УТВЕРЖДАЮ

Генеральный директор

ООО «Кея Энд Бьюти»

_____ Тарасова А.И.

«04» августа 2023 г.

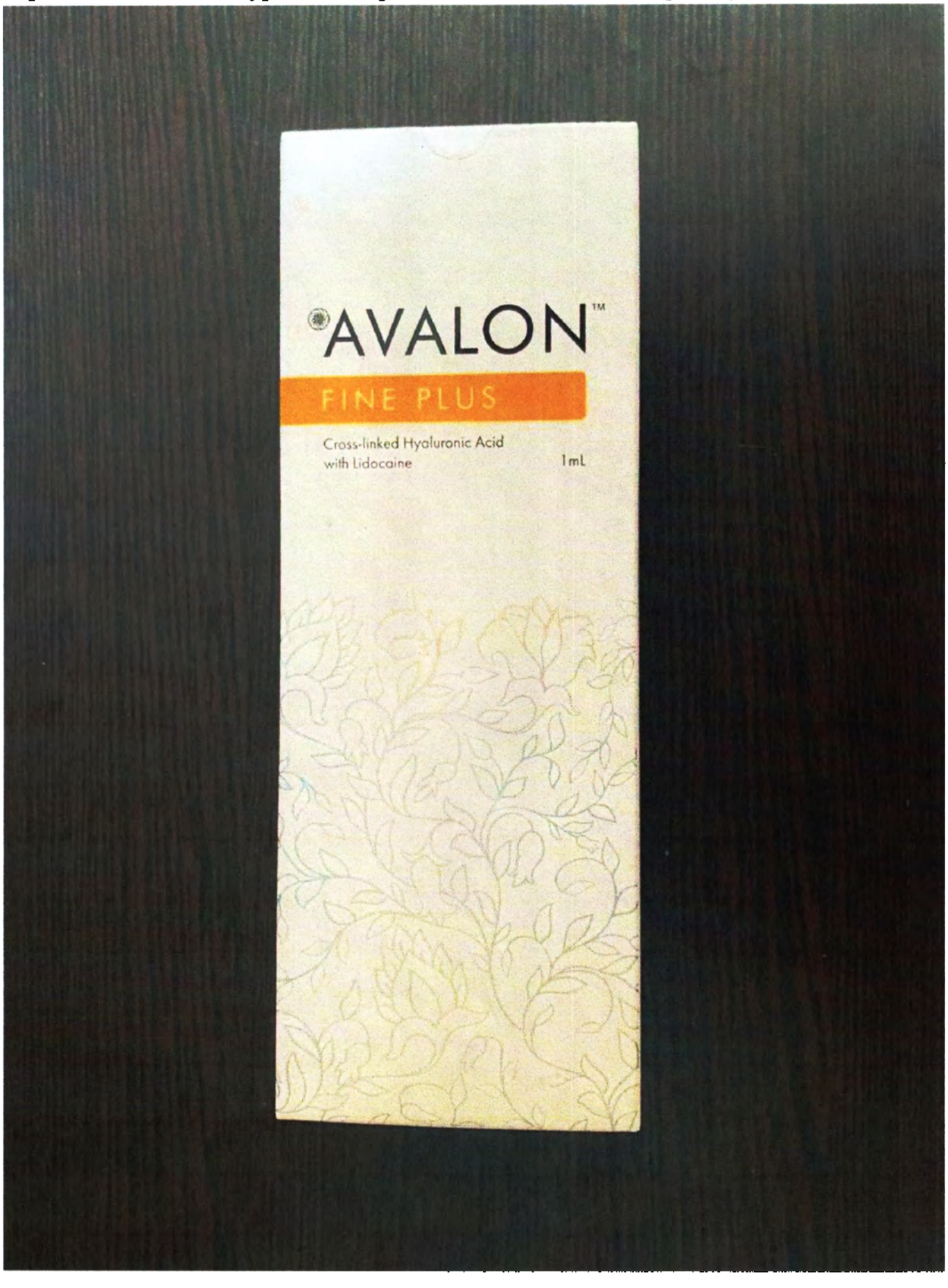
ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ ИЗДЕЛИЯ:

Филлер внутридермальный AVALON™ объемом 1.0 мл, производства Koru Pharma Co.,Ltd/ («Кору Фарма Ко.,Лтд»), Корея

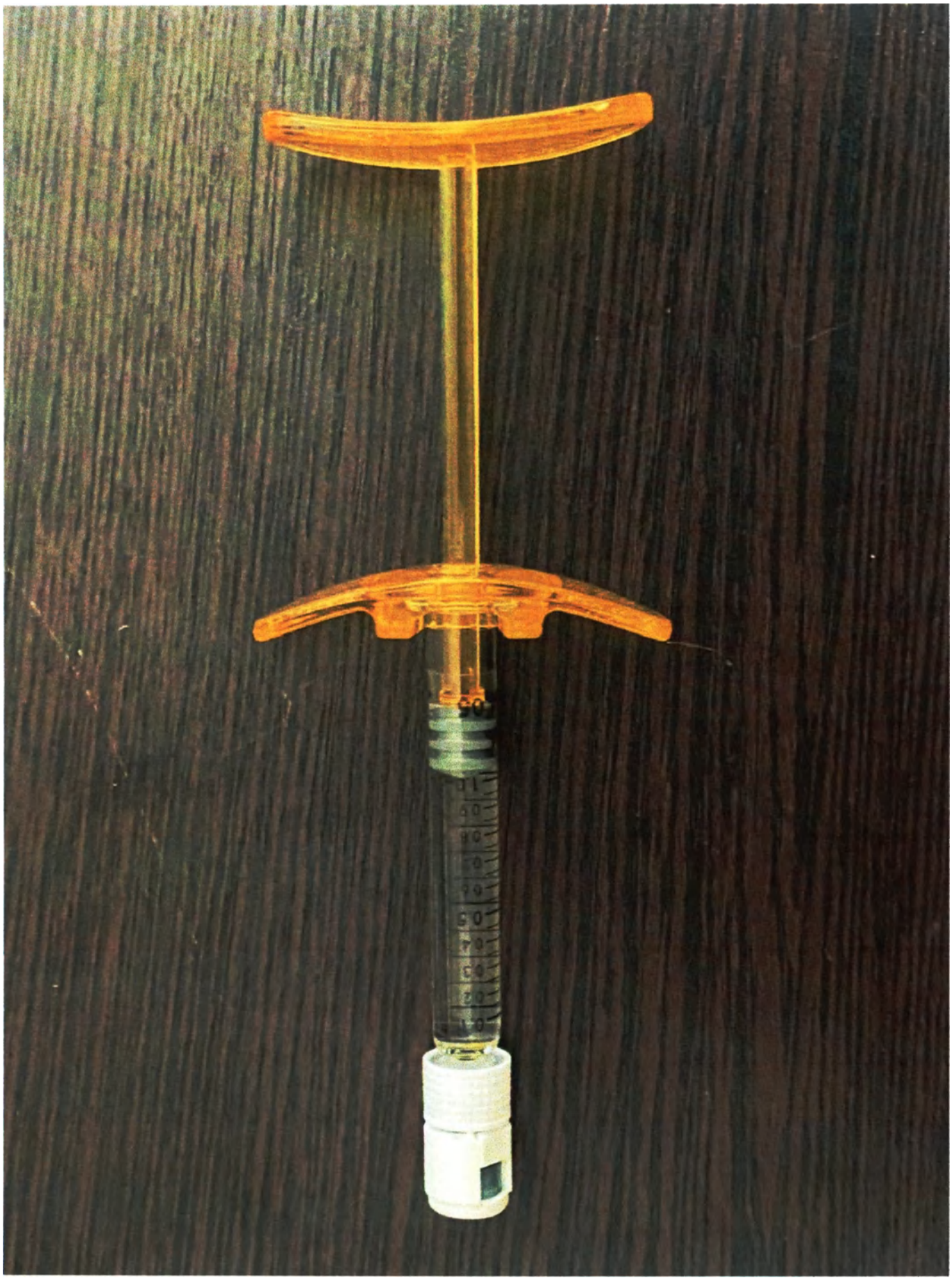
2023

Оглавление

1 Филлер внутридермальный AVALONTM FINE PLUS объемом 1.0 мл [2,0% поперечно-сшитого гиалуроната натрия + 0,3% лидокаина гидрохлорида], в составе:



1.1 -Шприц объёмом 1,0 мл, заполненный гелем на основе гиалуроновой кислоты и лидокаина - 1 шт.;



1.2 -Игла 30G 1/2", производитель "Джапан Био Продактс Ко., Лтд.", место производства Feel Tech Co., Ltd., Корея - 2 шт.;

1.3 -Этикетка съемная для карты пациента -2 шт.;

1.4 -Инструкция по применению.

