

Brand name: Zenol Diclodirect

RISK CATEGORIES
Second-class OTC drug

CHARACTERISTICS
[Thick stick applicable widely to the painful part of shoulder/lower back]
The thick stick can cover over a wide area from shoulder to neck. Apply the drug as if compressing it to the painful area and the surrounding region. The drug is released if it is turned downwards. Release the drug for 4-5 mm. This product contains diclofenac sodium 1.0% [Thick stick easy to use] The drug can be applied sufficiently to the painful area of lower back and the surrounding region.
Applicable widely to the painful area of arm and leg muscles.



Content of active ingredients (per 100 g)
Diclofenac sodium 1.0 g, I-Menthol 3.0 g

Detailed information

Distributor	Taiho Pharmaceutical Co., Ltd.
Manufacturer/distributor	Mikasa Pharmaceutical Co., Ltd.
Dosage form	Stick preparation
Packing unit	42 g x 1 box
Manufacturer's suggested retail price	JPY 1,760 (JPY 1,600 excluding tax)
JAN Code	4987117372335
Expiration date	3 years

Dosage and Administration

Apply an appropriate amount to the affected area three to four times daily. However, do not cover the treated area with a wrap film or other poorly-ventilated materials. Do not use this product with other topical agent containing diclofenac sodium.

Indications
Joint pain, shoulder pain associated with stiff shoulder, tenosynovitis (hand and wrist pain), elbow pain (e.g., tennis elbow), muscle pain, lower back pain, bruises, and sprains.

<Precautions on dosage and administration>

- (1) The dosage and administration mentioned above need to be followed strictly.
- (2) This product is intended for treatment of symptoms (pain, swelling, etc.), rather than treatment of the disease responsible for pain, swelling, etc. So, it should be used only when you have symptoms.
- (3) This product should be administered only topically. It may not be administered orally.
- (4) The product may not be used in a quantity exceeding 50 g per week.
- (5) Take care to avoid exposure of eyes to this drug. If eyes have been exposed to the drug, wash off the drug from the eyes immediately with water or warm water.
If symptoms after exposure of the eyes are severe, consult an ophthalmologist.
- (6) Do not apply any other drug for topical application to the site to which this product has been applied.
- (7) Do not cover the applied site tightly with a poorly air-permeable material such as wrap film or corrective belt.
- (8) Wipe off the sweat before the product is applied to the affected area.
- (9) To avoid direct contact of the container with the affected skin area, release 4-5 mm of the drug from the container before use.

(10) If the receiving dish on the container bottom becomes visible and the upper surface of the dish is exposed, do not use the product any more. Do not apply by force the drug remaining on the receiving dish.

Precautions

1. The following individuals are required to consult a physician, a pharmacist or the registered salesperson before using this product.

- (1) Individuals receiving treatment from a physician
- (2) Individuals having a history of allergy to drugs, etc.
- (3) Individuals receiving treatment with the following drugs

Neuquinolone antimicrobial agents

2. If any of the following symptoms appears after use, it may reflect an adverse reaction. Discontinue use of the product immediately in such an event, and visit a physician, a pharmacist or the registered salesperson, carrying this leaflet, to seek consultation.

[Related site] [Symptom]

Skin: Eruption/redness, itching sensation, rash, swelling, pain, irritation, hot feeling, rough skin, dandruff (detached skin), blister, pigmentation

Although rarely, the following serious symptoms may appear. In such an event, immediately consult a physician.

[Symptom name] [Features]

Shock (anaphylaxis): Skin itching, urticaria, hoarse voice, sneezing, throat itching, feeling of dyspnea, palpitation, clouding of consciousness, or other symptoms may occur immediately after using this product.

Contact dermatitis, photosensitivity: Severe symptoms of dermatitis (e.g., eruption/redness, swelling, irritation, blister, sore) accompanied by intense itching sensation as well as pigmentation and leukoderma may appear on the applied area, occasionally resulting in spread of eruption/redness, itching sensation, etc. to the whole body. Furthermore, symptoms may appear or exacerbate in the area exposed to sunlight.

3. If the symptoms do not alleviate after using the product for 5-6 days, visit a physician, a pharmacist or the registered salesperson, while carrying this leaflet, to seek consultation.