

本製品は日本国法に基づき製造販売されたものです。また、この添付文書は日本国法に基づき作成した添付文書を翻訳したものであり、日本国外の法規に準じているわけではありません。

This product is manufactured and marketed for domestic sales in accordance with the Japanese laws.
This leaflet, translated from the original package insert created in accordance with Japanese laws, is not in compliance with laws outside Japan.

2nd Class OTC drug

Please read the package insert carefully before use and keep it with this medicine.

Topical
anti-inflammatory
analgesics medicine

バンテリン[®]ゲル α
VANTELIN KOWA GEL α

Precautions for use

To be avoided

(Failure to follow the directions below may worsen existing symptoms or increase the risk of adverse reactions)

1. Do not use if you:

- (1) Have had an allergic reaction to this medicine or any of its ingredients.
- (2) Have had asthma.
- (3) Are a child under 11 years old.

2. Do not use:

- (1) Around the eyes, mucosa etc.
- (2) Eczema, dermatitis, wound site.
- (3) Affected area of athletic foot/tinea, or of suppuration.

3. Do not use over a long period consecutively.

What to ask a doctor, pharmacist or registered salesperson

1. Ask a doctor, pharmacist or registered salesperson before use if you:

- (1) Are currently treated by a doctor.
- (2) Are pregnant or may possibly be pregnant.
- (3) Have ever had allergic reaction to any medicines, etc.

2. The following symptoms have occurred due to this product, may be observed as adverse reactions. If any of the symptoms occur after use, stop use immediately and ask a doctor, pharmacist or registered salesperson with the package insert.

Related area	Symptom
Skin	Rash/redness, itching, swelling, tingling pain, feeling hot, feeling dry

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

Ingredients/contents (per gram)

Ingredients/contents	
Indomethacin	10mg
<i>l</i> -menthol	60mg
Arnica tincture	5mg (1mg as Arnica)

[Inactive ingredients] Carboxyvinyl polymer, hypromellose, disodium edetate, sodium hydrogen sulfite, fragrance, diisopropanolamine, polyoxyethylene hydrogenated castor oil, propylene glycol, benzyl alcohol, diisopropyl adipate, isopropanol

Indications

Shoulder pain associated with stiffness, muscle pain, low back pain, arthritic pain, tenosynovitis (hand/wrist pain), elbow pain (tennis elbow, etc.), contusion, sprain

(Continued overleaf)

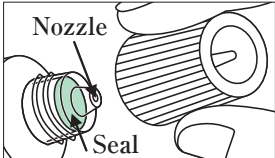
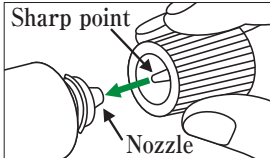
Dosage/directions

Rub appropriate amount onto the affected areas up to four times a day.

<Precautions for dosage/directions>

- (1) Follow the dosage/directions.
- (2) This medicine should be applied to children 11 years and older only under supervision of their guardians.
- (3) Take care not to get it in your eyes. In case it gets into your eyes, immediately rinse them with water or lukewarm water.
In severe cases, immediately consult with an ophthalmologist.
- (4) For topical use only.
- (5) Do not use more than 50 g per week.
- (6) Do not wrap around the affected area with a poor air permeability material, such as a wrap film, where the medicine was just rubbed.

[How to use the container]

<p>[1] As shown in the picture, <u>the inside of the nozzle is sealed.</u></p> 	<p>[2] The first time the tube is opened, press the sharp point of the cap into the sealed end of the tube. Push down firmly until the seal is open.</p> 
--	---

- Do not grip the tube tightly. The product is soft and may shoot out when the tube is pressed hard.
- After use, cleanly wipe off any remaining product on the nozzle, and pay attention not to let it stick to the surrounding area.
- Be sure to screw the cap on tightly after use.

Precautions for storage and handling

- (1) Store in a cool place avoiding high temperatures and direct sunlight, with cap tightly closed.
- (2) Keep out of reach of children.
- (3) Do not transfer the product to another container. (It may cause misuse and deterioration in the quality.)
- (4) Do not touch the mucosa such as the eyes with hands exposed to this medicine.
- (5) If the medicine adheres to clothes or bedclothes and they become soiled, wash them with water or a cleanser as quickly as possible.
- (6) Avoid contact of the medicine with metals such as glasses, watches, and accessories, clothes, plastics, the coated surface of the floor or furniture, because the adhesion may cause their deterioration.
- (7) Keep fire away from this product.
- (8) Do not use this product after its validity date (printed on the outer box and on the tube) has expired.

Marketing Authorization Holder Kowa Company, Ltd. 3-4-14, Nihonbashi-Honcho, Chuo-ku, Tokyo

Y1628 T1K A2