

# VANTELIN GEL

## **PATIENT INFORMATION LEAFLET:**

Please read this leaflet carefully before using this application. If you have any questions please ask doctor or pharmacist.

### **What is VANTELIN GEL:**

VANTELIN GEL is an external preparation containing 10mg Diclofenac sodium in 1gm of the gel. It is available in aluminium tubes of 20g and 45g. VANTELIN GEL appears as a colorless transparent gel. The other ingredients are propylene glycol, l-menthol powder, triethanolamine, isopropyl alcohol, carbopol and purified water.

### **What is VANTELIN GEL used for and how long to use for:**

VANTELIN GEL can be used to relieve pain and reduces inflammation of muscle, joints, tendons, ligaments due to:

- sprains, strain, bruises, backache, injuries.
- localized and mild arthritis.

It may also be used for other conditions when recommended by your doctor. Unless recommended by your doctor, do not use for more than:

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

Use no more than is required for shortest period of time needed.

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

### **How to use VANTELIN GEL:**

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

### **Care that should be taken when using VANTELIN GEL:**

- 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 not to use VANTELIN GEL:**

Do not use if you are known to be sensitive to diclofenac, or menthol, aspirin or other non-steroidal anti-inflammatory drugs, or if you are asthmatic. 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. Please tell your doctor or pharmacist if you are taking medicines, including those obtained without a medical prescription.

### **What are the side effects:**

Like all medicines, VANTELIN GEL can cause side effects, although not everybody gets them.

#### **Some rare and very rare side effects might be serious.**

If you experience any of the following signs of allergy, STOP using VANTELIN GEL and tell a doctor or pharmacist immediately:

- Skin rash with blisters; hives (may affect between 1 and 10 in every 10,000 people).
- Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (may affect less than 1 in every 10,000 people).
- Swelling of the face, lips, tongue or throat (may affect less than 1 in every 10,000 people).

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist).

#### **Common side effects** (may affect between 1 and 10 in every 100 people).

- Skin rash, itching, reddening or smarting of the skin.

#### **Very rare side effects** (may affect less than 1 in every 10,000 people).

- the skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

**If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

### **How to keep VANTELIN GEL:**

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

#### **Manufacturer:**

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#### **Product Registration Holder:**

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