

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Viprosal B® ointment

### 2. QUALITATIVE AND QUANTITATIVE CONTENT

1 g of the ointment contains 0.05 IU venom of *Vipera berus* (*Venenum Viperae berus siccum*); 30 mg of camphor, racemic (*Camphora*); 30 mg of turpentine oil (*Terebinthini aetheroleum*); 10 mg of salicylic acid (*Acidum salicylicum*).

Excipient(s): cetostearyl alcohol.

For full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Ointment

White or yellowish-white ointment with odour of camphor and turpentine oil.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Used as a topical analgesic for joint and muscular pain.

#### 4.2 Posology and method of administration

A small amount of ointment (50-10 g corresponding to 1-2 teaspoons, taking into account the size of affected area) is spread to the painful skin area and, depending on the pain intensity, is gently massaged into the skin 1-2 times a day, until the pain disappear. Duration of treatment course depends on the type and severity of condition.

The gel is meant for external use.

There is no experience for use in children (see section 4.4).

#### 4.3 Contraindications

Hypersensitivity to any of the active substances or to any of the excipients.

Skin ulcers or other skin diseases.

Acute pulmonary tuberculosis.

Coronary and cerebrovascular disorders.

Patients prone to angiospasm.

Severe hepatic or renal disease.

#### 4.4 Special warnings and precautions for use

Viprosal B ointment should not be applied on damaged skin surface. To avoid a severe irritation, the ointment should not get in eyes or on the mucous membranes.

This medicine is not recommended for use in children and adolescents, because there is no sufficient data available on use in these age groups.

Viprosal B ointment contains excipient cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

#### **4.5 Interaction with other medicinal products and other forms of interaction**

There are no studies performed regarding interactions.

#### **4.6 Fertility, pregnancy and lactation**

There are no adequate data on the use of this product in pregnant women. Therefore, Viprosal B ointment should not be used during pregnancy and lactation period.

#### **4.7 Effects on ability to drive and use machines**

None

#### **4.8 Undesirable effects**

In patients with increased skin sensitivity to any of ingredients of Viprosal B, the use of the ointment can cause itching, swelling or hives. In this case, the ointment should be washed from the skin and the treatment should be stopped. These symptoms usually disappear after discontinuation of the treatment.

To avoid undesirable effects, it is advised to apply a small amount of ointment before the treatment to test skin sensitivity to the product.

#### **4.9 Overdose**

There are no reports of overdose. When coming into contact with mucous membranes, ointment causes a severe irritation.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Topical analgesics for joint and muscular pain.

ATC code: M02AX10

The main active ingredient of VIPROSAL B ointment is venom of *Vipera berus* (*Vipera berus*), which contains phospholipase, phosphodiesterase, hyaluronidase and other active substances. Viper venom contains also peptides of specific action that cause haemolysis, increase capillary permeability and affect blood clotting. When used topically, viper venom has an irritant and analgesic activity, while its absorption activates the body's defense mechanisms.

Viprosal B ointment contains also substances that irritate the receptors of sensory nerve ends, thus causing locally irritant and analgesic effects. Local skin irritation changes and selectively improves blood supply and trophicity of organs, which are innervated by respective nerves of the spinal cord segments. Additional irritation causes a further activation of antinociceptive system of the respective spinal cord segment, thus preventing the primary pain impulse transmission to the cerebral cortex and pain perception. In addition to analgesic activity, camphor, salicylic acid and turpentine oil acts also antiseptically; salicylic acid has keratolytic properties.

#### **5.2 Pharmacokinetic properties**

Viprosal B ointment is rapidly absorbed through the skin and within few minutes causes a sensation of burning, mild skin redness and warmth. Analgesic activity begins within 20-30 minutes and continues up to 1.5-2 hours.

### **5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Paraffin, white soft  
Cetostearyl alcohol  
Paraffin, hard  
Sodium cetostearyl sulphate  
Glycerol  
Sodium, chloride  
Water, purified

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25 °C. Do not refrigerate and freeze.

### **6.5 Nature and contents of container**

30 g or 50 g ointment in aluminium tube. 1 tube in a cardboard box.

### **6.6 Special precautions for disposal and other handling**

No special requirements.

## **7. MARKETING AUTHORISATION HOLDER**

JSC GRINDEKS.  
Krustpils street 53, Rīga, LV-1057, Latvia  
Telephone: +371 67083205  
Fax: +371 67083505  
E-mail: grindeks@grindeks.lv

## **8. MARKETING AUTHORISATION NUMBER(S)**

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

## **10. DATE OF REVISION OF THE TEXT**

09/2010