

## Package leaflet: Information for the patient

### Veral, 10 mg/g (1%), gel

Diclofenac sodium

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

#### What is in this leaflet

1. What Veral is and what it is used for
2. What you need to know before you use Veral
3. How to use Veral
4. Possible side effects
5. How to store Veral
6. Contents of the pack and other information

#### 1. What Veral is and what it is used for

Veral is a transparent gel dedicated for rubbing into the skin. The active substance - diclofenac which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Due to the hydro-alcoholic medium Veral exerts a soothing and cooling.

The drug has analgesic, anti-inflammatory and anti-oedematous effects.

It is used in the local treatment:

##### **Adults and adolescents above 14 years of age:**

- trauma of the tendons, ligaments, muscles and joints (eg due to sprains, strains and bruises)
- back pain
- localised forms of soft tissue rheumatism, such as tendinitis, tennis elbow, bursitis, peri-arthritis.

##### **Adults (above 18 years of age):**

- localised and mild forms of osteoarthritis.

#### 2. What you need to know before you use Veral

##### **Do not use Veral:**

- if you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6).
- if you have ever previously experienced an allergic reaction (e.g. rash, difficulty in breathing or coughing) after using medicines containing aspirin, ibuprofen or other medicines used to treat joint and muscle pain.
- in the third trimester of pregnancy.
- in people under 14 years of age.

Do not use this medicine in the third trimester of pregnancy.

Do not use this medicine in children and adolescents under 14 years of age.

### **Warnings and precautions**

- Do not apply the gel to skin that has cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Veral is designed for external use. Do not use it in the mouth. After use, wash your hands. Avoid contact of gel with eyes. If the drug gets into your eyes, rinse with clean water and contact your doctor or pharmacist.
- Co-bandaging for sprains may be used but airtight bandages cannot be used.

### **Other medicines and Veral**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

No clinically significant interactions have been reported after topical administration.

### **Children and adolescents**

As data on safety and efficacy in children and adolescents below 14 years of age are not sufficient, do not take Veral in this group.

In adolescents over 14 years, in case the use of the drug for longer than 7 days for the treatment of pain is required or in the case of worsening symptoms, you should contact your doctor.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Veral must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. Veral should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Veral should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, Veral should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

### **Driving and using machines**

Veral doesn't have any effect on ability to drive or use machines.

## **3. How to use Veral**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Apply topically to the skin three or four times a day gently rubbing. Amount of gel to be adjusted to the size of the affected site 2 g to 4 g of Veral (corresponding to the size of the fruit of a cherry to a walnut) are sufficient to treat an area of about 400 cm<sup>2</sup> to 800 cm<sup>2</sup>. After use, wash your hands, unless it is the place they are treated.

**Do not use** Veral for more than:

- In adults and adolescents above 14 years of age: 14 days for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis.
- In adults (above 18 years of age): 21 days for arthritis, unless your doctor tells you otherwise.

If the pain and swelling does not disappear within 7 days or in case of worsening of symptoms, you should contact your doctor.

### **If you forget to use Veral**

Do not take a double dose to make up for a forgotten dose.

### **If you use more Veral than you should**

You should immediately contact your doctor if you use excessive amounts of Veral or in case of accidental ingestion.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Some side effects that occur rarely or very rarely can be severe.**

**If you notice any of the following side effects (it may be an allergic reaction) stop taking this medicine and contact your doctor or go to the nearest hospital.**

- *Rare (may affect between 1 and 10 in every 10,000 people):* Skin rash with blisters, flaking of the skin, burning sensations
- *Very rare (may affect less than 1 in every 10,000 people):* Wheezing, shortness of breath or feeling of tightness in the chest (asthma), swelling of the face, lips, tongue or throat; hives.

### **Other side effects**

Other side effects which may occur are usually mild, passing and harmless. If you notice one of the following side effects you should contact your doctor or pharmacist as soon as possible.

- *Common (may affect between 1 and 10 in every 100 people):* Skin rash, itching, reddening or smarting of the skin.
- *Very rare (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.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, Poland, tel.: + 48 22 49 21 301, fax: + 48 22 49 21 309, e-mail: ndl@urpl.gov.pl.

Any side effects can be also reported to the Marketing Authorization Holder (MAH) and MAH representative in Poland.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Veral**

Store in original package in order to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after: "Expiry date (EXP)" and on the tube after: "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

**What Veral contains**

- The active substance is diclofenac sodium. 1 g of gel contains 10 mg of diclofenac sodium.
- The other excipients are: isopropylalcohol, ethanol 96%, ammonia solution 10%, carbomer, purified water.

**What Veral looks like and contents of the pack**

Homogenous, colourless and transparent gel of characteristic smell of ethanol.

Aluminium tube with membrane, with PE or PP cap, in carton box.

Available pack sizes: 55 g of gel, 100 g of gel.

**Marketing Authorisation Holder**

Herbacos Recordati s.r.o., Pardubice, Štrossova 239, PSČ 53003, Czech Republic

**Manufacturer**

Saneca Pharmaceuticals a.s., Nitrianska 100, Hlohovec 920 27, Slovak Republic

**This leaflet was last revised in 04/2019.**