

Disclaimer

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Please keep this written explanation with your medicine and read it carefully when using your medicine.

Santen

Sterilizing and disinfecting eye drop


SAN-IODE

Medicines requiring guidance
Face-to-face selling
Over-The-Counter Pharmaceutical

Iodine, a component of SAN-IODE, has a rapid bactericidal and disinfectant effect against various viruses, bacteria, fungi, and other microorganisms and has been used as an ethical pharmaceutical to sterilize and disinfect the eyes.

SAN-IODE is a sterilizing and disinfecting eye drop that can be used to sterilize and disinfect the eyes by applying diluted drops of the drug solution into the eye.

Precautions

 **When not to use the product**
(If you do not follow these instructions, the current symptoms may worsen or adverse reactions are more likely to occur.)

This product should not be used in the following persons:
Patients who have had an allergic symptom to this drug or its ingredients

Consultation

1. The following persons should contact a physician or pharmacist for a consultation BEFORE use.

- (1) Patients undergoing medical treatment from a physician
- (2) Patients who have experienced allergic symptoms associated with drugs, etc.
- (3) Persons with the following symptom: Severe eye pain

2. If the following symptoms are observed AFTER using this drug, these may be adverse reactions, so immediately discontinue the use, and show this document to your physician or pharmacist for a consultation.

Area affected	Symptom
Skin	rash/redness, itching
Eyes	congestion of the eye, itching, swelling, pain, sensation of foreign body

3. The following symptoms may be observed AFTER using this drug. If these symptoms persist or worsen, discontinue the use of this drug, and show this document to your physician or pharmacist for a consultation.

A sensation of eye irritation

4. If the eye symptom worsens AFTER using this drug, stop using this drug, and consult a physician or pharmacist, being sure to take this document with you.

5. Do not use this drug for more than one week. Consult a physician or pharmacist if you intend to use this drug for more than one week.

Dosage and Administration

Dilute five times with the diluent provided (total volume) and apply 1 to 3 drops at a time 4 to 5 times a day.

● Precautions of Dosage and Administration

- (1) When allowing children to use the medicine, a guardian must be present to watch and tell such them how to use it.
- (2) Do not use this medicine while wearing contact lenses.
- (3) Ensure that the tip of the container does not touch the eye, eyelid or eyelashes (doing so could cause the solution to become contaminated with eye discharge or bacteria). Do not use when the medicine appears cloudy.
- (4) **Use this medicine only for ophthalmic instillation.** Do not use it on any area of the body other than the eye.
- (5) Dilute the product with the diluent provided, following **How to dilute SAN-IODE** instructions on the back of this document. (Be sure to use the diluent provided.)

Indication

Sterilization and disinfection of eyes

Ingredient and amount

Ingredient	Amount (in 1mL)
Iodine	2mg
Polyvinyl alcohol (partially saponified)	80mg

The product contains potassium iodide as an additive.
A saline solution is provided as a diluent to dilute the drug solution.

Precautions for storage and handling

- (1) Before dilution, store the product in a refrigerator, upright.
- (2) After diluting the drug solution, store the eye drop in the attached carrying bag tightly closed in a cool place away from direct sunlight and **use the eye drop within three days**. Please discard any unused drug solution after three days. To preserve the quality of the product, do not leave it in a hot place such as inside a car or near a heater. If the product is left in a hot place, the container may get deformed causing the solution to leak and degrading its quality. Please do not use the product in such a case.
- (3) Do not transfer the medicine to a different container. (It may lead to misuse or alter the quality of the drug.)
- (4) Keep out of reach of children.
- (5) Do not share with others.
- (6) Use the product promptly after purchase.
- (7) Depending on the storage condition, the ingredients may crystallize and form reddish-purple deposits around the eyedropper tip or inside the cap. If this occurs, gently wipe off the deposits with a clean piece of gauze before using the product.
- (8) The reddish-purple color of this drug is the color of iodine. It will become stained if the drug solution is spilled and adheres to clothing or other objects during dilution or eye drop application. Be careful not to get the drug solution on clothing. If it gets on clothes, etc., wash it immediately with water.

Content

SAN-IODE

(Drug solution: 1mL
Diluent: 4mL)

Inquiries

For inquiries about this product, please contact the store from which you purchased it or the call center below.

