

This document is an English summary of the package insert written in Japanese, and is provided only for convenience of the consumers who buy and use this product in Japan. Please make sure that you read this document and understand the information of the package insert before taking this product. Please keep the package insert so that you can show it to your doctor, dentist, pharmacist, or certified drug salesperson whenever you need.

Dental materials 5 Dental adhesive filling materials
 ● Liner type denture adhesives (Cushion type)

For plastic base



SHIONOGI & CO., LTD.

Cushion Correct

Approval No.: 15900BZZ00400000
 JMDN code: 16388020
 Classification of medical device:
 Controlled medical device

Contraindications/prohibitions

Do not use this product in the following cases.

- (1) You have a history of irritation symptoms (rash and/or redness, itching, swelling, etc.) caused by this product or alcohol.
- (2) You have symptoms such as roughness, pain, wound and swelling at the site of direct contact with dentures.
- (3) You have difficulty in swallowing food etc. (This product may possibly get stuck in the throat.)

In general, poor-fitting dentures lead to discomforts associated with spaces between dentures and gums or loosening of dentures. Denture adhesives reduce temporarily the discomforts.

There are two types of denture adhesives.

- ① Cushion type : Denture adhesive paste is filled in the spaces between dentures and gums, and makes the dentures stick stably to gums. Ingredients are not dissolved by saliva etc. and the adhesive paste becomes gradually hard and remains on the dentures.
- ② Glue type : Denture adhesive glue increases adhesive performance with liquid and saliva in the mouth, and makes the dentures adhere stably to gums. Ingredients are dissolved by saliva etc. and the denture adhesive glue gradually disappears.

Cushion Correct is a cushion type denture adhesive. This product is recommended to persons who cannot chew food well due to pain, when some food is stuck between dentures and gums or when poor-fitting dentures get contact with gums.

.....Characteristics.....

Cushion Correct...

- 1. is a denture adhesive pasty product with a high adsorptive performance and a sufficient elasticity to chew food well.
- 2. is filled in the spaces between dentures and gums, and the moderate elasticity reduces gum pain related to eating. Therefore, you can chew something harder than before, without altering taste of food.
- 3. is not dissolved by food and then remains on dentures.
- 4. allows dentures to be removed easily from gums and to be cleaned with a denture cleaning agent, even when Cushion Correct stays on dentures.
- 5. has adequate elasticity for 4 to 5 days once it is applied. Duration of effect depends on individual differences in factors such as condition of denture, situations of drinking and eating, and secretion volume of saliva.
- 6. is similar in color to gums so that it looks natural.
- 7. has a roll-up tool that makes it easy to squeeze denture adhesive paste from a tube.

.....Form, design, principle etc.....

Ingredients Polyvinyl acetate resin, dehydrated ethanol (contains alcohol)
 A major ingredient of Cushion Correct, polyvinyl acetate resin which is also used in chewing gum, is not dissolved by saliva etc., hardens gradually and remains on dentures.

Form Red-purple clear paste (gummy matter)

Principle Cushion Correct makes dentures stick to oral mucosa by adsorbability (negative pressure).

.....Intended use.....

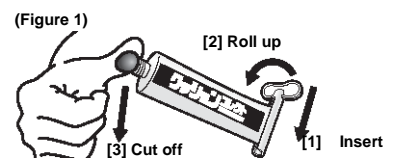
Denture stability (Cushion Correct stabilizes dentures by filling spaces between dentures and gums.)

.....Specifications.....

Adhesion strength: Not less than 5 kPa, pH4-pH10

.....How to use.....

- 1. How to use
 - (1) Wash dentures clean with a toothbrush and dry them well. (Cushion Correct poorly adheres to wet dentures.)
 - (2) Squeeze just enough adhesive paste from a product tube by use of an accompanying roll-up tool, and cut off the adhesive paste as shown in Figure 1. (Standard amount of the adhesive paste for one-time use is roughly equal to a 1-cm diameter ball for each of the upper and lower arches of complete dentures. However, it is necessary to find out an adequate amount individually from personal experiences because an application amount depends on the size of dentures and on the volume of spaces between dentures and gums. Especially, in case of partial dentures which vary in size and shape, adjust an application amount for individual dentures.)
 - (3) Apply adhesive paste mainly to sites of dentures contacted directly with gums, and coat thickly sulcus of dentures with adhesive paste. (See Figures 2-1, 2-2, 2-3, and 2-4)
 - (4) After application, pour water on dentures to decrease stimulation of alcohol as shown in Figure 3.
 - (5) Wear dentures and bite down 2 to 3 times. (See Figure 4)
 - (6) If you mind adhesive paste overflowed from dentures, cut it off at the edge of dentures as shown in Figure 5. And then press the remaining part well to make it smooth.

