# Category 2 OTC medicines

# External Anti-Inflammatory/Analgesic アンメルツゴールドEX NEO

販売名:アンメルツゴールドEX NEO

#### Precautions for use

#### What you should Not do:

(If you do not follow the precautions listed below, your current symptoms may worsen and you may be at an increased risk of side effects.)

- 1. The following persons should not use this product.
  - (1) Persons who have had allergies to this product or ingredients of this product
  - (2) Persons who have had asthma
  - (3) Persons who are or may be pregnant
  - (4) Children under 15 years of age
- 2. Do not use this product to the following areas.
  - (1) Around eyes, mucosa, etc.
  - (2) Sensitive skin areas (e.g. face, head, armpit)
  - (3) Eczema, irritated skin, wound site
  - (4) Foot ringworm and tinea, or affected area with pus formation
- Do not use other external anti-inflammatory/analgesics while using this product.
- 4. Do not use this product regularly for long periods.

# Who should seek consultation

- 1. The following persons should consult a doctor, pharmacist or registered salesperson before using this product:
  - (1) Persons under treatment by a doctor
  - (2) Persons who have experienced allergic symptoms to medicines
  - (3) Persons receiving treatment with the following medicines. New quinolone antimicrobial agents
- 2. Stop using this product immediately and ask a doctor, pharmacist, or registered salesperson with this package if the following symptoms appear while or after using this product because they may be side effects of the product.

Affected area	Symptoms
Skin	Rash/redness, itching, irritated skin, swelling, pain, feeling of
	stimulation, heating sensation, roughness of skin, desquamation
	(exfoliation of skin such as dandruff and scurf), blisters,
	pigmentation

In rare cases, the following serious symptoms might occur. In that case, consult a doctor immediately.

Name of symptoms	Symptoms
Shock	Symptoms such as itching of the skin, hives, hoarseness,
(anaphylaxis)	sneezing, itching of the throat, breathing difficulties, palpitations
	and clouding of consciousness will appear immediately after
	using the medicine.
Contact dermatitis,	Rash/redness associated with severe itching on the application
photosensitivity	area, swelling, feeling of stimulation, symptoms of severe
	dermatitis such as blisters and erosions, pigmentation, and
	leukoderma will appear, and in some cases, symptoms such as
	rash/redness and itching may spread to the entire body. Further,
	symptoms may appear on the areas that are exposed to sunlight
	and worsen.

3. If symptoms do not improve after using this product for 5 to 6 days, stop using this product and ask a doctor, pharmacist, or registered salesperson with this package.

# **INDICATIONS**

Shoulder pain associated with stiff shoulder, lower back pain, arthralgia, muscular ache, tenosynovitis (hand and wrist pain), elbow pain (e.g. tennis elbow), bruise, sprain

### DOSAGE AND DIRECTIONS

Apply an appropriate amount to the affected area 3 to 4 times daily. However, do not cover the application area with objects that are not breathable such as wrap film. Avoid concomitant use of this product with other topical products.

- <Pre><Pre>cautions regarding dosage and directions>
- (1) Follow the designated dosage and directions.
- (2) Since this product is a drug to treat symptoms such as pain and swelling only, not to treat the disease responsible for pain and swelling, etc., use only when the symptoms are present.
- (3) For external use only and do not ingest.
- (4) Do not use an amount exceeding 50 g in 1 week.
- (5) Avoid contact with the eyes. If this product gets into the eye, immediately wash the eye with cold or lukewarm water. If the symptom is severe, consult an ophthalmologist.
- (6) Avoid concomitant use of this product on the site of application with other topical products.
- (7) Do not cover and seal the application site with objects (e.g. wrap film, correction belt) that are not breathable.
- Persons whose skin is particularly sensitive should not use on the same place continuously.
- If this product is used before and after getting sweaty such as playing sports and bathing, tingling sensation, pain and heat sensation may increase. When these symptoms are severe, they will be relieved if you wash off with soap.

# **INGREDIENTS AND CONTENTS**

In 100 g

Diclofenac sodium 1 g
I-menthol 5 g
Tocopherol acetate 100 mg
Vanillylamide nonylate 12 mg
Nicotinic acid benzyl ester 10 mg

As inactive ingredients, this product contains glycyrrhetinic acid, isopropyl myristate, propylene glycol, dipropylene glycol, lactic acid and ethanol.

#### PRECAUTIONS FOR STORAGE AND HANDLING

- (1) Keep the cap tightly closed and store this product in a box in a dry and cool place (cold dark place) away from direct sunlight.
- (2) Keep away from flame.
- (3) Keep out of the reach of children
- (4) Do not transfer this product to another container (it may cause improper use or loss of quality).
- (5) Do not use the product after its expiration date. In addition, use the product as soon as possible after opening even within the expiration date.
- Liquid may leak if the cap is not tightly closed.
- Wash immediately according to the washing instructions if the clothes are is stained.

#### **Highly flammable**

Class 1 petroleum, Hazardous Rank II Ethanol-containing product

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