AVALON™ FINE PLUS
INSTRUCTIONS FOR USE

COMPOSITION

Cross linked Hyaluronic Acid	20 mg/mL
Lidocaine Hydrochloride	3 mg/mL
Phosphate-buffered Saline	q.s.

One syringe contains 1.0 mL of **AVALON™ FINE PLUS**

DESCRIPTION

AVALON™ FINE PLUS is a sterile, transparent, pyrogen-free viscoelastic gel of cross-linked non animal origin hyaluronic acid with the addition of 0.3% (w/v) lidocaine hydrochloride. This product is presented in a pre-filled, disposable glass syringe with a volume of 1.0 mL for single use only.
Each box of **AVALON™ FINE PLUS** contains one 1.0 mL pre-filled syringe, sterile 30 G ½" disposable needles, an instruction leaflet.

STERILIZATION

The contents of the **AVALON™ FINE PLUS** syringe are sterilized by steam and dry heat.
The provided needles are sterilized by EO gas.

INTENDED USE

Used to temporarily improve facial wrinkles for adults through physical restoration by injecting cross-linked hyaluronic acid containing lidocaine into (subcutaneous/ dermis/ subcutaneous fat layer).

INDICATIONS

AVALON™ FINE PLUS is designed to be injected into the superficial dermis for the correction of fine wrinkles and facial lines (such as crow's feet or perioral wrinkles). The presence of lidocaine is meant to reduce the patient's discomfort during treatment.

CONTRAINDICATIONS

- Do not inject **AVALON™ FINE PLUS** into the periorbital area
- Do not inject into the blood vessels
- Do not overcorrect

AVALON™ FINE PLUS must not be used in:

» patients who showed anaphylaxis to raw materials of filler
» patients who have a history of serious allergy or anaphylaxis
» patients with bleeding disorders
» patients taking thrombolytic agents or anticoagulants
» patients who tend to develop keloids, hyperpigmentation or hypersensitivity to lidocaine or to amide-type local anesthetics
» patients who have a history of autoimmune diseases
» patients who are known to be hypersensitive to Hyaluronic acid
» patients who have a coagulation disorder
» patients who have a history of Streptococcus diseases
» patients who have acute rheumatic fever with heart complications
» women who are pregnant or breast-feeding
» children.

AVALON™ FINE PLUS must not be injected into areas with inflammatory and/or infectious problems

AVALON™ FINE PLUS must not be used in association with treatment such as laser therapy, chemical peeling or dermabrasion.

PRECAUTIONS FOR USE

- **AVALON™ FINE PLUS** must be administered by medical professionals who have undertaken specific training in the injection technique for filling.
- Before beginning treatment, patients must be informed of product's indications, contraindications, incompatibilities and potential undesirable effects.
- Do not use **AVALON™ FINE PLUS** for injections other than intra-dermal injections.
- **AVALON™ FINE PLUS** may cause serious side effects like blindness when injected into blood vessels. It is highly recommended to inject cautiously into thin skin areas due to the increased possibility of injecting into blood vessels especially around the periorbital area.
- **AVALON™ FINE PLUS** must be injected into healthy, non-inflamed and disinfected skin. There is no establishment of safety and expiry date in controlled clinical trials.
- Avoid injecting into an area where permanent implants have been made.
- Patients who show a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to a dual test before any injection is administered.
- Patients who are undergoing anti-coagulant treatment must be warned of the increased risk of hematomas and bleeding during the injection.
- It is highly recommended to avoid taking aspirin of high doses or vitamin C the week before injection.
- It is highly recommended not to apply make-up for 24 hours after injection and to avoid prolonged exposure to sunlight, UV light, cold temperatures, using saunas or steam baths for two weeks after injection.
- It is very important that the needle is properly assembled to the syringe. Improper assembly may cause separation of the needle and syringe during injection.
- If the needle is blocked, do not increase the pressure on the plunger rod, but stop the injection and replace the needle.
- Athletes should be made aware that this product contains an active principle that may produce a positive result in anti-doping tests.
- Medical practitioners must take into account the fact that this product contains lidocaine.
- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine (more than 400 mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.
Therefore, **AVALON™ FINE PLUS** should never be placed in contact with such substances with medical surgical instrumentation which has been treated with this type of substance.
There has been no registered case of using the product in conjunction with other medicine or equipment.
There has been no verified medical result of injecting into an area that has previously been treated within another filler.

UNDESIRABLE EFFECTS

- Before treatment, medical practitioners must inform the patient that potential side effects associated with use of **AVALON™ FINE PLUS** can occur immediately or may be delayed. These include, but are not limited to, etc.) that may be associated to itching, pain due to pressure can occur following injection.
These reactions may last a few hours, days and in some cases for a week:
– Local bleeding or hematomas in the injected area
– Induration, staining and poor effect at the injection site
– Cases of necroses in the glabella region, granuloma, hypersensitivity and abscess formation have been reported for other products after the injection of Hyaluronic acid.
- Patients must report all secondary reactions which persist for more than one week to a medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
- The following undesirable effects associated with lidocaine injections have been reported:
– Shock: Medical practitioners must do close observation for occuring shock. If patients show decreased blood pressure, pallor of face, abnormality of pulse, respiratory depression, etc., the medical practitioner should discontinue the injection as soon as possible and use an appropriate treatment.
– Malignant hyperthermia: Severe malignant hyperthermia accompanied by cryptogenic tachycardia, arrhythmia, blood pressure fluctuation, rapid increase of body temperature, muscle rigidity, cyanosis, hyperventilation, diaphoresis, acidosis and/or hyperkalemia, myoglobinuria (erythruhia) may occur rarely.
Treatment should be stopped immediately if these symptoms appear when **AVALON™ FINE PLUS** injection is administered and then use an appropriate treatment (intravenous injection of dantrolene sodium, general hyperthermy, hyperventilation by pure oxygen, correction of acid-base equilibrium, etc.). In this case, urine output should be monitored because these symptoms can lead renal failure.
– Central nervous system:
1. Medical practitioners must do close observation for occurring tremors, convulsion, etc. Treatment should be stopped immediately if these symptoms appear and then use an appropriate treatment (diazepam, ultrashort-acting barbiturate, thiopental sodium, etc.).

* Medical practitioners must do close observation for occurring somnolence, anxiety, irritability, inattention, dizziness, nausea, vomiting, etc. and then use an appropriate treatment if necessary.
- Anaphylaxis: Skin symptoms such as urticaria or swelling may occur.

METHOD OF USE - POSOLOGY

• Preparations before use:
– Before the first treatment session, it is recommended to contact your local representative or distributor for more information about injection techniques and training opportunities
– Check the expiry date on the product label
– Check the package for any damage
– Before beginning treatment, the patient must be informed of product's indications, contraindictions, incompatibilities and potential undesirable effects
– Medical practitioners must understand and read the instructions
– **AVALON™ FINE PLUS** is to be used as supplied. Modification or use of the product outside the Instructions for use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.
• Method of use:
– The area to be treated must be disinfected properly before injection
– Separate the cap from the luer lock completely (Fig.1)
– Hold the luer lock area, turn the injection needle clockwise until firmly fixed (Fig.2)
– Make sure the needle is fixed tightly (Fig.3 and Fig.4)
– Remove the needle cap (Fig.5)
– Inject the needle into treatment area and start the injection slowly into the dermis, the quantity to inject depends on the area to be corrected
– After injections, the medical practitioner should gently massage the treated area immediately.
• Storage and control after use:
The product is disposable, discard the syringe and remaining product after use.

