



TRANSPERFECT

I, Marc Adler, hereby declare that (1) I prepare Japanese to English translations for TransPerfect (a translation services company) and I am qualified to do so, (2) I personally prepared the translation attached as Exhibit 1, and (3) the attached translation is, to the best of my knowledge and belief, a true and accurate translation from Japanese to English of the following document, attached as Exhibit 2: Drug Information Sheet for Tapros Mini ophthalmic solution 0.0015%, available at <http://www.rad-ar.or.jp/siori/kekka.cgi?n=37446>.

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

MARC ADLER
[Print Name]

Marc Adler
[Signature]

3-22-18
[Date]

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**DOCKET
ALARM**

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Exhibit 1

“Kusuri No Shiori” lets you search through 16,181 drugs.



Medicines

General drug search

List of participating companies

< Kusuri No Shiori – managers



Drug Search

What is Kusuri No Shiori?

How to Purchase Data

Previous

English Print Word format Package insert

Kusuri No Shiori [Drug Information Sheet]

External application

Santen Pharmaceutical Co., Ltd.

Revised July 2017

Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: TAPROS Mini ophthalmic solution 0.0015%
Active ingredient: Tafluprost
Dosage form: Colorless, transparent ophthalmic solution, 0.3 mL (container) clear, transparent, (label) white (front), red (back)
Print on sheet:



Effects of this medicine

This medicine lowers pressure in the eye by promoting aqueous humor outflow through stimulation of the prostanoid FP receptor. It is usually used to treat glaucoma or ocular hypertension.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines. If you have: aphakic/pseudophakic eyes, bronchial asthma/history of bronchial asthma, or intraocular inflammation (iritis, uveitis). If you wear contact lenses.
- If you are pregnant or nursing.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing (How to take this medicine)

Your dosage (to be filled in by a healthcare professional)

[Empty box for dosage]

- In general, apply 1 drop at a time, once a day. Strictly follow the instructions.
- Before applying, wash your hands thoroughly with soap and running water. Next, twist off the tab (the part where no solution is contained) and discard 1 or 2 drops. Then, pull down your lower eyelid so that the dropper tip does not touch your eye or eyelashes and apply the medicine. After applying, keep your eyes closed for 1 to 5 minutes pressing the inner corner of the eye lightly. Wipe off any excess liquid with a wet gauze or tissue immediately, or wash your face with eyes closed. After applying, make sure to dispose of the dropper. Once the tab is removed, remaining solution must not be stored for later applying. If you need to apply other eye drops at the same time, wait more than 5 minutes.
- If you miss a dose, apply 1 drop as soon as possible in case of the same day. If you notice on the next day, skip the missed dose and continue your regular dosing schedule. You should not apply twice a day or 2 drops at one time.
- If you accidentally apply more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop applying this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- This medicine may cause blurred vision temporarily after applying. Do not operate machinery or drive a car until these symptoms recover.

[Empty box for precautions]

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include bloodshot eyes, changes in eyelashes (increased length, thickness and number of lashes), itchy/stinging eyes, eyelid pigmentation (darkening around the eyes), corneal epithelial disorder (eye pain, focus disorder, foreign body sensation in eyes), and hypertrichosis of eyelid. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- changes in the color of the iris [iris pigmentation]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children.
- Store in a refrigerator (2 to 8°C) before opening foil pouch.
- After opening the foil pouch, store in a shading bag in a refrigerator (2 to 8°C) and use within 1 year, or store in a shading bag at room temperature (1 to 30°C) and use within 1 month.
- Discard the remainder. Do not store them. Ask your pharmacy or medical institution how to discard.

For healthcare professional use only: Day _____ Month _____ Year

[Empty box for professional use]

For details, talk to your doctor or pharmacist. The Pharmaceuticals and Medical Devices Agency website has “Drug Guides for Patients” and “package inserts” for healthcare professionals.

Next

Keyword Search

Search by product name

Enter keyword

Search all companies

Search for English version?

Refine search

Q Perform search

Search product name index

A	KA	SA	TA	NA
HA	MA	YA	RA	WA

Drug Database
iyakuSearch

Package inserts link to the "iyakuSerch" database belonging to the Japan Pharmaceutical Information Center (JAPIC).

Exhibit 2

Explore Litigation Insights

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