

本製品は日本国法に基づき製造販売されたものです。また、この添付文書は日本国法に基づき作成した添付文書を翻訳したものであり、日本国外の法規に準じているわけではありません。

This product is manufactured and marketed for domestic sales in accordance with the Japanese laws.
This leaflet, translated from the original package insert created in accordance with Japanese laws, is not in compliance with laws outside Japan.

1st Class OTC drug

Hair regrowth agent for
androgenetic alopecia
(male pattern hair loss)

リザレック α5
RESURRECK KOWA α5

Please read the package insert carefully before use
and keep it with this medicine.

Precautions for use

To be avoided

(Failure to follow the directions below may worsen existing symptoms or increase the risk of adverse reactions)

① The following persons should not use Resurreck:

- (1) Persons who have had allergies to this product or any of the ingredients of this product.
- (2) Females.
(The safety of this product in women in Japan has not been confirmed.)
- (3) A person aged younger than 20 years.
(There has been no clinical experience in Japan.)
- (4) Persons with alopecia which is other than androgenetic alopecia (e.g., alopecia areata, alopecia associated with thyroid disease), or persons with alopecia of unknown cause.
(This product is effective against androgenetic alopecia only.)
- (5) Persons whose hair loss is sudden or patchy.
(These persons are highly likely to be suffering from hair loss other than androgenetic alopecia.)

② Do not apply Resurreck to the following sites:

- (1) This product is for application to the scalp only and must not be taken orally.
(Decreased blood pressure or such events may occur.)
- (2) Scalp which shows any such skin damage as wounds, eczema, or inflammation (redness).
(Wounds or such may worsen.)

③ During treatment with this product, other hair regrowth agents or topical agents (e.g. ointment, liquid formulations) must not be applied to the scalp. Or application of this product must be discontinued while any other such agents are being used.

(These agents may affect the absorption of this product.)

What to ask a doctor or pharmacist

① The following persons should consult a physician or pharmacist before using this product:

- (1) Persons who have had allergic reactions (e.g., rashes/redness, itchiness, contact dermatitis) to medicines, cosmetics, or any allergens.
- (2) Persons with hypertension, persons with hypotension.
(This product may affect blood pressure.)
- (3) Persons with cardiac or renal disorders.
(This product may affect the heart or kidneys.)
- (4) Persons with edema.
(Edema may be intensified.)
- (5) Persons without a family history of androgenetic alopecia.
(Genetic factors are thought to be greatly associated with the onset of androgenetic alopecia.)
- (6) Elderly persons (aged 65 years and older).
(In general, unfavorable symptoms are likely to develop in elderly persons.)
- (7) Persons diagnosed with the following conditions:
Thyroid dysfunction (hypothyroidism, hyperthyroidism).
(Thyroid disease may cause hair loss.)

② If any of the symptoms listed below develop after Resurreck application, stop applying this product immediately and consult a physician or pharmacist because these symptoms might be side effects of the product. Take this package insert to the consultation.

Related area	Symptom
Skin	Scalp rashes/redness*, itchiness, contact dermatitis, scurf, application site warmth, etc.
Neuropsychiatric	Headache, fainting, dizziness
Cardiovascular	Chest pain, accelerated heart rate
Metabolism	Acutely increased body weight of unknown cause, edema of extremities

* Rashes/redness may appear on areas other than the scalp.

(Continued overleaf)

③Stop applying Resurreck and consult a physician or pharmacist, taking this package insert to the consultation, if there is no improvement in any of the followings after 6 months of application:

Degree of hair loss, growth of new downy hair/soft hair, regrowth of usual hair, and degree of fallen hair (the decreased amount of thin and short fallen hair as well as thick hair are indicators for improvement.)

(In the case of no improvement, the condition may be alopecia which is other than androgenetic alopecia or may be hair loss due to other causes.)

④Stop applying Resurreck and consult a physician or pharmacist, taking this package insert to the consultation, even within 6 months after the start of application, if hair loss status worsens or if any of the following types of hair loss is observed:

Non-scalp body hair loss, patchy hair loss, sudden hair loss, etc.

(In the case of no improvement, the condition may be alopecia which is other than androgenetic alopecia or may be hair loss due to other causes.)

Other precautions

(1)Regrowth of scalp hair is naturally slow. It will take at least 4 consecutive months for any positive results to appear even when this product is applied every day.

(The efficacy of minoxidil lotion 5% formulations is observed after 4 months of application.)

(2)There are individual variations in the degree of scalp hair growth, and persons do not respond equally to this product.

(3)Resurreck application must be continued to maintain its effects. If application of this product is discontinued, hair loss will gradually revert to the previous condition.

