

(2012.7.18)

Revised: July 2012 (Revisions associated with amendments of package insert guide)

Important: Read this document carefully before use and keep it for reference.**Designated Category 2 Drug**

- LAXATIVE CONTAINING INGREDIENTS FROM ALOE AND SENNA -

New Saralin

Normal bowel movements are a sign of good health, and healthy, active people should not experience difficulty moving their bowels. However, constipation may develop due to changes in environment or diet, and may also be a sign of poor health or disease. Constipation may cause loss of appetite due to a feeling of abdominal fullness as well as skin eruptions.

Characteristics and Advantages of New Saralin

- (1) New Saralin is a laxative containing active ingredients obtained from the medicinal herbs: aloe and senna. The tablets are odorless and are coated with a light-orange film. Taking New Saralin at bedtime should result in a regular bowel movement on the following morning.
- (2) Aloe extract and sennosides are converted to their active forms when they arrive in the large intestine. They draw water into the large intestinal contents, resulting in a stool-softening effect, and also stimulate the secretion of intestinal mucus, which serves as a lubricant and enhances peristalsis, resulting in a comfortable bowel movement.

* Aloe extract is obtained from the leaves of the aloe plant, which is a member of Liliaceae (lily) family. The aloe plant is native to South Africa.

* Sennosides are extracted from the small leaves or fruits of the senna plant, which is a member of the Leguminosae (pea) family. The senna plant is native to Africa.

PRECAUTIONS CONCERNING USE

Important precautions

(The following points should be strictly observed. Failure to do so may cause the condition to deteriorate or lead to adverse reactions.)

1. Other laxatives or purgatives must not be used together with New Saralin.
2. Lactating women (nursing mothers) should not take New Saralin. If New Saralin is taken, breast feeding should be avoided.
3. Be sure not to take an excessive number of tablets.

Conditions that require consultation

1. The following people should consult a physician, pharmacist, or registered salesperson before using New Saralin.
 - (1) People who are receiving treatment from a physician.
 - (2) Pregnant women or women who may be pregnant.
 - (3) People with a history of hypersensitivity reactions to medications.
 - (4) People with severe stomach pain, or people with nausea or vomiting.
2. The following symptoms may be adverse reactions. If any of these symptoms are observed after taking New Saralin, discontinue the use of New Saralin immediately and consult a physician, pharmacist, or registered salesperson. Bring this document with you for reference.

Affected part	Symptoms
Skin	Rash, redness, or itching.
Digestive tract	Severe stomach pain, nausea, vomiting, or rumbling of the stomach.

3. Diarrhea may occur. If diarrhea is prolonged or severe, discontinue the use of New Saralin and consult a physician, pharmacist, or registered salesperson.
 4. If symptoms fail to improve after the use of New Saralin for 1 week, discontinue the use of New Saralin and consult a physician, pharmacist, or registered salesperson.
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INDICATIONS

- Constipation
 - Relief of the following symptoms associated with constipation: headache, hot flashes, skin problems, skin eruptions, anorexia (lack of appetite), abdominal fullness, excessive bowel gas, and hemorrhoids.
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DIRECTIONS

New Saralin should be taken with water at bedtime or on an empty stomach as shown in the table below. New Saralin tablets should be swallowed whole.

Age	Dosage per administration	Frequency of administration
Older than 15 years of age	1 to 3 tablets	Once daily
From 11 to 15 years of age	1 or 2 tablets	
Less than 11 years of age	New Saralin should not be taken.	

It is recommended to start with a minimum dosage and gradually adjust the dosage based on the degree of constipation and effectiveness of the product.

<Precautions>

- (1) Children (not less than 11 years of age and up to 15 years of age) should receive New Saralin only under careful parental supervision.
- (2) Be sure to follow the recommended dosage and administration guidelines given above.

(3) How to remove the tablets

Press the convex part of the press-through package (PTP) sheet with your fingertip to break the aluminum foil on the other side and take out the tablet. (If the PTP is swallowed, the sharp edges of the package may cause serious throat injury.)



INGREDIENTS

Three tablets of New Saralin contain the following ingredients.

Aloe Extract 190 mg Equivalent to 380 mg of Aloe.

Sennosides 49.8 mg Equivalent to 21 mg of Sennosides A and B.

* Cellulose, Anhydrous Silic Acid, Magnesium Stearate, Hypromellose, Partially Saponified Polyvinyl Alcohol, Titanium Oxide, Talc, Soybean Lecithin, Carnauba Wax, and Yellow No. 5 (Sunset Yellow-FCF) are included as inactive ingredients.

<Precautions>

New Saralin may cause yellowish-brown or reddish-brown discoloration of the urine. This is due to the sennosides contained in the product and is completely harmless.

PRECAUTIONS FOR HANDLING AND STORAGE

- (1) Keep tightly sealed and store in a cool, dry place away from direct sunlight.
- (2) Keep this product out of the reach of children.
- (3) To avoid misuse and to ensure that the quality, the tablets should not be stored in other containers.

- (4) Do not use the product after the expiration date indicated on the package.
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Prevention of Constipation

It is important to eat regularly and to maintain an active lifestyle. It should also be noted that constipation may be a symptom of disease in the large intestine.

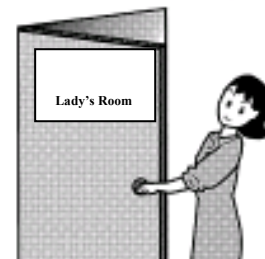
- (1) Eat a well-balanced diet containing sufficient natural fiber.



- (2) Exercise regularly and maintain an active lifestyle.



- (3) Try to maintain regular bowel habits.



PACKAGING

30 or 90 tablets

If you experience any problems after using this product, please notify the store where you purchased the product or contact the office below:

Customer Service Office

Otsuka Pharmaceutical Co., Ltd.

2-9 Kanda Tsukasamachi, Chiyoda-ku, Tokyo 101-8535, Japan

Phone: 03-3293-3212 (main number) Please call between 09:00 and 17:00 (except for Saturdays, Sundays, and holidays).

Inquiries about Adverse Drug Reaction Relief System should be made to:

Pharmaceuticals and Medical Devices Agency (PMDA)

Phone: 0120-149-931 (toll-free, Japan)

<http://www.pmda.go.jp/kenkouhigai.html>

The PMDA provides relief benefits for health damages such as diseases and disabilities requiring hospitalization that were caused by adverse effects of pharmaceuticals that were prescribed at hospitals and clinics as well as pharmaceuticals purchased at pharmacies, etc., even if such pharmaceuticals were properly used.

Distributed by:

Otsuka Pharmaceutical Co., Ltd.

2-9 Kanda Tsukasamachi, Chiyoda-ku, Tokyo, Japan

Manufactured and distributed by:

Otsuka Pharmaceutical Factory, Inc.

115 Kuguhara, Tateiwa, Muya-cho, Naruto, Tokushima, Japan

(This is an English translation of the original Japanese package insert prepared by Otsuka Pharmaceutical Factory, Inc.)