#### Disclaimer on Multilingual OTC Product Information

- This product is a pharmaceutical product approved under a Japanese law, the Law for Ensuring the Quality, Efficacy and Safety of Drugs and Medical Devices, with a view to its sale and use in Japan.
- Multilingual product information is a translation of the product labeling written in Japanese and provided for your information only. It does not warrant that its contents and the product itself conforms to laws and regulations in countries other than Japan.
- Multilingual product information is a tentative translation by Our Company, and may be modified or altered without notice.
- Our Company assumes no responsibility for any occurred problem attributable to the contents of the multilingual product information.

You should read this written explanation before use. Please keep it so that you can read it when you need to.

Revised: April 2017

#### Containing herbal drugs

# BORRAGINOL<sup>®</sup> EP ORAL

#### [Category 2 OTC medicines]

(Oral antihemorrhoidals)

# CHARACTERISTICS

- 1. BORRAGINOL<sup>®</sup> EP ORAL is an oral antihemorrhoidals containing three kinds of herbal drug extracts (such as Moutan cortex extract) and vitamin E acetate.
- 2. BORRAGINOL<sup>®</sup> EP ORAL improves blood circulation in the anorectal area that causes hemorrhoids (piles) and anal fissure. This product also improves pain, bleeding, swelling, and itching due to hemorrhoids (piles) and anal fissure by suppressing inflammation.
- 3. This product is formulated into easy-to-take, readily soluble, light grayish-yellow to light grayish-brown granules.
- 4. This product is supplied in packets convenient to carry.
- 5. This product is taken orally twice a day.

# ▲ 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 taken in the following persons.

Persons who have had an allergic symptom to this product or its ingredients.

# Consultation

- 1. The following persons should contact a physician, pharmacist, or registered salesperson for a consultation before taking this product.
  - (1) Persons undergoing medical treatment from a physician.
  - (2) Pregnant women or women suspected of being pregnant.
  - (3) Persons who have experienced allergic symptoms associated with drugs, etc.
  - (4) Persons diagnosed as phenylketonuria.
- 2. If the following symptoms are observed after taking this product, these may be adverse reactions, so immediately discontinue taking this product, and show this leaflet to your physician, pharmacist, or registered salesperson for a consultation.

Affected parts	Symptoms
Skin	Rash/redness, itching
Gastrointestinal system	Loss of appetite, nausea/vomiting

- 3. The following symptoms may be observed after taking this product. If these symptoms persist or worsen, discontinue taking this product, and show this leaflet to your physician, pharmacist, or registered salesperson for a consultation. Diarrhea
- 4. When symptoms do not improve even after taking the preparation for about 1 month, stop taking this product and consult a physician, pharmacist or registered salesperson, being sure to take this leaflet with you.

#### USES

Relief of symptoms associated with hemorrhoids (piles), anal fissure, and hemorrhoidal bleeding.

# DOSAGE AND DIRECTIONS

Take the following dose after a meal with water or lukewarm water.

Age	Dose	Time of medication per day
Adults (15 years old and over)	1 packet	$2  ext{ times}$
Under 15 years old	This product should not be taken.	

#### Precautions of dosage and directions

Take this product strictly as directed under DOSAGE AND DIRECTIONS in this leaflet.

# **INGREDIENTS**

Per 2 packets (2 g, adult daily dose)

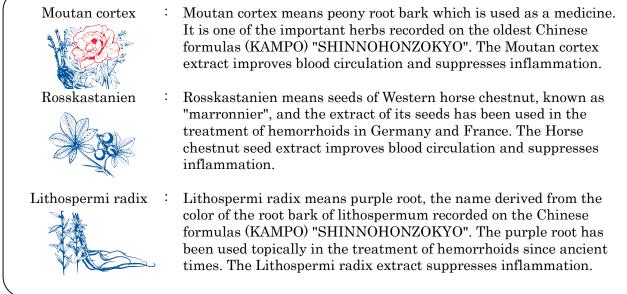
	Ingredients	Contents (in 2 packets)
Moutan corte	Moutan cortex extract	300 mg (extracted from 1,200 mg of Moutan cortex)
Herbal drug extracts	C	100 mg (extracted from 600 mg of Rosskastanien)
	Lithospermi radix aqueous extract	300 mg (extracted from 900 mg of Lithospermi radix)
Vitamin	Vitamin E acetate (Tocopherol acetate)	100 mg

Additives:Aspartame (L-phenylalanine compound), lactose hydrate, light anhydrous silicic acid, powdered cinnamon bark, carmellose sodium, glycyrrhiza extract

#### Precautions of ingredients

Because this product contains herbal drugs (medicinal herbal roots, barks, etc.), the color and taste of granules may slightly vary in some products. However, this does not alter the effectiveness of this product.

- About herbal drugs contained in this product



# PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Store in a cool, low humidity place away from direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer the product to a different container. (It may lead to misuse or alter the quality of the product.)
- (4) Do not take this product after the expiration date.

### HOW SUPPLIED 16 Packets

#### - How to prevent hemorrhoids - Prevent hemorrhoids by maintaining a healthy life style. -(1) To keep (2) Keep the anal (3) Avoid regular area clean. excessive bowel Bathing is strain movement, particularly during eat effective in bowel promoting blood balanced movement. meals three circulation in the anus. times a day.

Marketing authorization held by: AMATO PHARMACEUTICAL PRODUCTS, LTD.

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