WARNING

- Check the expiry date on the product label
- Do not use if package is damaged
- Do not re-sterilize
- Do not re-use
- Do not use with another filling product
- Discard the syringe and remaining product after use

STORAGE CONDITIONS

- Store between 1 °C and 30 °C
- Fragile
- Protect from freezing, heat, and sunlight

EXPIRY DATE

Indicated on package

SYMBOLS

	Do not re-use
	Read instructions for use
	Caution, refer to instructions for use
	Fragile item, handle carefully
	Do not expose to sunlight
	Temperature limitation (1 °C and 30 °C)
	Use by date
LOT	Batch code
STERILE R	Moist heat sterilization
STERILE EO	Ethylene Oxide sterilization
	Do not re-sterilize
	Do not use if package is damaged
	Manufacturer
	Keep dry

Fig.1

Fig.2

Fig.3 Fig.4

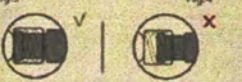


Fig.5

Kora Pharmaceuticals Co., Ltd.
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+82-70-4651-5197
www.korupharma.com info@korupharma.com

Rev. No. AVA-FIN-P-20220120-05

AVALON™

FINE PLUS

Cross-linked Hyaluronic Acid with Lidocaine 1 mL

2 Филлер внутридермальный AVALON™ GRAND PLUS объемом 1.0 мл [2,4% поперечно-сшитого гиалуроната натрия + 0,3% лидокаина гидрохлорида], в составе:

2.1 -Шприц объёмом 1,0 мл, заполненный гелем на основе гиалуроновой кислоты и лидокаина - 1 шт.;

2.2 -Игла 25G 1/2", производитель "Джапан Био Продактс Ко., Лтд.", место производства Feel Tech Co., Ltd., Корея - 2 шт.;

2.3 -Этикетка съемная для карты пациента -2 шт.;

2.4 -Инструкция по применению.

AVALON™ GRAND PLUS
INSTRUCTIONS FOR USE

COMPOSITION

Cross-linked Hyaluronic Acid
Lidocaine Hydrochloride
Phosphate-buffered Saline
One syringe contains 1.0 mL of AVALON™ GRAND PLUS

DESCRIPTION

AVALON™ GRAND PLUS is a sterile, transparent, pyrogen-free viscoelastic gel of cross-linked non-animal origin Hyaluronic acid with the addition of 0.3% (w/v) lidocaine hydrochloride. This product is presented in a pre-filled, disposable glass syringe with a volume of 1.0 mL for single use only.
Each box of AVALON™ GRAND PLUS contains one 1.0 mL pre-filled syringe, two sterile 25 G ½" disposable needles, an instruction leaflet.

STERILIZATION

The contents of the AVALON™ GRAND PLUS syringe are sterilized by steam and dry heat.
The provided needles are sterilized by EO gas.

INTENDED USE

Used to temporarily improve facial wrinkles for adults through physical restoration by injecting cross-linked hyaluronic acid containing lidocaine into subcutaneous dermis (subcutaneous tier layer).

INDICATIONS

AVALON™ GRAND PLUS is intended to be used for facial augmentation. It is indicated for injection into the deep dermis for the correction of moderate to severe facial wrinkles and folds, cheeks, chin augmentation and shaping of the contours of the face and lipvine. The presence of lidocaine is meant to reduce the patient's discomfort during treatment.

CONTRAINDICATIONS

- Do not inject AVALON™ GRAND PLUS into the periorbital area
- Do not inject into the blood vessels
- Do not overcorrect

AVALON™ GRAND PLUS must not be used in:

- patients who showed anaphylaxis to raw materials of filler
- patients who have a history of serious allergy or anaphylaxis
- patients with bleeding disorders
- Patients taking thrombolytic agents or anticoagulants
- patients who tend to develop keloids
- patients who have a history of hypersensitivity to lidocaine hyperpigmentation or hypersensitivity to lidocaine or to amide-type local anesthetics
- patients who have a history of autoimmune diseases
- patients who are known to be hypersensitive to Hyaluronic acid
- patients who have a coagulation disorder
- patients who have a history of Streptococcus diseases
- patients who have acute rheumatic fever with heart complications
- women who are pregnant or breast-feeding
- children

AVALON™ GRAND PLUS must not be injected into areas with inflammatory and/or infectious problems.
AVALON™ GRAND PLUS must not be used in association with treatment such as laser therapy, chemical peeling or dermabrasion.

PRECAUTIONS FOR USE

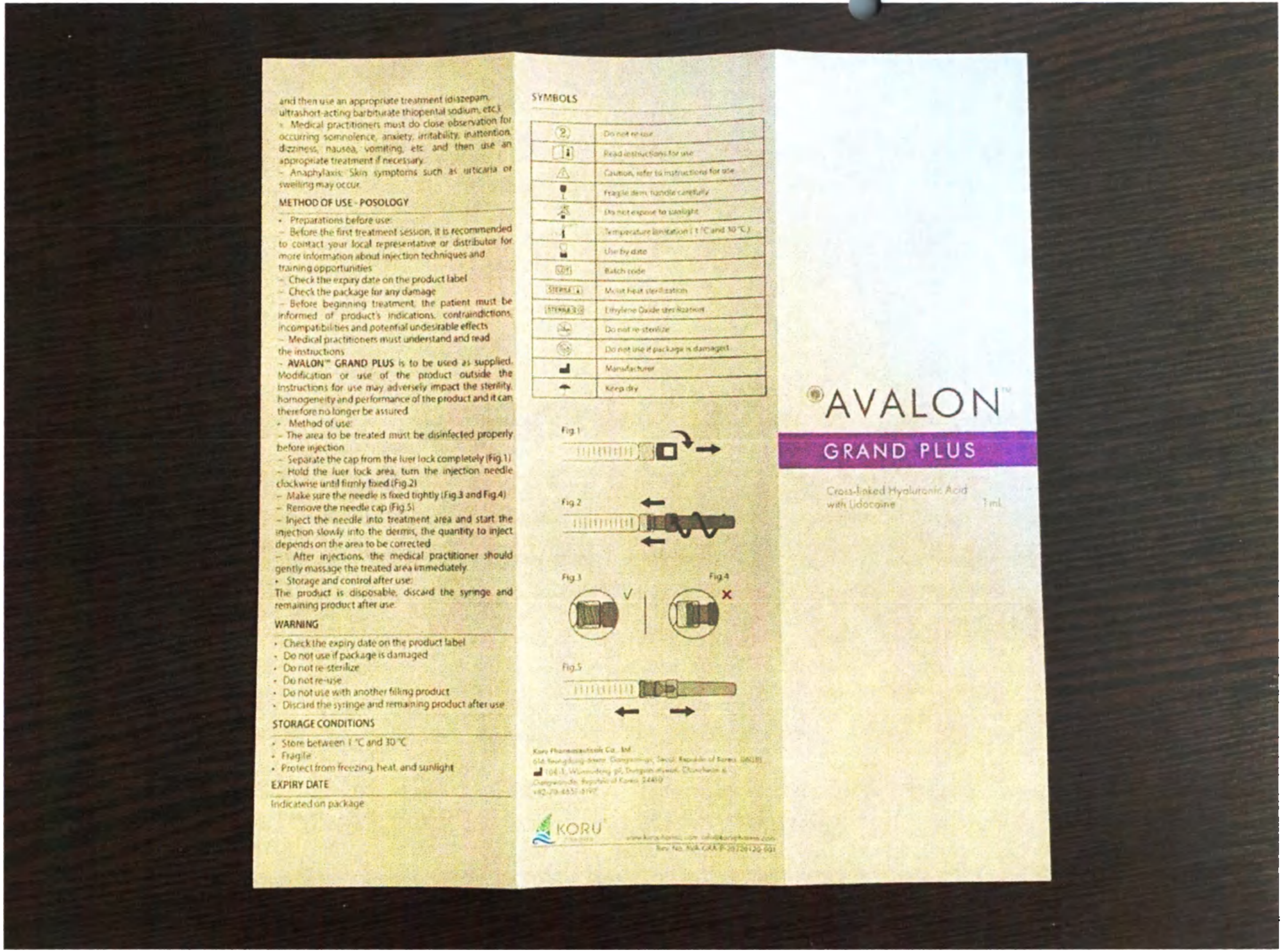
- AVALON™ GRAND PLUS must be administered by medical professionals who have undertaken specific training in the injection technique for filling.
- Before beginning treatment, patients must be informed of product's indications, contraindications, incompatibilities and potential undesirable effects.
- Do not use AVALON™ GRAND PLUS for injection other than intra-dermal injections.
- AVALON™ GRAND PLUS may cause serious side effects like blindness when injected into blood vessels. It is highly recommended to inject cautiously into thin skin areas due to the increased possibility of injecting into blood vessels especially around the periorbital area.
- AVALON™ GRAND PLUS must be injected into healthy, non-inflamed and disinfected skin. There is no establishment of safety and expiry date in controlled clinical trials.
- Avoid injecting into an area where permanent implants have been made.
- Patients who show a history of streptococcal disease, recurrent sore throats, acute rheumatic fever) shall be subjected to a dual test before any injection.
- Patients who are undergoing anti-coagulant treatment must be warned of the increased risk of hematomas and bleeding during the injection.
- It is highly recommended to avoid taking aspirin of high doses or vitamin C the week before injection.
- It is highly recommended not to apply make up for 24 hours after injection and to avoid prolonged exposure to sunlight, UV light, cold temperatures, using saunas or steam baths for two weeks after injection.
- It is very important that the needle is properly assembled to the syringe. Improper assembly may cause separation of the needle and syringe during injection.
- If the needle is blocked, do not increase the pressure on the plunger rod, but stop the injection and replace the needle.
- Athletes should be made aware that this product contains an active principle that may produce a positive result in anti-doping tests.
- Medical practitioners must take into account the fact that this product contains lidocaine.
- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine (more than 400 mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.
patients who have acute rheumatic fever with heart complications
AVALON™ GRAND PLUS should never be placed in contact with such substances with medical-surgical instrumentation which has been treated with this type of substance.
There has been no registered case of using the product in conjunction with other medicine or equipment.
There has been no verified medical result of injecting into an area that has previously been treated with another filler.

