

Relieve painful stomatitis by patch(film)

MADE IN JAPAN

トラフル[®]ダイレクト_a

Trafal Direct a

Adhesive patch for stomatitis

Designated class 2 OTC medicine



Indications

Stomatitis (aphthous type)

Dosage and Administration

Age	Directions
Adults (15 years or over)	Apply one patch to one affected part, once or 2 times a day. The white-colored face should be applied to the mucous membrane of the affected site.
Children (5 to 14 years)	
Under 5 years	Do not use.

<Precautions related to Dosage and Administration>

1. Follow the Dosage and Administration strictly.
2. As the patch dissolves by itself in time, do not try to peel it off by force.
3. Discontinue use when the pain has been relieved. (There is no need to remove in-use patch.)
4. Use for children should be supervised by guardians.
5. Do not use for infants under 5 years.
6. Be careful when applying this patch to the mouth of children, who may try to remove the film by their finger after application.
7. The patch is an adhesive device for oral mucosa. Do not swallow the patch as it provides no effect if swallowed.
8. If you swallow the patch by mistake, apply a new one to the affected area immediately. If there found no change in symptoms or developed worrisome matter, consult a doctor, dentist or pharmacist.
9. The patch may not adhere to oral mucosa if used incorrectly, so apply it correctly after reading the Directions carefully. Depending on the location of the affected area, it may be difficult to get the patch to adhere. If you cannot apply the patch properly, consult a doctor, dentist or pharmacist.
10. If you forget to use this product, apply it as soon as you realize it.
11. As this patch may adhere poorly if the mucous membrane of the affected part is remarkably wet with saliva or such, apply it after wiping out saliva of affected area by the tissue or gauze.
12. This patch may peel off if it was strongly touched by tongue after its adherence to mucous membrane of the affected part. If the patch peels off before its dissolution, do not swallow and throw it away.
13. How to pick out the patch
Pick out the patch by carefully peeling off the aluminum sheet containing the medicine from the opening.
(If the sheet is accidentally swallowed, it could pierce the mucous membrane of the esophagus.)

<Directions>

Trafal Direct is an adhesive patch for mouth sores.

As this product provides efficacy by adhering to mucous membrane, do not swallow it and attach it properly to the affected part as described below.

This product is for the “stomatitis (aphthous type)” which is a general term for inflammation accompanying one or more small, shallow but painful whitish ulcers (less than 10 mm in diameter) with depressed areas surrounded by reddening on the inside of the cheeks or on the tongue, inside of the lips or such, as shown in the figure below.



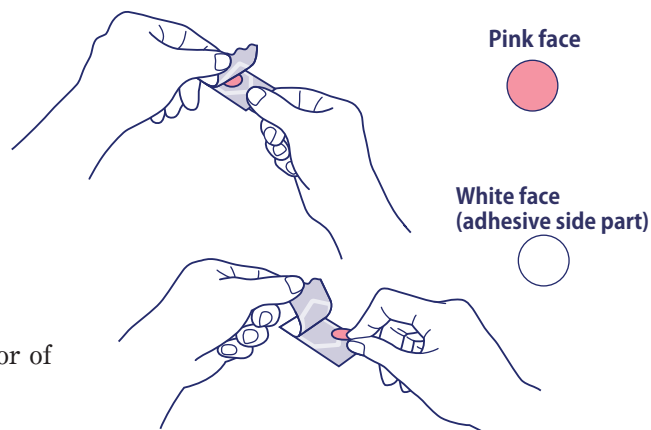
Wipe the affected area

[1] Remove the saliva of the area affected by stomatitis with the lightly applied tissue or gauze.

Pick up the patch(film)

[2] Carefully peel off the aluminum sheet from the opening and pick up only the patch(film).

[3] Pick up the patch(film) with fingertips and confirm the color of both sides (pink or white face).

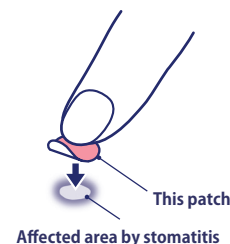


Attach and press

While looking in the mirror, attach the patch to cover the affected area and press firmly.

[4] Lightly press the orange face against the affected area, hold it in place with a fingertip for about 3 seconds (to a count of three), and then remove your fingertip.

- If the patch does not adhere well, try to press for longer.
- Be sure to press the patch firmly including surrounding area of the lesion so that it will adhere securely. If there left weak adhesion area, the patch will be easy to peel off.



Minimize touching

[5] As the patch may slip from its position during a few minutes after application, minimize the touching of tongue to the patch. (Application is available before sleeping.)

- Avoid eating and drinking right after application.

No need to peel off, it melts away

[6] It will melt and disappear as time goes by. Do not peel it off forcibly.

Ingredients and Quantities

Per 1 patch

Ingredient	Quantity
Triamcinolone acetonide	0.025 mg

Other ingredients: Povidone, hydroxypropyl cellulose, tannic acid, citric acid, macrogol, titanium oxide, Red 102, ethyl cellulose

Precautions

Things to avoid

(If you fail to follow these precautions, your present symptoms may worsen, or side effects may occur more readily.)

1. This product should not be used by the following persons:

(1) Persons considered to have infectious stomatitis (Consult a doctor, dentist or pharmacist).

- Persons who have white spots, which are easily peeled off by rubbing with gauze or such, throughout their oral cavities (A candida infection is suspected).
- Persons having yellow pus at the affected area (A bacterial infection is suspected).
- Persons having numerous vesicles of rice grain to adzuki bean size in the oral cavity or persons having vesicles or rash on the lips or skin, other than the oral mucosa (A viral infection is suspected)
- Persons having systemic symptoms such as fever, loss of appetite, general malaise or swelling of lymph nodes (A viral infection is suspected).

(2) Persons having infection in the oral cavity.

(As there have been reports that infections can be exacerbated by the steroids, do not use this product onto parts where the oral infections such as pyorrhea or gingivitis are found)

(3) Persons who show no improvement in symptoms even after use of this product for 5 days

(4) Persons who show worsening of symptoms after use of this product for 1 to 2 days

Things to consult

1. The following persons should consult a doctor, dentist or pharmacist before use.

(1) Persons who are receiving medical treatment from a doctor or dentist.

(2) Women who are pregnant or considered to be pregnant.

(3) Women who are breastfeeding.

(4) Elderly people.

(5) Persons who have had allergic symptom with medicines or such.

(6) Persons having mouth sores or inflammation at extensive area (that cannot be covered by this patch).