CONTRAINDICATIONS (SALCOAT is contraindicated in the following patients.)
Patients with a history of hypersensitivity to any of the ingredients of SALCOAT.

RELATIVE CONTRAINDICATIONS (As a general rule, SALCOAT is contraindicated in the following patients. If the use of SALCOAT is considered essential, it should be administered with care.)
Patients with infection in the oral cavity [Since SALCOAT may exacerbate the symptoms, when its use is necessary, pre- or concomitant treatment with antibacterial or antifungal agent should be considered.]

DESCRIPTION
<table>
<thead>
<tr>
<th>Brand name</th>
<th>SALCOAT Capsule for Oral Spray 50μg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage form</td>
<td>Capsule (for oral spray)</td>
</tr>
<tr>
<td>Active ingredient</td>
<td>Beclometasone Dipropionate</td>
</tr>
<tr>
<td>Content of active ingredient</td>
<td>50 μg</td>
</tr>
<tr>
<td>Inactive ingredient</td>
<td>Hydroxypropylcellulose, Magnesium stearate, Stearic acid</td>
</tr>
<tr>
<td>Color/ description</td>
<td>No. 2 hard capsules with a pale bluish white body and a blue cap</td>
</tr>
<tr>
<td>Appearance</td>
<td>[Image]</td>
</tr>
<tr>
<td>Weight</td>
<td>Approx. 267 mg</td>
</tr>
<tr>
<td>Identification code</td>
<td>TJN 284</td>
</tr>
</tbody>
</table>

INDICATIONS
Intractable stomatitis with erosion or ulceration

DOSAGE AND ADMINISTRATION
Usually, one capsule (50 μg of beclometasone dipropionate) is uniformly sprayed onto the affected area 2 or 3 times a day with a compact spray device, which is exclusively made for its use. The dose may be adjusted according to the patient’s symptoms.

PRECAUTIONS
1. Careful Administration (SALCOAT should be administered with care in the following patients.)
   (1) Patients with a history of candidiasis by the use of SALCOAT [Candidiasis may occur.]
   (2) Patients with reduced immune function [Candidiasis may occur.]
   (3) Patients with a wound surface, e.g. immediately after a biopsy [The wound surface may bleed.]

2. Important Precautions
   Prolonged continuous use of SALCOAT may inhibit the function of the pituitary-adrenal system.

3. Adverse Reactions
   A total of 7 adverse reactions were observed in 7 (2.2%) of 314 patients evaluated for safety at the time of approval. Those are 6 events (1.9%) of candidiasis and 1 event (0.3%) of abdominal discomfort.
   No changes in laboratory values that were considered to be adverse reactions were observed.
wound surfaces may bleed. With wound surface, e.g., immediately after a biopsy, because administration, etc.

For drugs that are dispensed in a press-through package (PTP), instruct the patient to remove the drug from the package prior to use. (It has been reported that, if the PTP sheet is swallowed, the sharp corners of the sheet may puncture the esophageal mucosa, resulting in severe complications such as mediastinitis.)

PHARMACOKINETICS
(Reference Information)
Intraoral distribution, adhesion and retention properties
Five (5) mg of SALCOAT, containing ³H-labeled beclometasone dipropionate as the active ingredient (equivalent for 1.25 µg of beclometasone dipropionate), was sprayed into the oral cavity of rats, and the time-course of the distribution of the labeled active ingredient within the oral cavity was examined by microradiography. The results showed that the formulation adhered and was retained for a while at the site of application on the oral mucosa. The high level of active ingredient was maintained in the keratinized epithelium and that allowed the active ingredient to penetrate well into the underlying layers, which are the stratified squamous epithelium, connective tissue, and muscle layer. Sufficient level of the active ingredient was retained in these tissues.3, 5

CLINICAL STUDIES
Clinical effects
The efficacy rate of SALCOAT based on an effective or better evaluation, with pain, size, redness, etc., as the indices, was 71.2% (205/288 cases) in clinical trials including a comparative clinical studies on stomatitis with erosion or ulceration as the target disease in a total of 325 patients in 42 institutions in Japan that had been conducted by the time of approval.3, 4

PHARMACOLOGY
1. Effects of the main ingredient beclometasone dipropionate
In the vasoconstriction study in human skin, beclometasone dipropionate exhibited a local anti-inflammatory action approximately 5 times stronger than that of triamcinolone acetonide and approximately 600 times stronger than that of dexamethasone.3

2. Properties of the base material
The base material of SALCOAT is composed of high-molecular bases of which hydroxypropyl cellulose is the main ingredient. It is strongly adhesive to mucous membranes, such as that of the oral cavity. It swells in contact with saliva, forming a soft, thin layer that coats and protects the lesion area (lesion area coating and protective property), and relieves contact pain. In addition, it possesses the properties of not readily being removed by physical friction (wound surface adhesiveness), slowly dissolving, and prolonged local adhesion and retention (local sustained release).

PHYSICOCHEMISTRY
Nonproprietary name: Beclometasone Dipropionate
Chemical name:
9-Chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3, 20-dione 17, 21-dipropionate
Structural formula:
Molecular formula: C_{28}H_{37}ClO_{7}
Molecular weight: 521.04
Melting point: approximately 208°C (with decomposition)
Description: Beclometasone dipropionate occurs as white to pale yellow powder. It is odorless. It is freely soluble in chloroform, soluble in methanol, sparingly soluble in ethanol (95) and in 1,4-dioxane, slightly soluble in diethyl ether, and practically insoluble in water.

PRECAUTIONS FOR HANDLING
1. Storage:
   (1) Patients should be advised to be careful of moisture absorption once the capsules are removed out from the PTP package.
   (2) The color of the capsules may fade slightly as a result of exposure to room light, but it has no effect on the content.

2. When spraying to the oral cavity
   (1) SALCOAT should be sprayed by using a compact spray device (Puvlizer®), which is exclusively made for its use. SALCOAT is not an internal use preparation.
   (2) Puvlizer® should be spray correctly by following the illustration inserted in the case.
   (3) If it does not spray properly, check again and see if the spraying is being performed according to the illustration.

PACKAGING
PTP: 100 capsules (10 capsules x 10)

REFERENCES

REQUESTS FOR LITERATURE SHOULD BE MADE TO:
Sales Training & Information Department
TEIJIN PHARMA LIMITED
2-1, Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100-8585
TEL: 03-3506-4053

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