UNDESIRABLE EFFECTS

- Before treatment, medical practitioners must inform the patient that potential side effects associated with use of AVALON™ GRAND PLUS can occur immediately or may be delayed. These include, but are not limited to:
- Inflammatory reactions (redness, oedema, erythema, etc.) that may be associated to itching, pain due to pressure can occur following injection.
These reactions may last a few hours, days and in some cases for a week.
- Local bleeding or hematomas in the injected area
- Induration, staining and poor effect at the injection site
- Cases of necroses in the glabella region, granulomas, hypersensitivity and abscess formation have been reported for other products after the injection of Hyaluronic acid.
- Patients must report all secondary reactions which persist for more than one week to a medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
- The following undesirable effects associated with lidocaine injections have been reported:
- Shock. Medical practitioners must do close observation for occurring shock if patients show decreased blood pressure, pallor of face, abnormality of pulse, respiratory depression, etc., the medical practitioner should discontinue the injection as soon as possible and use an appropriate treatment.
- Malignant hyperthermia. Severe malignant hyperthermia accompanied by Cryptogenic tachycardia, arrhythmia, blood pressure fluctuation, rapid increase of body temperature, muscle rigidity, Cyanosis, hyperventilation, diaphoresis, acidosis and/or hyperkalemia, myoglobinuria (erythruria) may occur rarely.
Treatment should be stopped immediately if these symptoms appear when AVALON™ GRAND PLUS injection is administered and then use an appropriate treatment (intravenous injection of dantrolene sodium, general hyperthermy, hyperventilation by pure oxygen, urine output should be monitored because these symptoms can lead renal failure.
- Central nervous system:
- Medical practitioners must do close observation for occurring tremors, convulsion, etc. Treatment should be stopped immediately if these symptoms appear



and then use an appropriate treatment (diazepam, ultrashort-acting barbiturate thiopental sodium, etc.)
- Medical practitioners must do close observation for occurring somnolence, anxiety, irritability, inattention, dizziness, nausea, vomiting, etc. and then use an appropriate treatment if necessary
- Anaphylaxis: Skin symptoms such as urticaria or swelling may occur.

METHOD OF USE - POSOLOGY

- Preparations before use:
- Before the first treatment session, it is recommended to contact your local representative or distributor for more information about injection techniques and training opportunities
- Check the expiry date on the product label
- Check the package for any damage
- Before beginning treatment, the patient must be informed of product's indications, contraindications, incompatibilities and potential undesirable effects
- Medical practitioners must understand and read the instructions
- **AVALON™ GRAND PLUS** is to be used as supplied. Modification or use of the product outside the instructions for use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured
- Method of use:
- The area to be treated must be disinfected properly before injection
- Separate the cap from the luer lock completely (Fig.1)
- Hold the luer lock area, turn the injection needle clockwise until firmly fixed (Fig.2)
- Make sure the needle is fixed tightly (Fig.3 and Fig.4)
- Remove the needle cap (Fig.5)
- Inject the needle into treatment area and start the injection slowly into the dermis, the quantity to inject depends on the area to be corrected
- After injections, the medical practitioner should gently massage the treated area immediately
- Storage and control after use:

The product is disposable, discard the syringe and remaining product after use.

WARNING

- Check the expiry date on the product label
- Do not use if package is damaged
- Do not re-sterilize
- Do not re-use
- Do not use with another filling product
- Discard the syringe and remaining product after use

STORAGE CONDITIONS

- Store between 1 °C and 30 °C
- Fragile
- Protect from freezing, heat, and sunlight

EXPIRY DATE

Indicated on package

SYMBOLS

	Do not re-use
	Read instructions for use
	Caution, refer to instructions for use
	Fragile item, handle carefully
	Do not expose to sunlight
	Temperature limitation (1 °C and 30 °C)
	Use by date
LOT	Batch code
STERILE	Moist heat sterilization
STERILE EO	Ethylene Oxide sterilization
	Do not re-sterilize
	Do not use if package is damaged
	Manufacturer
	Keep dry

Fig.1

Fig.2

Fig.3

Fig.4

Fig.5

Koru Pharmaceuticals Co., ltd

KORU

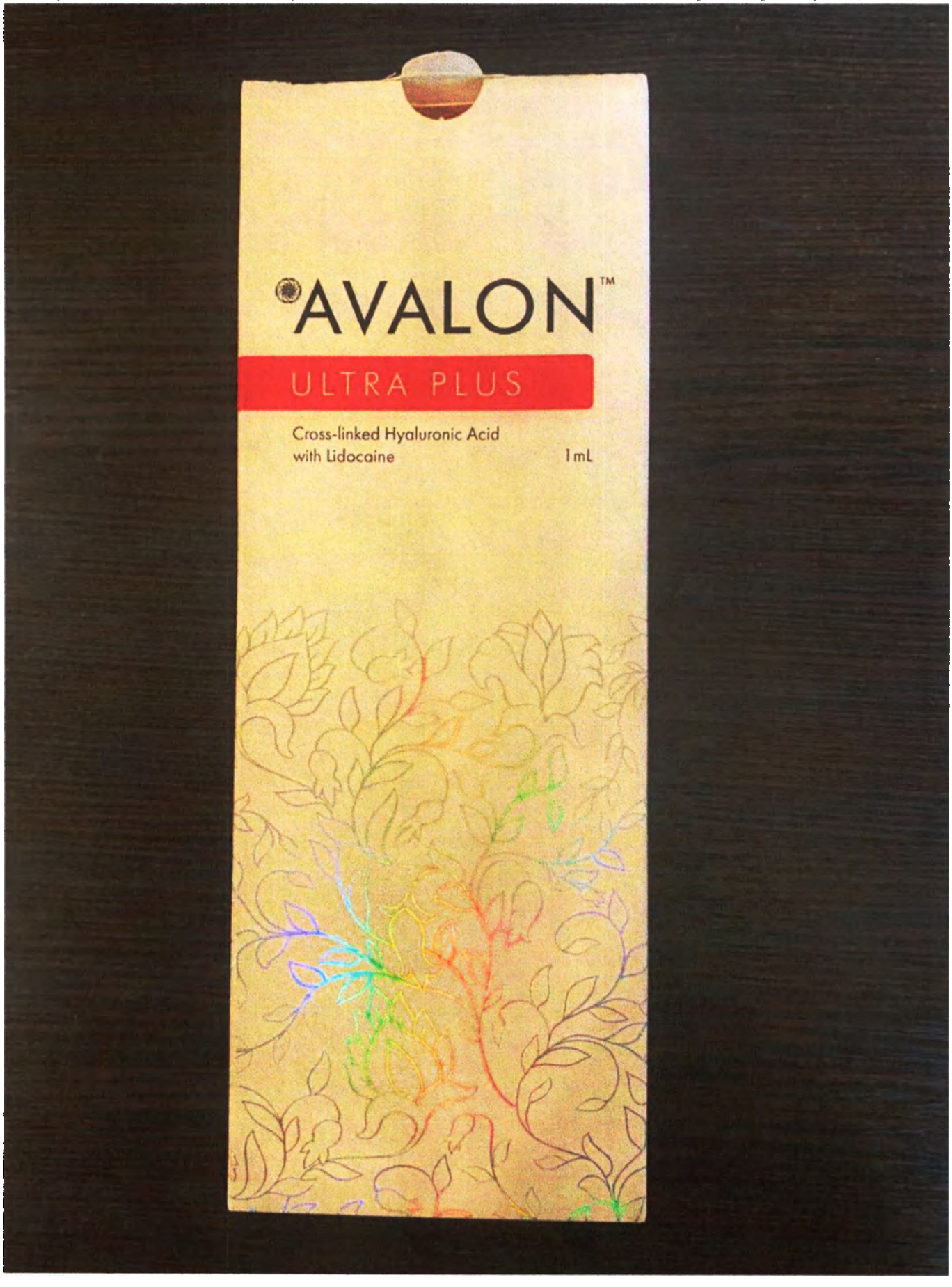
AVALON™

GRAND PLUS

Cross-linked Hyaluronic Acid with Lidocaine

1 mL

3 Филлер внутридермальный AVALONTM ULTRA PLUS объемом 1.0 мл [2,0% поперечно-сшитого гиалуроната натрия + 0,3% лидокаина гидрохлорида], в составе:



- Шприц объёмом 1,0 мл, заполненный гелем на основе гиалуроновой кислоты и лидокаина - 1 шт.;

3.1 -Игла 25G 1/2", производитель "Джапан Био Продактс Ко., Лтд.", место производства Feel Tech Co., Ltd., Корея - 1 шт.;

3.2 -Игла 27G 1/2", производитель "Джапан Био Продактс Ко., Лтд.", место производства Feel Tech Co., Ltd., Корея - 1 шт.;

3.3 -Этикетка съемная для карты пациента -2 шт.;

3.4 -Инструкция по применению.