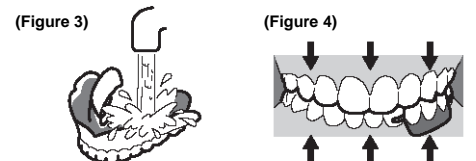
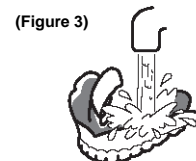


(Figure 2-1) Maxillary (upper) arch of complete dentures; Coat thickly sulcus of dentures with adhesive paste
 (Figure 2-2) Mandibular (lower) arch of complete dentures; Coat thickly sulcus of dentures with adhesive paste



(Figure 2-3) Partial dentures; Coat thickly sulcus of dentures with adhesive paste

(Figure 2-4) Partial dentures; Coat entirely base of dentures with adhesive paste



(Figure 5) Cut off adhesive paste overflowed from dentures



2. Material and type of dentures

- (1) Cushion Correct is available for plastic base but not for metal base.
- (2) Cushion Correct is available mainly for complete and partial dentures but not for a bridge, a prosthetic tooth and some partial dentures.

Precautions for use of Cushion Correct

1. Wait at least 1 or 2 hours to eat hard foods and have a hot drink after insertion of dentures, even though Cushion Correct is adaptable generally to eat and drink soon after insertion.
2. Do not use this product continuously for 6 days or more without renewed application. (Prolonged use without renewed application leads to poor dental health such as bacterial growth and causes difficulty in removing adhesive residue from dentures.)
3. Be aware of the followings during or after use.
 - (1) If you feel stimulation in the mouth after insertion of dentures, rinse them lightly with water and then reinsert them. If there is still stimulation strongly after rinsing with water, stop using the product.
 - (2) Remove dentures with Cushion Correct at bedtime.
 - (3) Do not dry dentures with Cushion Correct. Be sure to soak the dentures removed in water or lukewarm water. (When the dentures with Cushion Correct are left to dry, Cushion Correct may get hard and it becomes difficult or impossible to remove adhesive residue from dentures.)
 - (4) Close the cap of a product tube tightly after use. (If the cap is closed loosely, adhesive paste becomes difficult to be squeezed out due to hardening by evaporation of alcohol.)
4. Apply adhesive paste renewedly every 5th days. (Tear off adhesive residue from dentures with fingers little by little.) Even if the interval is less than 5 days, renew it in the case of weakened adhesive power.
5. When it is difficult to remove adhesive residue from dentures, soak the dentures in hot water (at about 40°C) and then tear off softened adhesive residue little by little from the end. If everything else fails, wipe the adhesive residue away using alcohol diluted 2-fold with water. Do not soak dentures directly in alcohol for cleaning because dentures can change in shape and get broken. Watch out for fire before using alcohol.
6. Even though it is difficult to remove adhesive residue, do not remove it forcedly by use of metal tools. (Dentures can be damaged.)
7. When atmosphere temperature is low (especially in winter, when adhesive paste is hard to be squeezed), warm up the top of a capped tube by soaking in hot water (at about 40°C) until adhesive paste becomes easy to be squeezed.
8. When atmosphere temperature is high (especially in summer, when adhesive paste sticks to fingers), cool down the top of a capped tube by soaking in cold water for 2 to 3 minutes until adhesive paste becomes easy to be handled.

.....Precautions.....

1. **Do not use this product continuously for a long time. (It may lead to gum recession or worsening of dental bite.)**
2. **If symptoms such as rash, redness, itching and swelling occur during or after use this product, stop using this product right away and ask your doctor, dentist, or pharmacist showing this document.**
3. **For stabilization of poor-fitting dentures caused by gum recession, limit this product to temporary use and ask your dentist for adjustment of the dentures as soon as possible.**
4. **Even if this product is applied to severely poor-fitting dentures, it will not provide sufficient stabilization.**
5. **If dentures are still not stabilized by use of this product, ask your dentist.**

.....Precautions for storage and handling.....

1. Keep this product out of reach of children.
2. Avoid fire and direct sunlight and store in a cool place with a cap closed tightly.

.....Contact information.....

As to inquiries about Cushion Correct, please contact the store you bought Cushion Correct or the following.
Drug Information Center
SHIONOGI & CO., LTD.
TEL: (Osaka) 06-6209-6948, (Tokyo) 03-3406-8450
Office hours: 9:00-17:00 (except Saturdays, Sundays and public holidays)

.....Packaging.....

Cushion Correct: 12 g, 36 g

Manufactured and Distributed by:
SHIONOGI & CO., LTD.
3-1-8, Doshomachi, Chuo-ku Osaka, Japan

Manufactured by:
KYOWA LIMITED
3-20-28, Tachibana, Nishinari-ku Osaka, Japan

- For stabilization of poor-fitting dentures caused by gum recession, limit this product to temporary use.
- Avoid long-term continuous use of this product.
- Visit a dentist regularly and have your dentures adjusted if necessary.