

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**Albothyl® concentrate**, 36%, vaginal solution

**Albothyl® pessaries**, 90 mg

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: policresulen

1 g vaginal solution contains: 360 mg policresulen.

1 pessary contains: 90 mg policresulen.

For a full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

**Vaginal solution:** clear red-brown solution

**Pessaries:** cream-coloured to reddish-brown pessaries

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Local treatment of bacterial vaginosis

#### 4.2 Posology and method of administration

For vaginal application

##### **Albothyl® concentrate**

##### Posology

Albothyl concentrate is used undiluted for swabbing superficial cervico-vaginal inflammations.

Up to 50 ml Albothyl concentrate is used to swab the vagina on each application.

##### Method of administration

Solution for vaginal application.

50 ml of the solution is placed in a kidney bowl. With the aid of a vaginal speculum and dressing forceps a gauze swab impregnated with Albothyl concentrate is introduced into the vagina and left there for 1-3 minutes while exerting gentle pressure. Any unused solution is discarded.

Albothyl concentrate is applied twice in total at an interval of 3-4 days. If the symptoms have then not resolved the doctor should be consulted.

##### **Albothyl® pessaries**

##### Posology

1 Albothyl® pessary (90 mg policresulen) per day.

### Method of administration

The pessary is inserted high into the vagina, preferably in the supine position. To prevent premature expulsion of the pessary it should be inserted in the evening before going to sleep. To make insertion easier the pessary can be briefly immersed in water prior to use. The use of a sanitary pad prevents soiling of clothing and bedding.

The pessaries should be used until the symptoms have disappeared, but not for more than 9 days. If the symptoms have not resolved after this period, treatment should be discontinued and a doctor consulted.

No data are available on the relapse rate after stopping treatment with Albothyl® pessaries.

### **4.3 Contraindications**

Albothyl concentrate/pessaries may not be used in cases of hypersensitivity to the pharmacologically active ingredient or any of the excipients listed in section 6.1.

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

#### Children and Adolescents

Albothyl concentrate /pessaries are not indicated for use in children and adolescents under the age of 18 years, as to date there is no experience in these age groups.

#### Elderly people

Albothyl concentrate /pessaries are not indicated for use in postmenopausal women, as there is no experience in these age groups.

Sexual intercourse must be avoided during treatment with Albothyl concentrate/ pessaries and in the following 10 days.

Washing with soaps that trigger irritation must be avoided during the treatment period.

Albothyl concentrate/ pessaries are not effective against HIV infections or other sexually transmitted diseases such as gonorrhoea or syphilis.

Albothyl concentrate/ pessaries should not be used during menstruation.

As a sign of the therapeutic effect necrotic tissue may be expelled from the vagina, sometimes in large amounts. For this reason sanitary pads should be worn and changed regularly when soiled to prevent tissue residues causing any irritation of the vulva.

If Albothyl concentrate/ pessaries have been swallowed by mistake, the person must immediately drink plenty of water and be medically examined and treated as quickly as possible for any erosive effect on the mouth, throat and oesophagus.

After contact with the eyes, Albothyl concentrate/ pessaries must be thoroughly rinsed out at once with water. It may be necessary to consult an ophthalmologist.

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

Albothyl concentrate/ pessaries are for local use only.

During treatment with Albothyl concentrate/ pessaries other medicinal products for vaginal use should be avoided as interactions cannot be excluded.

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

During pregnancy and breastfeeding Albothyl concentrate/ pessaries may be used only where strictly indicated, after due consideration of the risks to the mother and child.

There have not been any studies of the risks associated with use during pregnancy in humans. Studies in animals have not yielded any evidence of foetal malformation. It is not known whether the active substance is excreted in breast milk.

In addition for Albothyl concentrate:

Swabbing of the cervix should be avoided in pregnant women, especially in the advanced stage of pregnancy, as this could trigger labour.

Swabbing of the portio and the portio adjacent parts of the vagina should be performed with appropriate care and only in certain strictly defined indications.

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

Effects on the ability to drive, use machines or work without proper safeguards are not known.

#### **4.8 Undesirable effects**

The assessment of undesirable effects is based on the following frequencies:

<b>Very common</b>	( $\geq 1/10$ )
<b>Common</b>	( $\geq 1/100$ to $< 1/10$ )
<b>Uncommon</b>	( $\geq 1/1.000$ to $< 1/100$ )
<b>Rare</b>	( $\geq 1/10.000$ to $< 1/1.000$ )
<b>Very rare</b>	( $< 1/10.000$ )
<b>Not known</b>	(cannot be estimated from the available data)

##### Immune system disorders

**Not known:** systemic allergic reactions (e.g. angioedema, generalised urticaria) up to anaphylaxis.

##### Reproductive system and breast disorders

**Very common:** dryness in the vagina.

**Common:** burning sensation in the vagina, discharge of shreds of mucous membrane.

**Not known:** vaginal candidiasis, pruritus vulvae, discomfort, foreign body sensation in the vagina.

##### Skin and subcutaneous tissue disorders

**Not known:** urticaria.

If severe local irritation occurs Albothyl concentrate/ pessaries should be discontinued and an alternative antibacterial therapy being considered.