AVALON™ ULTRA PLUS
INSTRUCTIONS FOR USE

COMPOSITION

Cross-linked Hyaluronic Acid	20 mg/mL
Lidocaine Hydrochloride	3 mg/mL
Phosphate-buffered Saline	q.s.

One syringe contains 1.0 mL of **AVALON™ ULTRA PLUS**

DESCRIPTION

AVALON™ ULTRA PLUS is a sterile, transparent, pyrogen-free viscoelastic gel of cross-linked non-animal origin Hyaluronic acid with the addition of 0.3% (w/v) lidocaine hydrochloride. This product is presented in a pre-filled, disposable glass syringe with a volume of 1.0 mL for single use only.
Each box of **AVALON™ ULTRA PLUS** contains one 1.0 mL pre-filled syringe, Sterile 25 G½ and 27 G½" disposable needles, an instruction leaflet

STERILIZATION

The contents of the **AVALON™ ULTRA PLUS** syringe are sterilized by steam and dry heat.
The provided needles are sterilized by EO gas.

INTENDED USE

Used to temporarily improve facial wrinkles for adults through physical restoration by injecting cross linked hyaluronic acid containing lidocaine into (subcutaneous/ dermis/ subcutaneous fat layer).

INDICATIONS

AVALON™ ULTRA PLUS is designed to be injected into the dermis for the treatment of mid-depth and deep wrinkles and folds on the face, cheeks, chin augmentation and shaping of the contours of the face. The presence of lidocaine is meant to reduce the patient's discomfort during treatment.

CONTRAINDICATIONS

- Do not inject **AVALON™ ULTRA PLUS**
  into the the periorbital area
- Do not inject into the blood vessels
- Do not overcorrect

AVALON™ ULTRA PLUS must not be used in:

- patients who showed anaphylaxis to raw materials of filler
- patients who have a history of serious allergy or anaphylaxis
- patients with bleeding disorders
- patients taking thrombolytic agents or anticoagulants
- patients who tend to develop keloids, hyperpigmentation or hypersensitivity to lidocaine or to amide-type local anesthetics
- patients who have a history of autoimmune diseases
- patients who are known to be hypersensitive to Hyaluronic acid
- patients who have a coagulation disorder
- patients who have a history of Streptococcus diseases
- patients who have acute rheumatic fever with heart complications
- children
- women who are pregnant or breast-feeding

AVALON™ ULTRA PLUS must not be injected into areas with inflammatory and/or infectious problems.
AVALON™ ULTRA PLUS must not be used in association with treatment such as laser therapy, chemical peeling or dermabrasion.

PRECAUTIONS FOR USE

- **AVALON™ ULTRA PLUS** must be administered by medical professionals who have undertaken specific training in the injection technique for filling.
- Before beginning treatment, patients must be informed of product's indications, contraindications, incompatibilities and potential undesirable effects.
- Do not use **AVALON™ ULTRA PLUS** for injections other than intra-dermal injections.
- **AVALON™ ULTRA PLUS** may cause serious side effects like blindness when injected into blood vessels. It is highly recommended to inject cautiously into thin skin areas due to the increased possibility of injecting into blood vessels especially around the periorbital area
- **AVALON™ ULTRA PLUS** must be injected into healthy, non-inflamed and disinfected skin. There is no establishment of safety and expiry date in controlled clinical trials.
- Avoid injecting into an area where permanent implants have been made
- Patients who show a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to a dual test before any injection
- Patients who are undergoing anti-coagulant treatment must be warned of the increased risk of hematomas and bleeding during the injection
- It is highly recommended to avoid taking aspirin of high doses or vitamin C the week before injection.
- It is highly recommended not to apply make-up for 24 hours after injection and to avoid prolonged exposure to sunlight, UV light, cold temperatures, using saunas or steam baths for two weeks after injection.
- It is very important that the needle is properly assembled to the syringe. Improper assembly may cause separation of the needle and syringe during injection.
- If the needle is blocked, do not increase the pressure on the plunger rod, but stop the injection and replace the needle.
- Athletes should be made aware that this product contains an active principle that may produce a positive result in anti-doping tests.
- Medical practitioners must take into account the fact that this product contains lidocaine.
- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine (more than 400 mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.
Therefore **AVALON™ ULTRA PLUS** should never be placed in contact with such substances with medical surgical instrumentation which has been treated with this type of substance.
There has been no registered case of using the product in conjunction with other medicine or equipment.
There has been no verified medical result of injecting into an area that has previously been treated within another filler.

UNDESIRABLE EFFECTS

- Before treatment, medical practitioners must inform the patient that potential side effects associated with use of **AVALON™ ULTRA PLUS** can occur immediately or may be delayed. These include, but are not limited to:
- Inflammatory reactions (redness, oedema, erythema, etc.) that may be associated to itching, pain due to pressure can occur following injection.
These reactions may last a few hours, days and in some cases for a week.
- Local bleeding or hematomas in the injected area
- Induration, staining and poor effect at the injection site
- Cases of necrosis in the glabella region, granulomas, hypersensitivity and abscess formation have been reported for other products after the injection of Hyaluronic acid.
- Patients must report all secondary reactions which persist for more than one week to a medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
- The following undesirable effects associated with lidocaine injections have been reported:
- Shock: Medical practitioners must do close observation for occurring shock. If patients show decreased blood pressure, pallor of face, abnormality of pulse, respiratory depression, etc., the medical practitioner should discontinue the injection as soon as possible and use an appropriate treatment.
- Malignant hyperthermia: Severe malignant hyperthermia accompanied by cryptogenic tachycardia, arrhythmia, blood pressure fluctuation, rapid increase of body temperature, muscle rigidity, cyanosis, hyperventilation, diaphoresis, acidosis and/or hyperkalemia, myoglobinuria, erythruria) may occur rarely.

Treatment should be stopped immediately if these symptoms appear when **AVALON™ ULTRA PLUS** injection is administered and then use an appropriate treatment (Intravenous injection of dantrolene sodium, general hyperthermy, hyperventilation by pure oxygen, correction of acid base equilibrium, etc.). In this case, urine output should be monitored because these symptoms can lead renal failure.

- Central nervous system:
- Medical practitioners must do close observation for occurring tremors, convulsion, etc. Treatment should be stopped immediately if these symptoms appear and then use an appropriate treatment (diazepam, ultrashort-acting barbiturate thiopental sodium, etc.).

then use an appropriate treatment (diazepam, ultrashort acting barbiturate thiopental sodium, etc.)
- Medical practitioners must do close observation for occurring somnolence, anxiety, irritability, inattention, dizziness, nausea, vomiting, etc. and then use an appropriate treatment if necessary.
- Anaphylaxis: Skin symptoms such as urticaria or swelling may occur.

METHOD OF USE · POSOLOGY

- Preparations before use:
- Before the first treatment session, it is recommended to contact your local representative or distributor for more information about injection techniques and training opportunities
- Check the expiry date on the product label
- Check the package for any damage
- Before beginning treatment, the patient must be informed of product's indications, contraindications, incompatibilities and potential undesirable effects
- Medical practitioners must understand and read the instructions
- **AVALON™ ULTRA PLUS** is to be used as supplied. Modification or use of the product outside the Instructions for use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.
- Method of use:
- The area to be treated must be disinfected properly before injection
- Separate the cap from the luer lock completely (Fig.1)
- Hold the luer lock area; turn the injection needle clockwise until firmly fixed (Fig.2)
- Make sure the needle is fixed tightly (Fig.3 and Fig.4)
- Remove the needle cap (Fig.5)
- Inject the needle into treatment area and start the injection slowly into the dermis, the quantity to inject depends on the area to be corrected
- After injections, the medical practitioner should gently massage the treated area immediately.
- Storage and control after use:

The product is disposable, discard the syringe and remaining product after use.