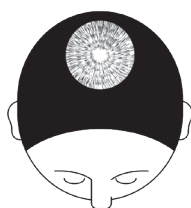
(This product will not eliminate the cause of androgenetic alopecia.)

Indications

Restoration and regrowth of scalp hair, and prevention of progression of hair loss (fallen hair) in androgenetic alopecia.

<Androgenetic alopecia, the target condition of Resurreck>

This product is effective against the following patterns of hair loss or thin hair:



Note)



Note)

Note) This product may not be effective against hair loss involving greater scalp areas than the above-described.

Dosage/directions

Resurreck is for only adult males (20 years of age and older); 1 mL of the lotion should be applied to the scalp in the hair loss area twice daily.

<Caution>

- ①Even if this product is applied at a higher dose and more frequently than the above-mentioned dosage and administration, the positive effects of the product will not be increased. The specified dosage and administration must be strictly followed. (More frequent applications and increasing the amount used beyond those specified will have almost no enhanced effects, and side effects are highly likely to occur.)
- ②Caution should be exercised to avoid Resurreck entering the eyes. If the lotion should enter the eyes, the eyes must immediately be rinsed with water or lukewarm water. If any severe reactions develop, consult an ophthalmologist.
- ③After application, wash your hands well to remove the product solution because it will cause irritation if coming into contact with the mucous membranes of the eyes or such.
- ④Avoid contact with any objects (frames of glasses, chemical fibers) which may melt/deteriorate when in contact with alcohol or such.
- ⑤If a hairdressing and hair setting spray is used, they must be applied after Resurreck application.
- ⑥On days when hair coloring agents (hair coloring, hair dye, hair dye for graying hair, etc.) are applied, Resurreck must not be applied until the hair coloring procedure is completely finished.

Ingredients /contents (per100mL)

- Minoxidil 5.0g ●Pantothenyl ethyl ether 1.0g ●Pyridoxine hydrochloride 0.05g ●Tocopheryl acetate 0.08g
●l-Menthol 0.3g

[Inactive ingredients] Ethanol, 1,3-butylene glycol, pH regulator

Precautions for Storage and Handling

- ❶ Close the cap of the container after each use, and store the product in a cool place away from direct sunlight, heat and low temperatures.
- ❷ Keep out of the reach of children.
- ❸ Do not transfer the product to another container to prevent improper use or loss of quality.
- ❹ Store and use away from fire, flame or heat.
- ❺ Do not use the product after the expiration date.
- Precautions concerning use

Your hair may stiffen, cannot smoothly be combed, or may appear partially white (due to crystalized ingredients), according to your hair type or if the product is applied intensively to a single spot. Wash your hair every day to keep the scalp clean. Use the product exactly according to the specified dosage and administration.

Be sure to read the "Instructions for Use of the Container" and use the product appropriately.

- If you are going to perform massage, you are recommended to perform massage before using the product.
- You are recommended to use this product after washing and drying the hair.

Instructions for Use of the Container

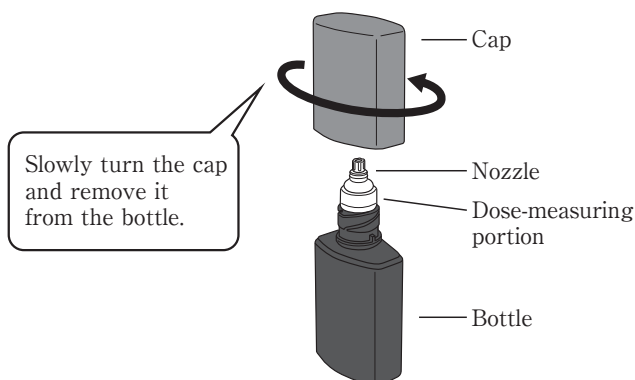
Application method

* The illustrations are images only.

Apply the dose amount (1 mL) following the procedures ❶ to ❺ described below.

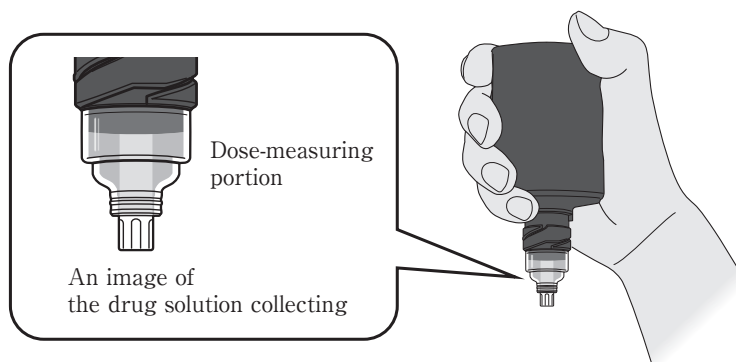
- ❶ Stand the bottle with the cap upward, and slowly turn the cap in the direction of the arrow and remove the cap.

