

Revised: May 2007 (4th version)

Standard Commodity Classification No. of Japan
875200

■501■

- Kampo-preparation -

TSUMURA Shiunko Ointment

Storage
Store in light-resistant, air-tight containers.

Expiration date
Use before the expiration date indicated on the container and the outer package.

Approval No.	(56AM)9
Date of listing in the NHI reimbursement price	June 1984
Date of initial marketing in Japan	August 1984

CONTRAINDICATIONS (Shiunko is contraindicated in the following patients.)

1. Patients with a history of hypersensitivity to any of the components of this product
2. Patients with severe burns/injury
3. Patients with suppurative wound accompanied by hyperthermia
4. Patients with severe skin wetting or soreness at the affected area

[2 - 4: These symptoms may be aggravated.]

DESCRIPTION

Composition	Shiunko (hereafter TJ-501) of 100 g consists of 27.0 g of JP White Beeswax, 1.8 g of JP Lard and 71.2 g of the oil extract prepared by mixing the ingredients in the following ratio (JP Sesame Oil: JP Japanese Angelica Root: JP Lithospermum Root =100.0 g: 10.0 g: 10.0 g).	
	(JP: The Japanese Pharmacopoeia)	
	Inactive ingredients	Nothing
Description	Dosage form	Ointment
	Color	Reddish violet
	Smell	Characteristic smell
	ID code	TSUMURA-501

INDICATIONS

TJ-501 is indicated for the relief of pain of a burn or hemorrhoids and for the healing of anal fissure.

DOSAGE AND ADMINISTRATION

Topical product

Clean the wound and apply an appropriate amount of TJ-501 directly to the affected area, or dress the wound with gauze with an appropriate amount of TJ-501, several times a day.

PRECAUTIONS**1. Important Precautions**

When TJ-501 is used, the patient's "SHO" (constitution/symptoms) should be taken into account. The patient's progress should be carefully monitored, and if no improvement in symptoms/findings is observed, continuous treatment should be avoided.

SHO: The term "SHO" refers to a particular pathological status of a patient evaluated by the Kampo diagnosis, and is patterned according to the patient's constitution, symptoms, etc. Kampo-preparations (Japanese traditional herbal medicines) should be used after confirmation that it is suitable for the identified "SHO" of the patient.

2. Adverse Reactions

TJ-501 has not been investigated (drug use investigations, etc.) to determine the incidence of adverse reactions. Therefore, the incidence of adverse reactions is not known.

	Incidence unknown
Hypersensitivity ^{Note 1)}	Rash, Pruritus, etc.

Note 1) If such symptoms are observed, administration should be discontinued.

3. Pediatric Use

The safety of TJ-501 in children has not been established. [Insufficient clinical data.]

4. Precautions concerning Use

Site of applications:

TJ-501 should not be applied to eyes.

PHARMACOLOGY**Promotion of wound healing**

When Shiunko was applied to mice with a third degree burn, regeneration of the epidermis was promoted¹⁾.

PRECAUTIONS FOR HANDLING

Caution should be exercised in handling TJ-501. If TJ-501 attaches to clothes, they are stained reddish violet, which is difficult to remove.

PACKAGING

500g

REFERENCES

- 1)Hirama, N. et al. J. Med. Pharm. Soc. WAKAN- YAKU. 1986, 3(3), p.370.

■ REQUEST FOR LITERATURE SHOULD BE MADE TO:

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