WARNING

- Check the expiry date on the product label
- Do not use if package is damaged
- Do not re-sterilize
- Do not re-use
- Do not use with another filling product
- Discard the syringe and remaining product after use

STORAGE CONDITIONS

- Store between 1 °C and 30 °C
- Fragile
- Protect from freezing, heat, and sunlight

EXPIRY DATE

Indicated on package

SYMBOLS

(2)	Do not re-use
i	Read instructions for use
⚠	Caution, refer to instructions for use
	Fragile item, handle carefully
	Do not expose to sunlight
	Temperature limitation (1 °C and 30 °C)
	Use by date
LOT	Batch code
STERILE	Moist heat sterilization
STERILE EO	Ethylene Oxide sterilization
	Do not re-sterilize
	Do not use if package is damaged
	Manufacturer
	Keep dry

Fig.1

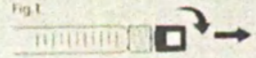


Fig.2

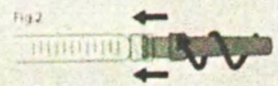
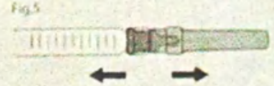


Fig.3

Fig.4

Fig.5



Koru Pharmaceuticals Co., Ltd

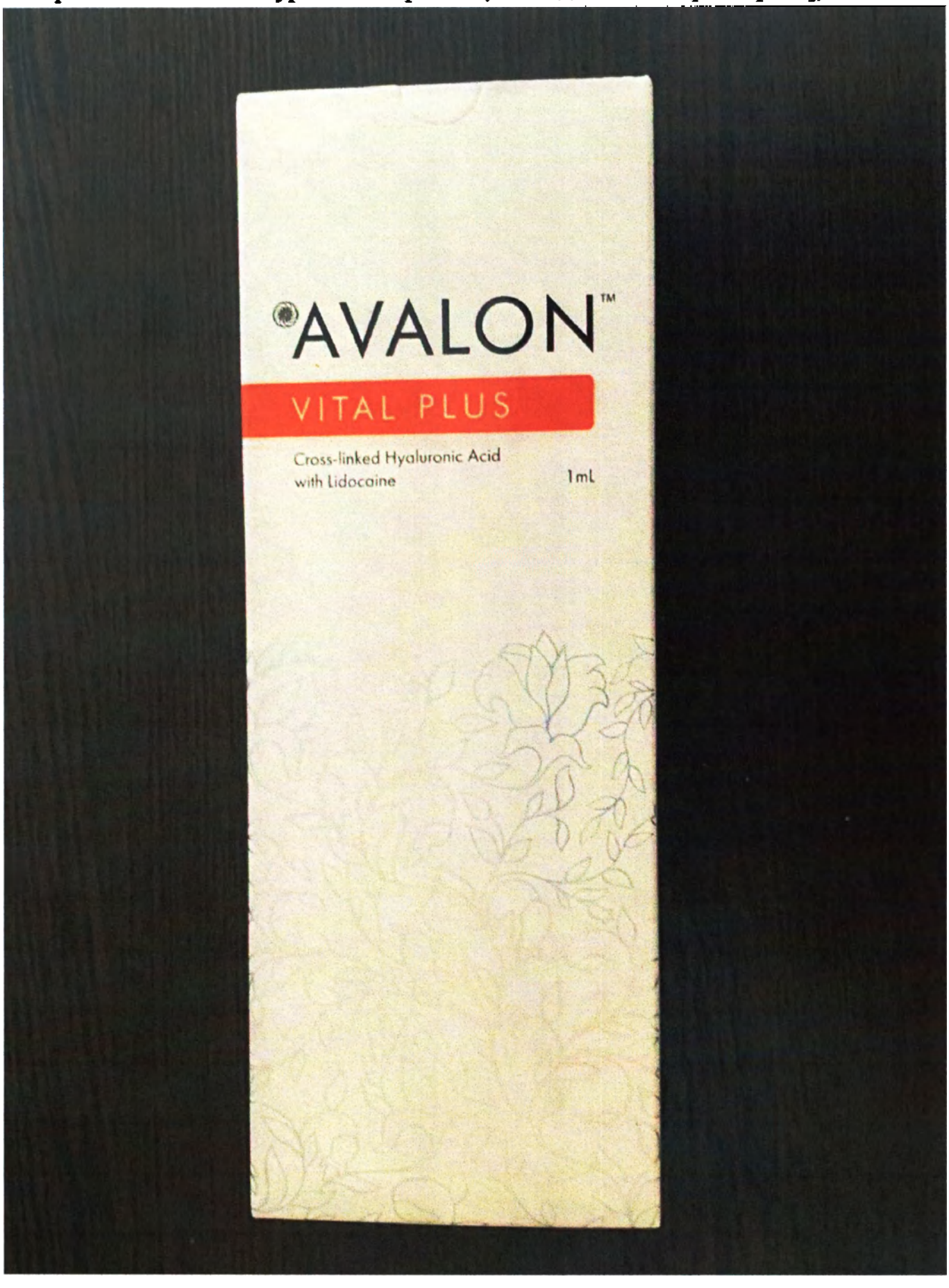
KORU

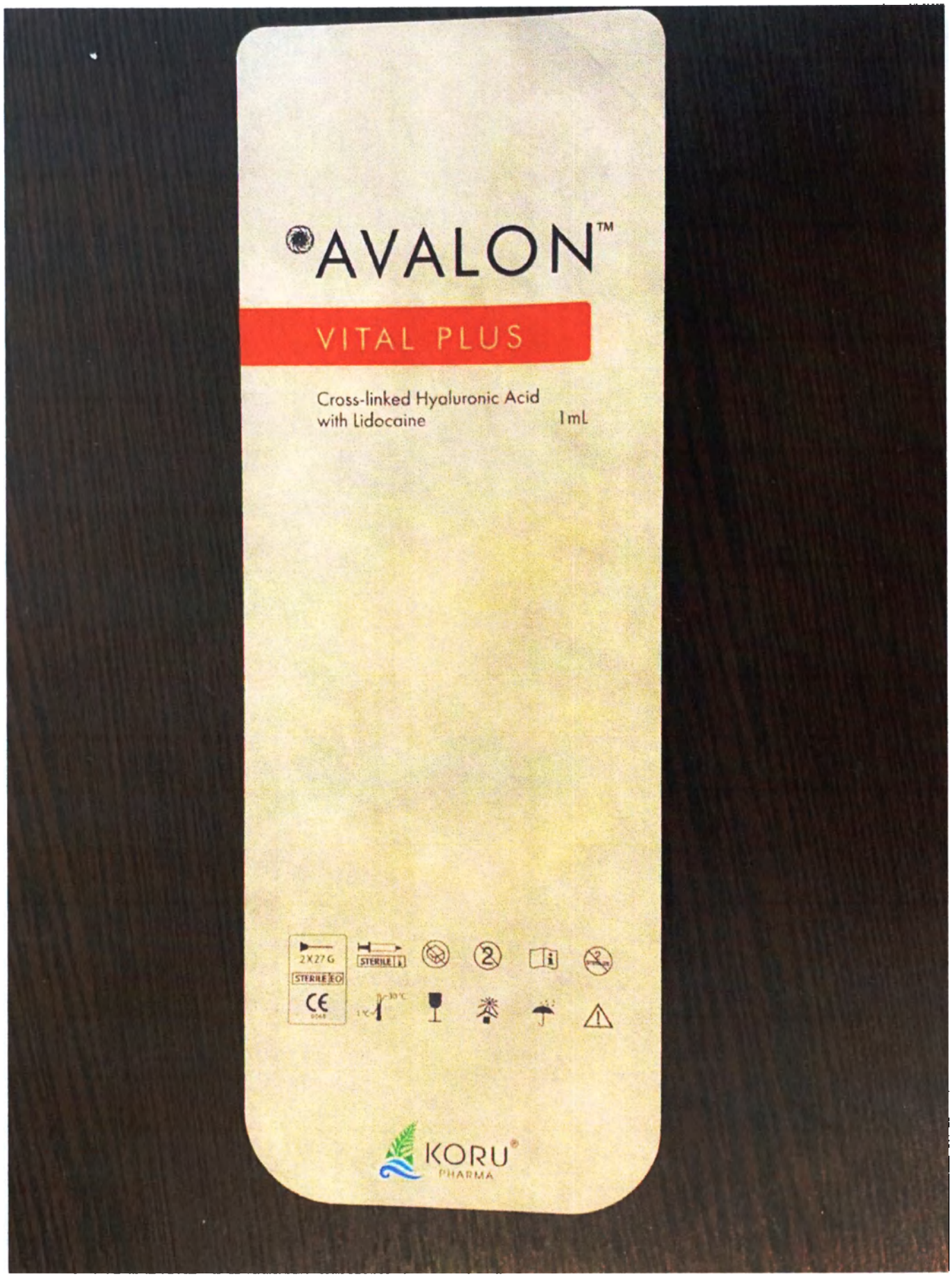
AVALON™
ULTRA PLUS

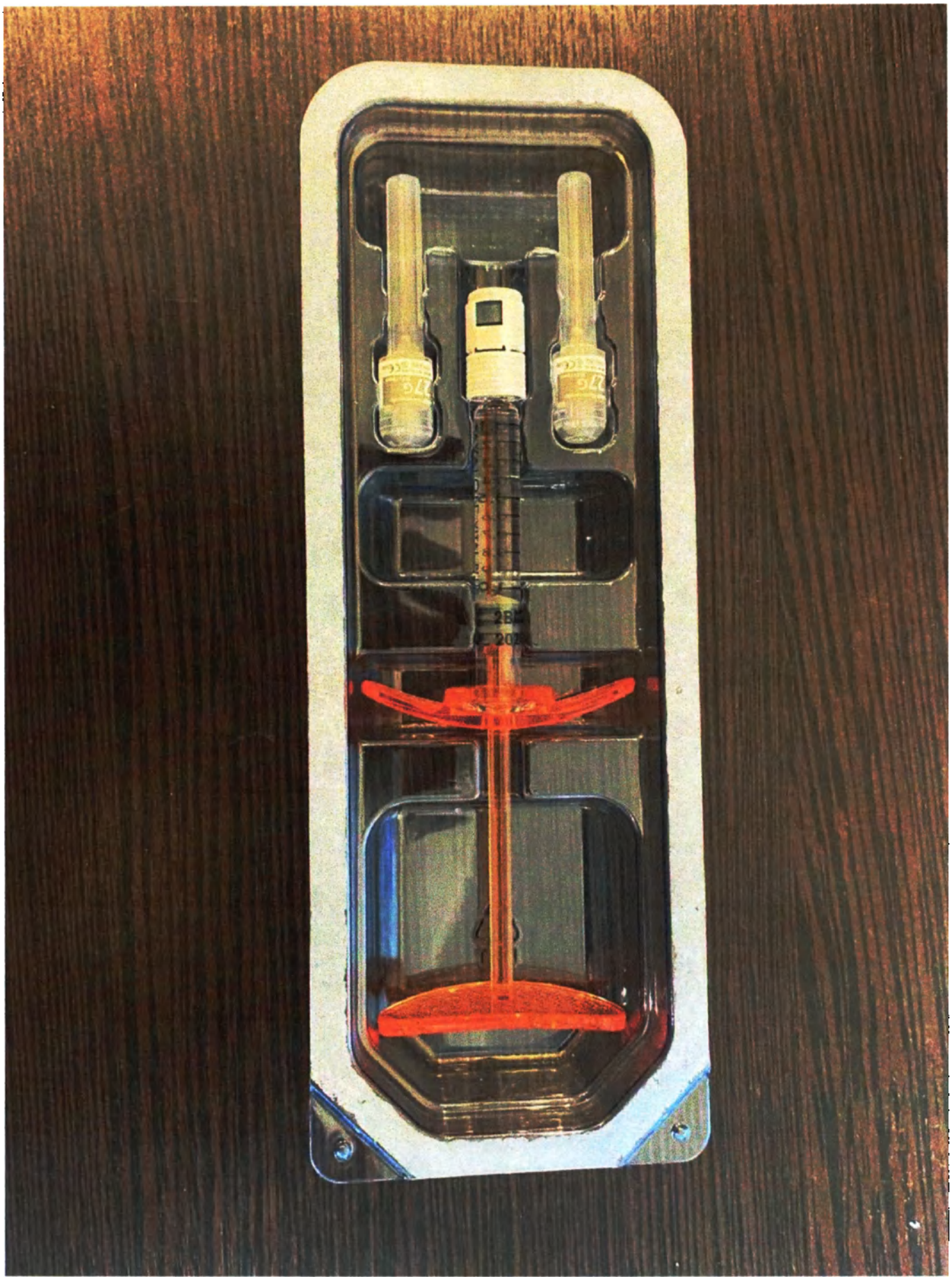
Cross-linked Hyaluronic Acid with Lidocaine

1 mL

4 Филлер внутридермальный AVALON™ VITAL PLUS объемом 1.0 мл [2,0% поперечно-сшитого гиалуроната натрия + 0,3% лидокаина гидрохлорида], в составе:



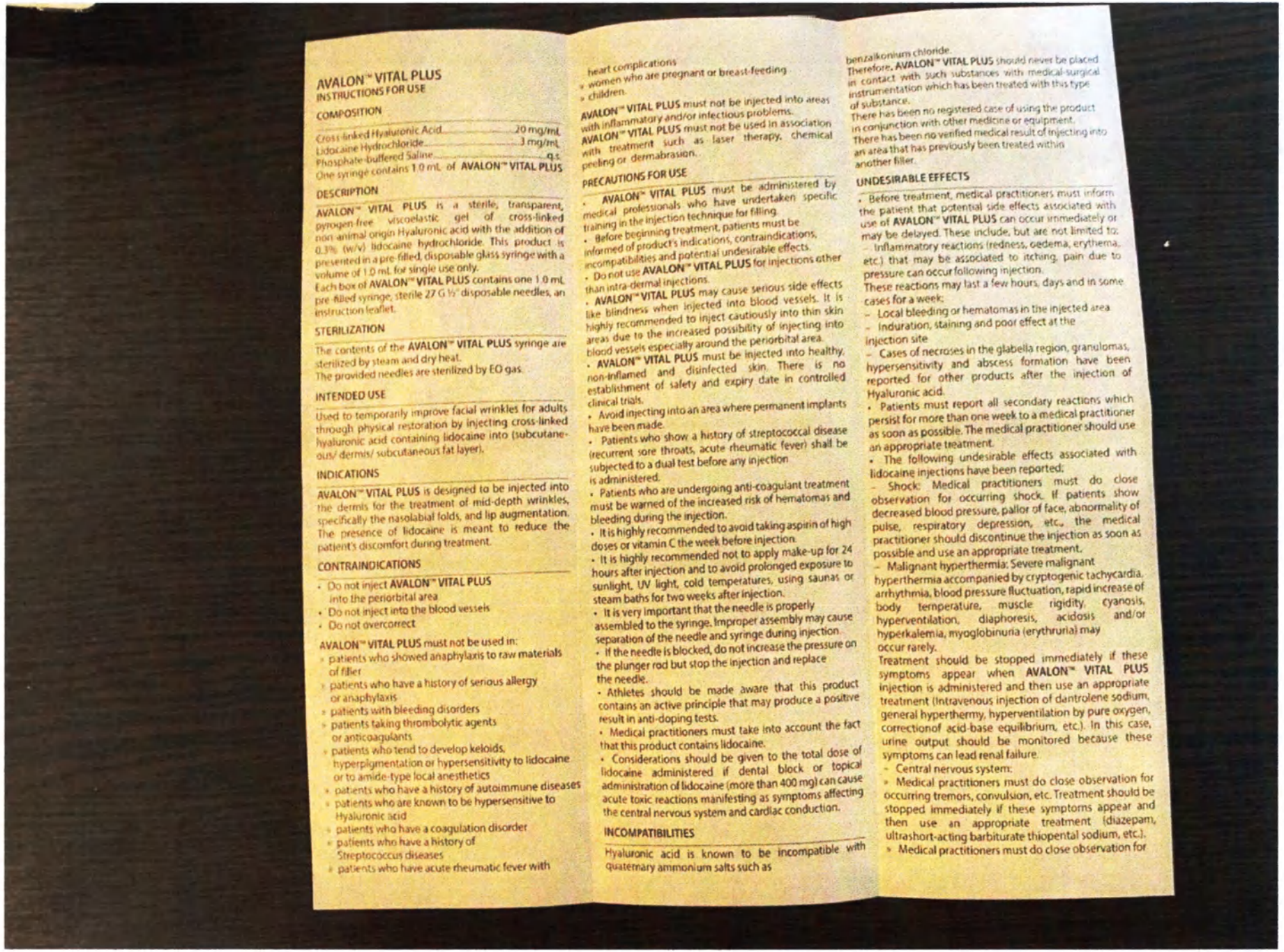




4.1 -Шприц объёмом 1,0 мл, заполненный гелем на основе гиалуроновой кислоты и лидокаина - 1 шт.;

4.2 -Игла 27G 1/2", производитель "Джапан Био Продактс Ко., Лтд.", место производства Feel Tech Co., Ltd., Корея - 2 шт.;

4.3 -Этикетка съемная для карты пациента -2 шт.;



AVALON™ VITAL PLUS
INSTRUCTIONS FOR USE

COMPOSITION

Cross-linked Hyaluronic Acid	20 mg/mL
Lidocaine Hydrochloride	3 mg/mL
Phosphate-buffered Saline	q.s.

