

Revised: June 2009 (8th version, section of Contact Information on Request for Literature and Product Information)
 Revised: June 2008

Anti-inflammatory Gargle
 Not Prescription-only drug
 AZULENE POWDER FOR GARGLE 0.4% "TOWA"

Storage:

Store at room temperature (See "PRECAUTIONS FOR HANDLING").

Expiration date:

Indicated on the package.

Shelf life:

3 years

Standard Commodity Classification No. of Japan 87226	
Approval No.	22000AMX00947
Date of listing in the NHI reimbursement price	June 2008
Date of initial marketing in Japan	October 1987

CONTRAINDICATIONS

There is no contraindication for AZULENE POWDER FOR GARGLE 0.4% "TOWA".

DESCRIPTION

Active ingredient in 1 gram	Sodium Azulene Sulfonate..... 4 mg
Inactive ingredients	Lactose Hydrate (q.s.), Povidone (40 mg), Sodium Bicarbonate (20 mg), Monosodium L-Glutamate Monohydrate (0.05 mg), Flavor (Trace)
Dosage form and appearance	Light blue powder having a slightly characteristic odor. They are dose-unit packages of 1.5g/pack.
Identification code	Package
	Tw.AZ1.5 (Displayed on dose-unit package)

INDICATIONS

Pharyngitis, tonsillitis, stomatitis, acute gingivitis, glossitis, oral wound

DOSAGE AND ADMINISTRATION

A dose of 4 to 6 mg of Sodium Azulene Sulfonate is dissolved in an appropriate amount (approximately 100 mL) of water or lukewarm water for gargle several times daily. The dosage may be adjusted according to the patient's age and symptoms.

PRECAUTIONS**1. Drug Interactions**

There is no interaction with other medicaments and other forms of interaction for AZULENE POWDER FOR GARGLE 0.4% "TOWA".

2. Adverse Reactions

No investigation such as a drug use investigation clearly showing the incidence of adverse reactions has been conducted.

	Incidence unknown
Oral cavity	Rough mouth, pharyngo-oral irritation

3. Precautions Concerning Use

Patients with oral injury after extraction of tooth, etc. should avoid vigorous mouth wash during a time period when formation of blood clots may be inhibited.

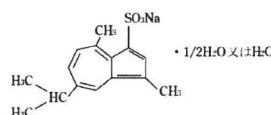
PHARMACOLOGY

Using male Sprague-Dawley rats (20 rats per group), AZULENE powder for gargle 0.4% "TOWA" and standard preparation (0.5 mL of suspension or solution in 300 mg/mL, 0.6 mg of Sodium Azulene Sulfonate) were administered into the mouth to examine and compare the inhibitory effects on enhanced oral mucous membrane capillary permeability by acetic acid.

Both preparations exhibited comparable inhibitory effects, which were assessed as bioequivalent ¹⁾.

PHYSICOCHEMISTRY

Structural formula:



Nonproprietary name:

Sodium Azulene Sulfonate

Chemical name:

Sodium 1,4-dimethyl-7-isopropylazulene-3-sulfonate semihydrate

Sodium 1,4-dimethyl-7-isopropylazulene-3-sulfonate monohydrate

Molecular formula:

$C_{15}H_{17}NaO_3S \cdot 1/2H_2O$ or $C_{15}H_{17}NaO_3S \cdot H_2O$

Molecular weight:

309.36 or 318.36

Description:

Sodium Azulene Sulfonate occurs as dark blue crystals or crystalline powder. It is odorless and tasteless. It is soluble in methanol, sparingly soluble in water and in acetic acid (100), slightly soluble in ethanol (95), and practically insoluble in acetic anhydride, in diethyl ether, and in hexane. The pH of a solution of Sodium Azulene Sulfonate (1 in 200) is between 6.0 and 9.0. It is degraded by prolonged exposure to light.

PRECAUTIONS FOR HANDLING**1. Precautions**

This product may gradually discolor due to exposure to air or ultraviolet light. This product should be stored in a well-closed container and placed in a dark place after opening.

2. Stability test

In an accelerated test using final packaged products (at 40°C and 75% relative humidity for 6.5 months), AZULENE POWDER FOR GARGLE 0.4% "TOWA" was estimated to be stable for 3 years under normal distribution conditions²⁾.

PACKAGING

AZULENE POWDER FOR GARGLE 0.4% "TOWA":
 1.5g x 800 packages

REFERENCES

- Internal data of Towa Pharmaceutical Co., Ltd.: Pharmacodynamic studies
- Internal data of Towa Pharmaceutical Co., Ltd.: Stability test

Manufacturer and Distributor
TOWA PHARMACEUTICAL CO., LTD.
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