

Diclofenac Sodium

VANTELIN GEL

10 mg (1% w/w) per g Topical Gel
Non-Steroidal Anti-Inflammatory Drug (NSAID)

Name of Product:

VANTELIN GEL

Description of the Product:

A colorless transparent gel

What is in the Medicine?

VANTELIN GEL contains the active substance diclofenac, which is a non-steroidal anti-inflammatory drug (NSAID). It is specially formulated for rubbing into the skin.

Strength of the Medicine:

1% w/w

What is this Medicine used for?

VANTELIN GEL can be used to treat mild-to-moderate pain and helps to relieve symptoms of arthritis (osteoarthritis or rheumatoid arthritis), such as inflammation, swelling, stiffness, and joint pain.

Do not use for more than

- 2 weeks for muscle and joint injuries (e.g. sprains, strains, bruises) or tendonitis.
- 3 weeks for arthritis pain.

without consulting a doctor or pharmacist.

If the pain and swelling do not improve within 7 days, or if they get worse, tell your doctor.

How to use VANTELIN GEL tube?

The first time you open the tube, press the sharp point of the cap into the sealed end of the tube. Push down to break the seal.

How much and how often should you use this Medicine?

- For adults and children over 12 years of age, gently rub a small amount of the gel into the skin where you have pain or swelling. The amount needed will vary depending upon the size of the painful or swollen area; an amount ranging in size from a cherry to a walnut will usually be sufficient. It can be used 3 to 4 times a day. Contact your doctor immediately if you have accidentally used more than the recommended amount or in case of accidental ingestion.
- VANTELIN GEL is for external use only. Do not use it in the mouth. Do not swallow it. Be careful not to get VANTELIN GEL in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.
- A brace or wrap commonly used for injuries like sprains can be used but do not use under airtight (plastic) bandages.

When should you not take this Medicine?

Do not use if you are known to be sensitive to diclofenac, menthol, aspirin or other non-steroidal anti-inflammatory drugs, or if you are asthmatic.

Care that should be taken when taking this Medicine?

Do not apply to cuts or open wounds or eczema. If you are pregnant or breast-feeding, ask your doctor first before using this gel. It should be avoided during the last 3 months of pregnancy. Do not use in children below 12 years of age.

Undesirable Effects of this Medicine:

VANTELIN GEL is usually well tolerated. Itching, reddening, smarting of the skin, rashes or skin eruptions may occasionally occur.

What other medicine or food should be avoided while taking this Medicine?

Please tell your doctor or pharmacist if you are taking or have recently taken any regular medication on prescription or over the counter products.

What should you do if you miss a dose?

If you miss your application of VANTELIN GEL at the correct time, apply it when you remember and then carry on as normal. Do not apply a double quantity to make up for the forgotten application. If you have any questions on the use of this product, ask your doctor or pharmacist.

Signs and Symptoms of Overdose / What to do when you have taken more than the recommended dosage?

Overdosage is extremely unlikely to occur as a result of topical use. However, the skin should be rinsed with water. There have been no clinical case of ingestion of VANTELIN GEL including overdosage.

How should you keep this Medicine?

Keep it out of reach of children. Store at temperatures not exceeding 30°C. Protect from light and moisture. Do not use after the expiry date on the carton or tube.

When should you consult your doctor?

Consult your doctor:

- If the pain and swelling does not improve within 7 days, or if they get worse.
- If you experience any first sign of any adverse drug reaction.

Name and Address of Importer and Distributor:

DKSH Market Expansion Services Philippines, Inc.

3rd Floor Science Hub Tower 2 Campus Avenue McKinley Hill Cyberpark, Pinagsama, Taguig City, Metro Manila

Name and Address of Manufacturer:

Y.S.P. INDUSTRIES (M) SDN. BHD.

Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

Name and Address of Brand Owner:

Kowa Company, Ltd.

4-14, Nihonbashi-honcho 3-chome, Chuo-ku, Tokyo, JAPAN

ADR Reporting:

For suspected adverse drug reaction, please report to the FDA at www.fda.gov.ph and to DKSH Market Expansion Services Philippines, Inc. Pharmacovigilance at pharmacovigilance.ph@dksh.com or PV hotline +63 998 965 4158.

The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

Registration Number:

DR-XY49364

Date of First Authorization/Renewal of the Authorization:

25 Mar 2025

Date of Revision of Patient Information Leaflet:

Apr 2025