##### 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 to the

Bundesinstitut für Arzneimittel und Medizinprodukte  
Abt. Pharmakovigilanz  
Kurt-Georg-Kiesinger Allee 3  
D-53175 Bonn  
Website: [www.bfarm.de](http://www.bfarm.de)

## 4.9 Overdose

No cases of overdose have been reported.

If Albothyl pessaries have been swallowed by mistake, a doctor should be consulted so that he can decide what further measures are necessary.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: gynaecological antiseptic

ATC code: G01AX03

#### Mechanism of action

The therapeutic activity of policresulen is based on two mechanisms of action that are interconnected:

- antimicrobial effect on bacteria
- denaturation of necrotic tissue.

Coagulation and subsequent elimination of necrotic and pathologically changed tissue stimulate wound healing processes and promote reepithelialisation. Squamous epithelium is less attacked by policresulen than columnar epithelium. However, exfoliation of the vaginal and cervical squamous epithelium has been observed.

### 5.2 Pharmacokinetic properties

#### Absorption

Only a negligible portion of policresulen is absorbed after vaginal use, resulting in a high concentration of active ingredient at the administration site. Results of clinical studies with Albothyl pessaries in healthy women have shown that low-molecular constituents of the active ingredient policresulen, such as m-cresol-4-sulfonic acid, m-cresol-6-sulfonic acid, m-cresol-4,6-disulfonic acid and dicresulene, are absorbed in small quantities. Serum concentrations measured in these studies were in the lower nanogram range per ml.

#### Elimination

Hence, due to rapid renal elimination, the overall systemic availability of these substances is low.

Absorption and systemic availability of policresulen and its low-molecular constituents after repeated administration on irritated vaginal skin, which is typical for bacterial vaginosis, have not been investigated.

### 5.3 Preclinical safety data

Policresulen is non-toxic when used locally, as has been demonstrated over about 50 years of clinical experience.

#### Acute toxicity

The acute toxicity was determined in mice at 340 to 380 mg/kg (i.v. administration) and 2,300 to 2,500 mg/kg (oral) and in rats at 390 to 420 mg/kg (i.v. administration) and 3,200 to 3,900 mg/kg (oral).

The LD<sub>50</sub> in the mouse is more than 200 times and in the rat more than 300 times the human dose.

#### Chronic toxicity

After 3 months, rats given 40 times the human dose and dogs 9 times the human dose exhibited no substance-specific signs of toxicity. Dermal tolerability of policresulen was investigated on depilated dorsal skin in mice and rabbits. Policresulen applied topically at various concentrations (4%, 12% and 36%) on 10 out of 14 days caused only transient redness that vanished after the 3rd application.

### Reproduction toxicity

Studies in pregnant rats and rabbits showed that this substance has no embryotoxic or teratogenic effects.

### Mutagenicity/ carcinogenicity

In-vitro tests were not indicative of a mutagenic effect.

No carcinogenicity studies are available.

Therapeutic use of policresulen for many decades has not revealed any mutagenic or carcinogenic properties.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Albothyl concentrate: water, edetic acid

Albothyl pessaries: Macrogol 1500 and 4000, edetic acid, water

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

Albothyl concentrate: 5 years.

Shelf life once the has been opened: 3 months

Albothyl pessaries: 2 years.

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

Albothyl<sup>®</sup> concentrate: Albothyl concentrate should be stored in the folding box.

Albothyl<sup>®</sup> pessaries: Do not store above 25°C.

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

Albothyl<sup>®</sup> concentrate:

Amber moulded glass bottles, type 3 glass as per Ph.Eur.,

Screw closure: HD-PE black, containing 100 ml solution.

Albothyl<sup>®</sup> pessaries:

Two-layer multiplast cells of PVC/PE white, opaque.

Pack of 6 pessaries.

### **6.6 Special precautions for disposal and other instructions for use/handling**

Textiles and leather should be cleaned with water immediately after coming into contact with Albothyl concentrate/pessaries before the substance begins to dry. Instruments etc. must be placed in a bowl of water (if appropriate adding 1-2% sodium hydrogen carbonate) immediately after use until sterilisation.

The spotted characteristics of the pessaries are caused by the natural appearance of the pessary base and do not affect the usability, efficacy or tolerability.



**7. MARKETING AUTHORISATION HOLDER**

**Acino Pharma AG**  
Birsweg 2, 4253 Liesberg  
Switzerland

**8. MARKETING AUTHORISATION NUMBERS**

1-95-83

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

02.06.2016

**10. REVISION OF THE TEXT**

October 2018

**11. PRESCRIPTION STATUS/LEGAL CATEGORY**

Pharmacy-only

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*It is herewith certified that this is a true and complete translation of the German original.  
Translation of the stamp: Cordula Kauert, Sworn translator of English and Arabic at the  
Berlin courts and for public notaries.*