

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Vagisil Medicated Creme.

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Lidocaine Ph Eur 2% w/w

Vagisil Medicated Creme contains Rose Perfume, a fragrance with benzyl alcohol, benzyl benzoate, cinnamal, cinnamyl alcohol, citral, citronellol, geraniol, limonene and linalool, which can cause local irritation.

For a full list of excipients see Section 6.1.

### **3. PHARMACEUTICAL FORM**

Emulsion Cream, in a decorated metal tube.

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

For symptomatic treatment of peri-anal or pruritus vulvae.

Vagisil Medicated Creme is indicated in adults and children aged over 12 years

### **4.2 Posology and method of administration**

#### Posology

Apply to the affected area. Repeat as needed three or four times daily.

#### *Paediatric Population*

Not suitable for children under 12 years of age

### Method of Administration

Vagisil Medicated Creme is applied topically

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### **4.4 Special warnings and precautions for use**

Not for use on extensive body areas or on the eyes.

If symptoms persist for more than one week, discontinue use and consult your doctor.

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

No interaction studies have been performed.

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

#### Pregnancy:

The safety of this medicinal product for use in human pregnancy has not been established. The product is, therefore, not recommended during pregnancy, unless considered essential by the physician.

#### Lactation:

Lidocaine enters the mother's milk, but in such small quantities that there is generally no risk of the child being affected at therapeutic dose levels.

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

Vagisil Medicated Creme has no influence on the ability to drive and use machines.

### **4.8 Undesirable effects**

May cause sensitivity. If this occurs, treatment should be stopped and advice sought.

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common:  $\geq 1/10$

Common:  $\geq 1/100$  to  $< 1/10$

Uncommon:  $\geq 1/1,000$  to  $< 1/100$

Rare:  $\geq 1/10,000$  to  $< 1/1,000$

Very rare:  $< 1/10,000$

Not known: cannot be estimated from the available data

System Organ Class	Undesirable Effect	Frequency
Immune system disorders or skin and subcutaneous tissue disorders	Sensitivity	Not known

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## **4.9 Overdose**

Overdose with Vagisil Medicated Creme is unlikely, but signs of systemic toxicity would be consistent with those of lidocaine and may include blurred vision, dizziness or drowsiness, difficulty breathing, trembling, chest pain or irregular heartbeat.

Accidental ingestion may result in anaesthesia of the upper respiratory tract, nausea, vomiting and abdominal discomfort. Ingestion of very large quantities could result in CNS and cardiovascular toxicity. Treatment should be symptomatic and supportive.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Pharmacotherapeutic Group: Local anaesthetic  
ATC code: D04AB

Lidocaine has a local anaesthetic action, relieving pain and discomfort in the affected areas. Local anaesthetics inhibit conduction of nerve impulses from sensory nerves. The action results from an alteration of cell membrane permeability to ions. Lidocaine blocks sodium ion channels required for the initiation and conduction of neuronal impulses which can result in local anaesthesia.

## **5.2 Pharmacokinetic properties**

2% Lidocaine is the active ingredient of the Vagisil Creme formulation. It is readily absorbed from mucous membranes and through damaged skin. The rate and extent of lidocaine absorption depends upon the specific site of application, duration of exposure and mode of application. Absorption through intact skin is considered poor.

### **5.3 Preclinical safety data**

A literature search on non-clinical data reveal no special hazard for humans based on conventional studies of safety and toxicity. Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lidocaine. The mutagenic potential of lidocaine has been determined in the in vitro Ames Bacterial Reverse Mutation Assay, the in vitro chromosome aberration assay using Syrian hamster ovary cells, and the in vivo rat micronucleus assay. Lidocaine was negative in all three assays.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Stearic acid  
Self-emulsifying Glyceryl Monostearate  
Glycerol  
Triethanolamine  
Zinc oxide  
Sulfonated castor oil  
Isopropyl alcohol  
Chlorothymol  
Fragrance  
Docusate sodium  
Diethylene Glycol Monoethyl Ether  
Purified Water.

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Three years.

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

No special precautions.

**6.5 Nature and contents of container**

20 g and 30 g aluminium tubes with a foil covered nozzle and white high density polyethylene cap.

Not all pack sizes may be marketed.

**6.6 Instruction for use, handling and disposal**

Vagisil cream is applied topically.

**7 MARKETING AUTHORISATION HOLDER**

Combe International Ltd,

Cedar Court

Guildford Road

Leatherhead

Surrey

KT22 9RX

**8. MARKETING AUTHORISATION NUMBER**

PL 03157/0013.

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

07/11/2005

**10 DATE OF REVISION OF THE TEXT**

24/02/2021