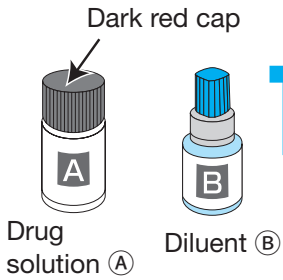
Santen Pharmaceutical Co., Ltd. Customer Consultations Office Telephone: 0120-127-023 Contact hours: 9:00 – 17:00 (except Saturdays, Sundays and public holidays)
Customer calls are recorded in order to ensure the accuracy of inquiries and to maintain and improve the quality of responses.

Marketing authorization holder: **Santen Pharmaceutical Co., Ltd.** 4-20 Ofuka-cho, Kita-ku, Osaka

Please be sure to read the reverse side.

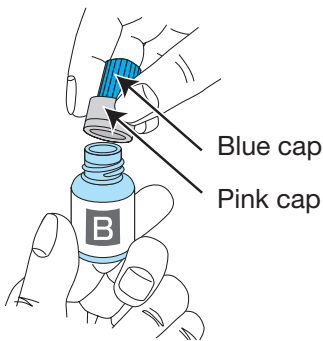
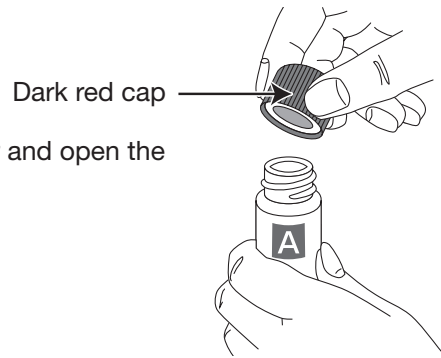
How to dilute SAN-IODE

These eye drops are a combination of (A) and (B). Dilute the drug solution (A) with the diluent (B) to make **reddish-purple eye drops**. When diluting, be sure to use diluent (B). Also, **the reddish-purple liquid may spill during dilution and adhere to the fingers. Prepare tissues, etc., before diluting, and wash hands with water immediately after completing dilution.**



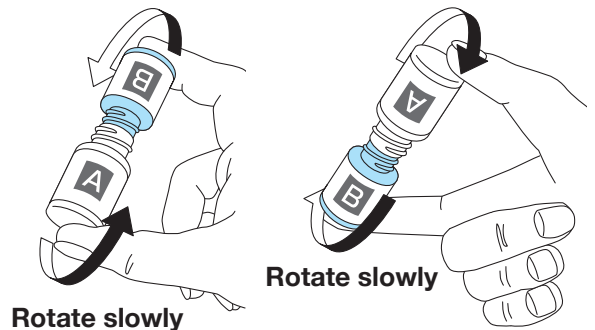
- Take (A) (B) out of the refrigerator and the box, and allow them to stand for about 10 minutes (until the drug solution (A) becomes liquid). At this time, keep the container upright.
 - *Drug solution (A) is solid in the refrigerated state, so wait until it dissolves.

- Make sure the content of (A) is at the bottom of the container and open the dark red cap.
 - *Open the cap just before diluting.

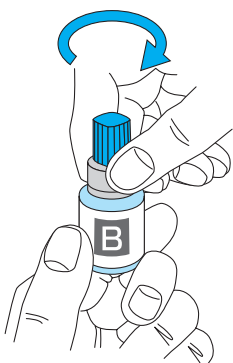


- Next, remove the pink cap from (B). At this time, be careful not to loosen the blue cap. (B is double capped in blue and pink.)

- After putting all the diluted liquid (B) into (A), being careful not to spill it, push in (B) tightly until the mouth of (B) is fixed on the mouth of (A). At this time, **make sure that (A) and (B) are joined straight**. Then gently and slowly rotate the combination of (A) and (B) until the drug solution in (A) dissolves. If vigorously, the product may foam and spurt out the liquid. In that case, allow some time until the bubbling settles down.



- Make sure that the drug solution is fully dissolved and that there are no deposits on the bottom and sides of the (A). After confirming that no adhesion has occurred, transfer the dissolved solution to (B) and remove (A) with (A) on top.
 - *The (B) (diluent container) is at the bottom.
 - *When removing the (A) (container of drug solution), the solution may get on your fingers, or a slight spurt of the solution may occur. If bubbling occurs, please wait until the bubbling settles down before removing the container.
 - *If the solution adheres to your hands, wash it with water.



- Reattach the removed pink cap to the (B).

- Remove only the blue cap and apply the drops.
 - *Use the eye drops within three days after dilution.
 - *Discard the first drop without putting it in the eye (light-colored liquid may come out first).