Caution: The product solution may leak from the bottle if the bottle is held at an angle or upside down while removing the cap.



- ❷ Hold the bottle straight upside down with the nozzle downward. The drug solution will collect in the measuring chamber in approximately 2 to 3 seconds.

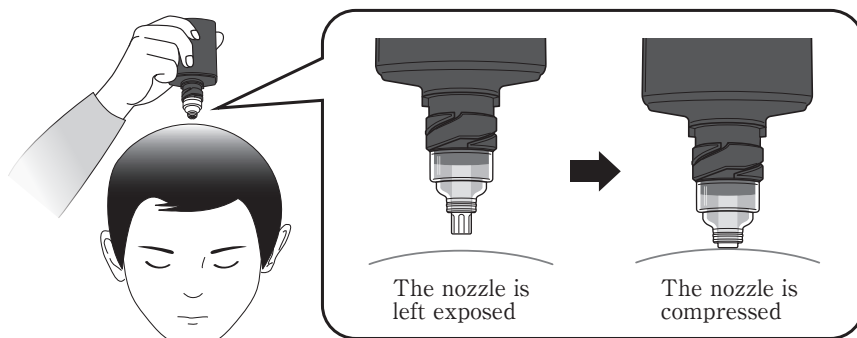
Caution: Do not shake the bottle. The product solution may leak.



- ❸ Invert the bottle and firmly press the nozzle at the tip of the bottle perpendicularly against your scalp while keeping the bottle inverted. The nozzle is compressed so that the amount of drug solution for one dose (1mL) will enter in the measuring chamber.

Caution❶: Inadequate compression of the nozzle may cause the excessive amount of drug solution to enter the measuring chamber.

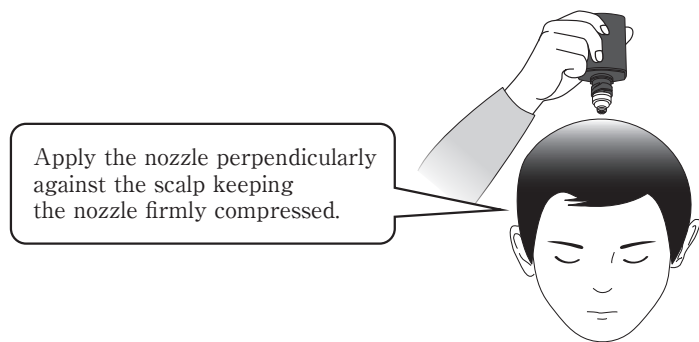
Caution❷: Since the product solution may run off the scalp, caution should be exercised to avoid the solution entering the eyes.



- ④ Apply the nozzle perpendicularly against the scalp, mainly to the area with thin hair (the area of concern) repeatedly by tapping the scalp multiple times while leaving a space of 1 to 2 cm between the application sites (several tens of applications) until no more drug solution comes out.

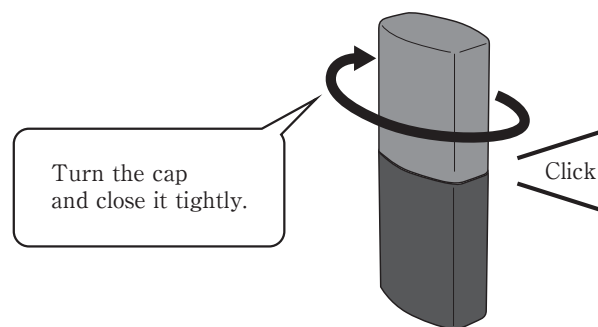
Caution①: Pressing the nozzle against the same site persistently or holding the bottle diagonally during the application may cause leakage of the measured drug solution.

Caution②: Since the product solution may run off the scalp, caution should be exercised to avoid the solution entering the eyes.



- ⑤ After use, turn the cap in the direction of the arrow to close it tightly, and store the container.

Caution: A loosely closed cap causes the nozzle left compressed, which prevents the drug solution from collecting in the measuring chamber when you use the drug next time.



- To prevent accidental ingestion, the dose-measuring portion and bottle are designed not to become detached easily.
- White crystals may appear on the nozzle and dose-measuring portion while the container is being stored; however, this will cause no problem with the product quality. If white crystals appear, wipe them off before use.
- Discoloration of the product solution (pale yellow) may occur according to the storage condition; however, this will cause no problem with the product quality.

Distributor: Kowa Company, Ltd. 3-4-14, Nihonbashi-Honcho, Chuo-ku, Tokyo

Marketing Authorization Holder: Ryoto Fine Co., Ltd. 1410 Takada, Kashiwa City, Chiba Prefecture

Y9057 K4K A1