One syringe contains 1.0 mL of **AVALON™ VITAL PLUS**

DESCRIPTION

AVALON™ VITAL PLUS is a sterile, transparent, pyrogen-free viscoelastic gel of cross-linked non-animal origin Hyaluronic acid with the addition of 0.3% (w/v) lidocaine hydrochloride. This product is presented in a pre-filled, disposable glass syringe with a volume of 1.0 mL for single use only.
Each box of **AVALON™ VITAL PLUS** contains one 1.0 mL pre-filled syringe, sterile 27 G ½" disposable needles, an instruction leaflet.

STERILIZATION

The contents of the **AVALON™ VITAL PLUS** syringe are sterilized by steam and dry heat.
The provided needles are sterilized by EO gas.

INTENDED USE

Used to temporarily improve facial wrinkles for adults through physical restoration by injecting cross-linked hyaluronic acid containing lidocaine into (subcutaneous/ dermis/ subcutaneous fat layer).

INDICATIONS

AVALON™ VITAL PLUS is designed to be injected into the dermis for the treatment of mid-depth wrinkles, specifically the nasolabial folds, and lip augmentation. The presence of lidocaine is meant to reduce the patient's discomfort during treatment.

CONTRAINDICATIONS

- Do not inject **AVALON™ VITAL PLUS** into the periorbital area
- Do not inject into the blood vessels
- Do not overcorrect

AVALON™ VITAL PLUS must not be used in:

- patients who showed anaphylaxis to raw materials of filler
- patients who have a history of serious allergy or anaphylaxis
- patients with bleeding disorders
- patients taking thrombolytic agents or anticoagulants
- patients who tend to develop keloids, hyperpigmentation or hypersensitivity to lidocaine or to amide-type local anesthetics
- patients who have a history of autoimmune diseases
- patients who are known to be hypersensitive to Hyaluronic acid
- patients who have a coagulation disorder
- patients who have a history of Streptococcus diseases
- patients who have acute rheumatic fever with heart complications
- women who are pregnant or breast-feeding
- children.

AVALON™ VITAL PLUS must not be injected into areas with inflammatory and/or infectious problems.
AVALON™ VITAL PLUS must not be used in association with treatment such as laser therapy, chemical peeling or dermabrasion.

PRECAUTIONS FOR USE

- **AVALON™ VITAL PLUS** must be administered by medical professionals who have undertaken specific training in the injection technique for filling.
- Before beginning treatment, patients must be informed of product's indications, contraindications, incompatibilities and potential undesirable effects.
- Do not use **AVALON™ VITAL PLUS** for injections other than intra-dermal injections.
- **AVALON™ VITAL PLUS** may cause serious side effects like blindness when injected into blood vessels. It is highly recommended to inject cautiously into thin skin areas due to the increased possibility of injecting into blood vessels especially around the periorbital area.
- **AVALON™ VITAL PLUS** must be injected into healthy, non-inflamed and disinfected skin. There is no establishment of safety and expiry date in controlled clinical trials.
- Avoid injecting into an area where permanent implants have been made.
- Patients who show a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to a dual test before any injection is administered.
- Patients who are undergoing anti-coagulant treatment must be warned of the increased risk of hematomas and bleeding during the injection.
- It is highly recommended to avoid taking aspirin of high doses or vitamin C the week before injection.
- It is highly recommended not to apply make-up for 24 hours after injection and to avoid prolonged exposure to sunlight, UV light, cold temperatures, using saunas or steam baths for two weeks after injection.
- It is very important that the needle is properly assembled to the syringe. Improper assembly may cause separation of the needle and syringe during injection.
- If the needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle.
- Athletes should be made aware that this product contains an active principle that may produce a positive result in anti-doping tests.
- Medical practitioners must take into account the fact that this product contains lidocaine.
- Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine (more than 400 mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.
Therefore, **AVALON™ VITAL PLUS** should never be placed in contact with such substances with medical-surgical instrumentation which has been treated with this type of substance.
There has been no registered case of using the product in conjunction with other medicine or equipment.
There has been no verified medical result of injecting into an area that has previously been treated within another filler.

UNDESIRABLE EFFECTS

- Before treatment, medical practitioners must inform the patient that potential side effects associated with use of **AVALON™ VITAL PLUS** can occur immediately or may be delayed. These include, but are not limited to:
  - Inflammatory reactions (redness, oedema, erythema, etc.) that may be associated to itching, pain due to pressure can occur following injection.
  These reactions may last a few hours, days and in some cases for a week;
  - Local bleeding or hematomas in the injected area
  - Induration, staining and poor effect at the injection site
  - Cases of necroses in the glabella region, granulomas, hypersensitivity and abscess formation have been reported for other products after the injection of Hyaluronic acid.
- Patients must report all secondary reactions which persist for more than one week to a medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
- The following undesirable effects associated with lidocaine injections have been reported:
  - Shock: Medical practitioners must do close observation for occurring shock. If patients show decreased blood pressure, pallor of face, abnormality of pulse, respiratory depression, etc., the medical practitioner should discontinue the injection as soon as possible and use an appropriate treatment.
  - Malignant hyperthermia: Severe malignant hyperthermia accompanied by cryptogenic tachycardia, arrhythmia, blood pressure fluctuation, rapid increase of body temperature, muscle rigidity, cyanosis, hyperventilation, diaphoresis, acidosis and/or hyperkalemia, myoglobinuria (erythruria) may occur rarely.
  Treatment should be stopped immediately if these symptoms appear when **AVALON™ VITAL PLUS** injection is administered and then use an appropriate treatment (Intravenous injection of dantrolene sodium, general hyperthermy, hyperventilation by pure oxygen, correctionof acid-base equilibrium, etc.). In this case, urine output should be monitored because these symptoms can lead renal failure.
  - Central nervous system:
    - Medical practitioners must do close observation for occurring tremors, convulsion, etc. Treatment should be stopped immediately if these symptoms appear and then use an appropriate treatment (diazepam, ultrashort-acting barbiturate thiopental sodium, etc.).
    - Medical practitioners must do close observation for

4.4 -Инструкция по применению.

occurring somnolence, anxiety, irritability, inattention, dizziness, nausea, vomiting, etc. and then use an appropriate treatment if necessary.
- Anaphylaxis: Skin symptoms such as urticaria or swelling may occur.

METHOD OF USE - POSOLOGY

- Preparations before use:
- Before the first treatment session, it is recommended to contact your local representative or distributor for more information about injection techniques and training opportunities.
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- After injections, the medical practitioner should gently massage the treated area immediately.
- Storage and control after use:

The product is disposable, discard the syringe and remaining product after use.

WARNING

- Check the expiry date on the product label
- Do not use if package is damaged
- Do not re-sterilize
- Do not re-use
- Do not use with another filling product
- Discard the syringe and remaining product after use

- Store between 1 °C and 30 °C
- Fragile
- Protect from freezing, heat, and sunlight

EXPIRY DATE

Indicated on package

SYMBOLS

2	Do not re-use
	Read instructions for use
	Caution, refer to instructions for use
	Fragile item, handle carefully
	Do not expose to sunlight
	Temperature limitation (1 °C and 30 °C)
	Use by date
LOT	Batch code
STERILE R	Moist heat sterilization
STERILE EO	Ethylene Oxide sterilization
	Do not re-sterilize
	Do not use if package is damaged
	Manufacturer
	Keep dry

Fig.1

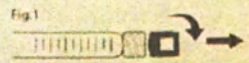

Fig.2

Fig.3 Fig.4

Fig.5

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Rev. No. AVA-VIT-P-20220120-001

AVALON™

VITAL PLUS

Cross-linked Hyaluronic Acid with Lidocaine 1 mL

Всего прошнуровано,
пронумеровано и скреплено
печатью 39 лист (ов)

_____ А.И. Тарасова