier que le dispositif fonctionne correctement avant utilisation.
- Si le Juvapen (Toxine) est endommagé, il doit être retourné à Juvaplus SA (se référer à la Garantie).
- Si la lumière du bouton On/Off passe à l'orange, changer la pile.
- Le Juvapen (Toxine) s'éteint automatiquement au bout de 2 minutes lorsqu'il n'est pas utilisé.
- Les porte-seringues sont destinés à l'usage exclusif avec le Juvapen (Toxine) et ne peuvent par conséquent pas être utilisés avec d'autres dispositifs tiers.
- Ne pas utiliser d'autres piles que celles fournies par Juvaplus SA. Endommager le Juvapen (Toxine) par l'utilisation de batteries tierces annule la garantie.
- Ne pas stériliser le Juvapen (Toxine), le porte-seringue ni la pile.
- Le port de gants à usage unique est recommandé pendant l'utilisation du dispositif.
- Aucune altération du dispositif n'est permise.
- Jeter la pile conformément aux règles environnementales en vigueur.
- Ne pas jeter le Juvapen (Toxine), mais le retourner à Juvaplus SA.
- Ne pas utiliser le Juvapen (Toxine) près d'équipements générant un champ électromagnétique.
- Utiliser uniquement les seringues fournies par Juvaplus SA.

Accessoires

Capuchon et pile Lithium 6V /170 mAh

Le Juvapen (Toxine) doit être utilisé uniquement avec une pile certifiée IEC60086-4

Toxinlink

Toxinlink: Plastique PC Makrolon 2458

Nettoyage

Après chaque utilisation, le Juvapen (Toxine) doit être nettoyé avec un agent approprié. Ne pas immerger le dispositif ou ses composants. Nous recommandons l'utilisation d'un agent de nettoyage en fonction de vos réglementations locales.

Conditions de manipulation

Il est recommandé de conserver et transporter le Juvapen (Toxine) dans son emballage original.

Conditions d'utilisation 0 - 2000 m

Température: 15 °C to 30 °C

Humidité: 60% RH AT 30 °C non-condensée

Conditions de transport

Température: -20 °C to 40 °C

Humidité: 60% RH AT 30 °C non-condensée

Conditions de stockage

Température: -20 °C to 40 °C

Humidité: 60% RH AT 30 °C non-condensée

Assemblage et utilisation

Veuillez vous référer au guide de prise en main ci-joint.

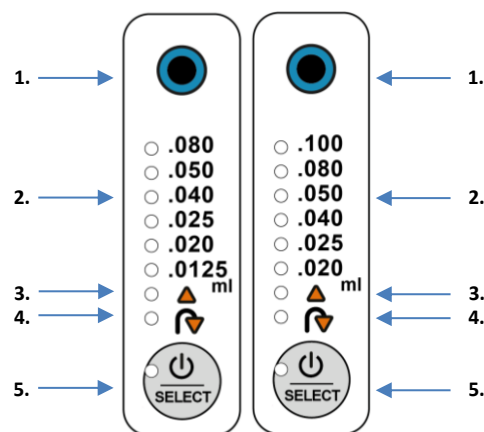
1. La pile se visse dans le Juvapen (Toxine) (ne pas toucher le clavier).
2. Déballez la seringue et la remplissez avec la quantité souhaitée de toxine.
3. Casser le piston au niveau du volume désiré.
4. Retirer les bulles d'air dans la seringue.
5. Connecter le Toxinlink au the Juvapen (Toxine) jusqu'à entendre un clic qui confirme le bon maintien.
6. Pour attacher la seringue au Toxinlink, pivoter la seringue dans la baïonnette. Le bon maintien est assuré quand les oreilles de la seringue sont alignées avec le dispositif.
7. Allumer le dispositif en appuyant sur le bouton du bas (la lumière verte confirme que le Juvapen (Toxine) est bien allumé).
8. Attacher l'aiguille à la seringue et retirer sa protection.
9. Sélectionner le mode continu, indiqué par une lumière orange à côté du triangle orange.
10. Retirer l'air de la seringue et remplir l'aiguille en appuyant sur le levier d'activation jusqu'à ce que tout l'air soit évacué.
11. Sélectionner la dose désirée en choisissant le volume ad hoc (une lumière bleue indique la dose choisie en millilitres).
12. L'injection peut être effectuée en appuyant sur le levier du Toxinlink et le Juvapen (Toxine) délivrera la dose sélectionnée.
13. Une fois la seringue vide, remettre en place la protection de l'aiguille.
14. Faire pivoter la seringue pour l'enlever et la jeter avec l'aiguille.
15. Sélectionner le mode retour (indiqué par une flèche orange inversée et une lumière orange) – Si la seringue a été complètement vidée, le Juvapen (Toxine) passera automatiquement en mode retour.
16. Appuyer une fois sur le levier du Toxinlink pour ramener la vis en position originale.

