

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ALBOTHYL

90 mg pessaries

POLIKREZULEN

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What Albothyl is and what it is used for
2. Before you take Albothyl
3. How to use Albothyl
4. Possible side effects
5. How to store Albothyl
6. Further information

#### 1. WHAT ALBOTHYL IS AND WHAT IT IS USED FOR

Albothyl pessaries are antibacterial agent for the vagina (gynecological antiseptic). Albothyl pessaries are used in the treatment of bacterial inflammation of the vagina.

#### 2. BEFORE YOU TAKE ALBOTHYL

Do not use Albothyl pessaries:

- If you are hypersensitive (allergic) to polikrezulen or any of the ingredients of Albothyl pessary.

#### **Be careful with the use of Albothyl pessary:**

During the treatment with Albothyl pessaries, you should avoid sexual relations for 10 days.

During treatment you should avoid the use of soap that causes irritation.

Pessaries Albothyl are not effective against HIV infection or other sexually transmitted diseases, such as gonorrhoea or syphilis.

Albothyl pessaries should not be used during the menstrual cycle.

As a sign of the therapeutic action peeling of dead vaginal tissue may occur, sometimes in large quantities. For this reason, sanitary napkins should be used so that remnants of the tissue would not irritate the outer part of the sexual organs.

If you mistakenly ingest Albothyl pessary, you should immediately drink a lot of water and urgently seek a medical examination and be urgently treated because of the erosive effects on the mouth, throat and esophagus.

In case that Albothyl pessary comes into contact with the eyes, the eyes should be immediately rinsed with water.

In case of contact with Albothyl pessaries the fabric and the skin should be rinsed with water before they dry.

### ***Children and elderly***

Albothyl pessaries are not indicated for use in children and adolescents under 18 years, nor in postmenopausal women, so no data are available about the experience in these groups of patients.

### ***Taking other medicines with Albothyl pessaries***

Tell your doctor if you are taking or have recently taken any other medicines, including those that are issued without a prescription!

During treatment with Albothyl, you should avoid the simultaneous use of other medicines for use in the vagina, because the possibility of interaction cannot be excluded.

### ***Pregnancy and breastfeeding***

Consult with a doctor or pharmacist before taking any medication.

During pregnancy and lactation Albothyl pessaries can be used only if they are strictly indicated, with an assessment of the benefit-risk for mother and child.

Risk of use in pregnancy has not been studied in humans. Animal studies showed no evidence of fetal malformation.

It is not known whether the active substance passes into milk in lactating women.

### ***Driving and using machines***

There are no known effects on the ability to drive, work on machines or work without protective equipment.

## ***3. HOW TO USE ALBOTHYL***

Always use Albothyl pessaries according to the instructions specified in this leaflet. If you are not sure, consult your doctor or pharmacist.

Unless otherwise ordered by a doctor, the usual dose is:

1 pessary (equivalent to 90 mg of polikrezulen) a day.

### ***Method of administration***

For vaginal use.

Albothyl pessary should be inserted deep into the vagina, preferably in the supine position. To prevent the falling out of pessaries, they should be applied at night before going to sleep. To facilitate the insertion, pessary can be moistened with water.

To prevent the defilement of clothes and bed linen, it is necessary to use the pads.

How long do you need to use Albothyl pessaries?

Pessaries should be used until the disappearance of symptoms, but no longer than 9 days. If the symptoms do not disappear, talk to your doctor.

It is not known how many women get a bacterial inflammation of the vagina after treatment with Albothyl pessaries (relapse).

Talk to your doctor or pharmacist if the effect of Albothyl pessary is too strong or too weak.

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

The cases (symptoms) of an overdose are not known.

### ***If you forget to use Albothyl pessary***

Do not take a double dose to make up for the missed dose. Continue the treatment at predetermined intervals.

### ***If you stop using Albothyl pessary***

If you want to stop the use of Albothyl pessary, inform your doctor.

If there was an interruption of treatment with Albothyl pessaries, inflammation can occur again and again, or it may be necessary to substitute medical treatment.

If you have any further questions about the use of Albothyl pessary, talk to your doctor or to the pharmacist.

## ***4. POSSIBLE SIDE EFFECTS***

Like all medicines, pessaries Albothyl can cause side effects.

The frequency of possible side effects is the following:

**Very common** (occurring in more than 1 in 10 patients)

**Common** (occurring at 1 to 10 in 100 patients)

**Uncommon** (occurring at 1 to 10 in 1 000 patients)

**Rare** (occurring at 1 to 10 in 10,000 patients)

**Very rare** (occurring at less than 1 in 10,000 patients)

**Unknown** (cannot be estimated on the basis of the available data)

### ***Immune system disorders***

**Unknown:** rash accompanied by itching (hives), allergic reactions that include whole body (for example, painful swelling of the skin and subcutaneous tissue, itchiness), anaphylaxis (the reaction of the whole body which manifests as harsh breathing problems and sudden fall of blood pressure).

### ***Reproductive system and breast disorders***

**Very common:** vaginal dryness.

**Common:** peeling the surface of the mucosa.

**Unknown:** fungal vaginal infections (Candida), itching outside of the sexual organs, discomfort, burning feeling and the presence of a foreign body in the vagina

### ***Disorders of skin and subcutaneous tissue***

**Unknown:** hives (urticaria).

In case of a serious irritation, the use of Albothyl pessary should be discontinued and an alternative antimicrobial therapy should be considered.

If you notice any side effect, you need to tell your doctor or pharmacist.

## ***5. HOW TO STORE ALBOTHYL***

Keep out of reach and sight of children.

You may not use pessaries after expiry date stated on the outer carton. Shelf life expires on the last day of that month.

Albothyl pessaries should be stored at a temperature lower than 25 ° c.

Note:

The existence of stains specific to pessaries are common phenomena caused by pessary base, and has no impact on the use, effects or tolerability.

Medicines should not be disposed of in household waste or waste water. Ask your pharmacist how to dispose of medicines no longer required. Such measures will help to protect the environment.

The shelf life of the medicine is 5 (five) years from the date of manufacture, which is indicated on the packaging of the medicine.

## **6. FURTHER INFORMATION**

### ***What Albothyl pessary contains:***

Active substance: polikrezulen.

1 pessarie contains 90 mg of polikrezulen.

Other substances: MACROGOL 1500, MACROGOL 4000, edetate acid, water.

### ***How pessary Albothyl looks like and contents of the Pack***

Pessaries are cream to reddish brown in color, interspersed, wax.

6 pessaries are packaged in PVC/PE blister, in a cardboard box.

### ***Regime of dispensing***

The medicine is issued on doctor's prescription

### ***Manufacturer***

NYCOMED GmbH

Byk-Gulden-Straße 2, Konstanz, Germany

### ***Manufacturer of the medicinal product***

NYCOMED GmbH

Byk-Gulden-Straße 2, Konstanz, Germany