Product information

[Drug Facts]

Please be sure to read this product information carefully before use. Keep this product information in a safe place so that you can read again, when you need it.

Transdermal Analgesic Anti-inflammatory (LOTION) TYANTERON DF COOL LOTION

- "TYANTERON DF COOL LOTION" is a non-steroidal analgesic and antiinflammatory medicine formulated with diclofenac.
- "Diclofenac sodium" reduces prostaglandin formation that causes pain, and exerts an excellent effect on pain in joints, muscles, hips and shoulders.
- "I-Menthol formulation" gives a pleasant refreshing sensation after application.

Active ingredients (in 100g)

Diclofenac sodium 1.0g

I-Menthol 3.0g

To cool, Anti-inflammatory

Topical pain medication

Purpose

<Kyowa-Gifu-Japan>

Uses Backache, Shoulder pain associated with stiff shoulders, Joint pain, Muscle aches, Myelitis (hand and wrist pain), Elbow pain (tennis elbow, etc.), Bruises, Sprains.

Do not use for infants under 15 years old.

Warnings [To be avoided]

(Failure to observe the following may result in the current symptoms worsening or adverse reactions occurring.)

1. Do not use to the following person:

- (1) A person with a medical history of being allergic to this medicine or substances in it.
- (2) A person who has experienced asthma.
- (3) A pregnant woman or a woman suspected of being pregnant.
- (4) A child under 15 years old.

2. Do not use for the next part:

(1) Around eyes, mucous membranes etc.

- (2) Weak part of the skin (face, head, armpit etc)
- (3) Eczema, rash, wound
- (4) Athlete's foot or Ringworm etc., or the affected area is purulent on.
- 3. While using this medicine, do not use other Transdermal analgesic antiinflammatory medicines
- 4. Do not use long-term continuously.

[Consult a doctor for the following]

- 1. The following persons should consult a doctor, pharmacist, or registered distributor before using this medicine.
- (1) A person undergoing medical treatment from a doctor.
- (2) A person with a medical history of being allergic to medicines and other substances.
- ⁽³⁾ A person who being administered the following medication: New quinolone antibacterial agent
- 2. The following symptoms appear after using, there is a possibility of a side effect, so please stop using it immediately and consult a doctor, pharmacist or registered distributor with the Japanese package insert.

Related area	Symptoms
Skin	Rash •Redness, Itching, Rash, Swelling, Pain, Irritation, Heat, Rough skin, Exfoliation (Skin peeling like dandruff, Redhead), Blisters, Pigmentation.

In rare cases, the following serious symptoms may occur. In that case, please get medical attention immediately.

Symptom name	Symptom
Shock(Anaphylaxis)	Immediately after using this medicine, itching of the skin, urticarial, hoarseness of voice, sneezing, throat itching, breathing, palpitations, turbulence of consciousness etc. appears.
Contact dermatitis, Photosensitivity	You may occur Rash, redness, swelling, irritability, intense skin inflammation and pigmentation such as blisters and sore, vitiligo appear in the application area, and symptoms such as rash, redness, itching spread throughout the body. In addition, symptoms may appear or worsen in areas exposed to sunlight.

3. If symptoms do not improve after using it for 5 to 6 days, stop using the medicine, bring the Japanese package insert, and consult a doctor, pharmacist or registered distributor.

Directions

Apply an appropriate amount to the affected area 3 to 4 times a day. However, please do not cover the applicate site with a poor breathable material such as wrap film. And do not use in combination with other external medicines including this same active ingredients.

[When using this product]

- (1) Please follow the recommended dosage and directions.
- (2) This medicine use only treat of symptoms such as pain or swelling, but not to restore from the cause of illness. So use only if you have these symptoms.
- (3) Use this medicine only for externally and do not take it internally.
- (4) Do not use more than 50 mL per a week.
- (5) Be careful not to get into eyes. If it gets in your eyes, please wash immediately with water or lukewarm water. And If the symptoms are severe, please be given medical treatment by an eye doctor immediately.
- (6) Do not use other external medicines at the same affected area.
- (7) Do not cover the affected area after using with a poorly breathable material (wrap film, straightening belt, etc.) and not keep the area in a sealed condition.
- (8) Please wash well your hands after use.

Other information

- (1) Store in a cool and dry with less humidity place free from direct sunlight by a seal tightly.
- (2) Do not get close to fire. In addition, please do not throw in fire after use.
- (3) Keep all medicine out of the reach of children.
- (4) Be careful not to adhere this medicine at some products, as it may soften the plastic, dissolve the paint, or discolor the metal.
- (5) Do not transfer this medicine to a different container. (In this case, cause misuse or change quality.)

(6) Do not use products that have expired. Please use as soon as possible even
within the expiration date after opening.

Inactive ingredients: Macrogol, Ethanol, Sodium pyrosulfite, Lactic acid, Hydrophobized hydroxypropyl methylcellulose

Questions or comments?

If you have any suggestions about this product, please contact the shop you purchased or the following address.

Consumer consultation window: Kyowa Pharmaceutical Industry Co., Ltd. Customer consultation room **2** 058-246-8771

Reception time $9:00 \sim 12:00 \cdot 13:00 \sim 17:00$ (Excluding weekends and holidays)

[Request of limited correspondence] <Kyowa-Gifu-Japan>

(1) In case of telephone consultation, please only in Japanese for a while.

(2) The latest Japanese package insert is available on the website of Kyowa Pharmaceutical Co., Ltd. (www.kyowa-ci.co.jp).

Disclaimer statement

(1) We use a format similar to the FDA OTC Drug Regulations, but this is not an OTC Drug approved under the FDA. Please note that it is licensed for domestic use in accordance with the Pharmaceutical Affairs Law of Japan.

(2) This English translation was created by a manufacturer and distributor, but Japanese is a correct sentence and it should be as a reference material. In the case of any discrepancy between the two versions, the original Japanese version prevails.

(3) The provider of this translation shall not be responsible for any damage that may be attributed to the use of the translation.

- (4) Do not use for commercial purpose reproduction, publication etc. of this English translation.
- (5) Although the English translation is prepared on the basis of the Japanese version of the attached document on the year and month, the attached document is revised from time to time, so the English translation may not be the latest.