

Albothyl® vaginal suppositories

for insertion into the vagina

Policresulen

Composition

1 vaginal suppository contains:

Active ingredient

Policresulen 90 mg

Excipients

Macrogol 1500 and 4000; water

Pharmaceutical form and contents

Vaginal suppositories

Packs with 6 or 10 vaginal suppositories.

Not all pack sizes may be marketed in all countries.

Pharmacotherapeutic/ indication group/ action mechanism

Antiseptic/Gynaecological agent

Holder of the marketing authorization

Takeda GmbH

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Manufacturer

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Indications

Local treatment of cervicovaginal inflammations or infections and tissue damage (e.g. vaginal and cervical discharge caused by bacteria, trichomonads and fungal infections, pressure sores in diaphragm users), condyloma acuminatum, etc.

Treatment in the periods between cauterizations, after initial treatment with Albothyl concentrate.

Contraindications

Contraindications are not known.

Albothyl vaginal suppositories may be used during pregnancy and breastfeeding only where it is 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, but animal studies have not yielded any evidence of fetal malformation.

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

Special warnings and precautions for use

- Care must be taken not to swallow the suppositories. If Albothyl vaginal suppositories have been swallowed inadvertently, you should immediately drink plenty of water and consult your doctor.
- Albothyl vaginal suppositories cause a sharp stimulation of the healing processes. There is no cause for concern if necrotic tissue from the diseased area is sloughed off even in large amounts.
- During the treatment period the use of soaps which cause irritation as well as sexual intercourse must be avoided.
- Like all vaginal therapeutics, Albothyl vaginal suppositories should not be used during menstruation.
- Protect your eyes from Albothyl vaginal suppositories! In case of contact with Albothyl vaginal suppositories, the eyes must be thoroughly rinsed out at once with water; it may be necessary to consult an ophthalmologist.
- If textiles or leather come into contact with Albothyl vaginal suppositories, they should be immediately rinsed with water before drying.

Pregnancy and lactation

Albothyl vaginal suppositories may be used during pregnancy and breastfeeding only where it is 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, but animal studies have not yielded any evidence of fetal malformation.

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

Effects on the ability to drive and to use machines

According to the information available so far, when Albothyl vaginal suppositories are used as prescribed they do not affect the ability to drive or to operate machinery.

Interactions

Albothyl vaginal suppositories are intended exclusively for local use. The use of other local drugs on the same area should be avoided during treatment with Albothyl, since interactions cannot be ruled out.

Please note that this information also applies to drugs which you might have used recently.

THIS IS A MEDICAMENT

A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacists are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor
- Keep all medicaments out of the reach of children.

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UNION OF ARAB PHARMACISTS

Posology and method of administration

The following information applies unless Albothyl vaginal suppositories have been otherwise prescribed by your doctor.

Please follow these instructions, as otherwise Albothyl vaginal suppositories may not have the desired effect!

Instructions for use / handling

Depending on the severity of the condition, one vaginal suppository is administered daily or every other day.

After initial treatment with Albothyl concentrate, 1 Albothyl vaginal suppository is introduced into the vagina every second day in the periods between cauterizations.

The vaginal suppository should be introduced in the evening.

To facilitate its introduction, the suppository may be moistened with water and then, preferably in the supine position, introduced deep into the vagina.

The additional use of a sanitary towel avoids soiling of clothing and bedding.

The duration of use depends on the nature and severity of the condition and is determined by the doctor.

Incorrect use and overdose

Incidences of overdose are not known.

If you forgot an application, do not use twice as many the next time, but continue the treatment at the specified intervals. Inform your doctor accordingly.

If you should wish to interrupt your treatment please notify your doctor.

Undesirable effects

Local irritation may be observed in isolated cases at the beginning of treatment with Albothyl vaginal suppositories; however, such irritation generally clears up quickly.

In the event of severe local irritation you must stop using Albothyl vaginal suppositories and notify your doctor.

If you experience any side effects not listed in this package leaflet, make sure you inform your doctor or pharmacist.

Storage conditions and shelf life

Albothyl vaginal suppositories stored below 25°C remain unchanged for 5 years.

The expiry date of this pack is printed on the container and on the folding box.

Do not use this pack after the expiry date!

Note

Any spots on the vaginal suppositories are due to the natural appearance of the suppository base and do not affect the applicability, effectiveness and tolerability.

Date of last revision of the text

June 2010