Les boutons de contrôle et les indicateurs lumineux

1. Bouton d'activation – activé en appuyant sur le porte-seringue.
2. Dosage en ml et indicateur lumineux bleu pour chaque dose.
3. Débit continu et indicateur lumineux orange
4. Mode retour et indicateur lumineux orange
5. Bouton Marche/Arrêt, sélection, et indicateur lumineux de statut.

Indicateur de statut	Continu ou clignotant	Indication	Action recommandée
Vert	Continu	Prêt à être utilisé	Utilisation normale
Orange	Continu	Attention : batterie en fin de vie	Batterie à remplacer bientôt
Orange	Clignotant	Piston en butée <i>Occlusion de l'aiguille</i>	Juvapen passe automatiquement en mode retour. Appuyer sur le levier pour ramener la vis en position originale. <i>Changer l'aiguille</i>
Rouge	Clignotant	Capteur défectueux	Contactez Juvaplus
Rouge	Continu	Batterie à remplacer	Changer la pile

Model 0.0125-0.080 Model 0.020-0.100



Garantie

Le Juvapen (Toxine) est garanti 2 ans à partir de la date d'achat.

Electromagnetic compatibility

The essential performance of the Juvapen (Toxin) is to deliver the following dosages:

Model	Available doses
0.0125-0.080	0.0125-0.020-0.025-0.040-0.050-0.080ml
0.020-0.100	0.020-0.025-0.040-0.050-0.080-0.100ml



WARNING:

The Juvapen (Toxin) is compliant with standard IEC 60601-1-2:2014, 4rd edition (Group 1, Class A according to CISPR 11). It needs special precautions regarding EMC and must be installed and put into service according to the EMC information provided in this document. Please note that portable and mobile RF communication equipment can affect the Juvapen (Toxin) System.



WARNING:

The Juvapen (Toxin) should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Juvapen (Toxin) should be carefully observed to verify normal operation for use in the particular configuration.

Table 1. Guidance and Manufacturer's declaration – electromagnetic emissions


The Juvapen (Toxin) is intended for use in the electromagnetic environment specified below. The customer or the user of the Juvapen (Toxin) should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Juvapen (Toxin) uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class A	The Juvapen (Toxin) is suitable for use in all establishments other than domestic or those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 Guidance and manufacturer's declaration – electromagnetic immunity

The Juvapen (Toxin) is intended for use in the electromagnetic environment specified below. The customer or the user of the Juvapen (Toxin) should ensure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the The Juvapen (Toxin) requires continued operation during power mains interruption, it is recommended that the The Juvapen (Toxin) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

NOTE U_T is the AC. mains voltage prior to application of the test level.

Table.3. Guidance and manufacturer's declaration – electromagnetic immunity














The Juvapen (Toxin) is intended for use in the electromagnetic environment specified below. The customer or the user of the Juvapen (Toxin) should ensure that it is used in such an environment.			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment including cables should not be used closer to any part of the Juvapen (Toxin) than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter (see below). Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, that are determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a	Field strengths from fixed transmitters, such as base stations for radios (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Juvapen (Toxin) is used exceeds the applicable RF compliance level above, the Juvapen (Toxin) should be inspected to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Juvapen (Toxin).
b	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4 Recommended separation distances between portable and mobile RF communications equipment and the Juvapen (Toxin)

The Juvapen (Toxin) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Juvapen (Toxin) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications can help prevent equipment (transmitters) and the Juvapen (Toxin) as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of the transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Legend, Légende

Juvapen (Toxin)	Trade Name Nom du dispositif
Model	Device model Modèle du dispositif
	Pen Serial Number Numéro de série du dispositif
	Manufacturing date Date de fabrication
	Do not expose to sunlight Ne pas exposer à la lumière directe
	Keep Dry Garder au sec
	Caution Attention
	Read user manual Lire la notice d'utilisation
	Non Sterile Non-stérile
	Type BF applied part Pièce appliquée de type BF
	Temperature limitation (-20°C/+40°C) Limitation de température (-20°C/+40°C)
To view instructions for use please consult our website: www.juvaplus.com	Where to find IFU Où trouver le mode d'emploi
	CE marking with notified body number Marquage CE avec le numéro de l'organisme de certification
	Manufacturer address Adresse du fabricant
	Interference may occur in the vicinity of equipment marked with the following symbol. Des interférences peuvent se produire à proximité d'un appareil marqué du symbole suivant.
	Single use (Syringe holder) Usage unique (porte-seringue)

