

**JUJIAFENHUANGQUAN YINDAOSHUAN- policresulen vaginal
suppository suppository
Heilongjiang Tianlong Pharmaceutical Co Ltd**

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Instruction for Usage of Policresulen Vaginal Suppository

Please read the instruction carefully and use the product under the advice of doctor

Warning: during pregnancy, especially in the last three months of pregnancy, any treatment of the cervix should not be used, while the treatment of the vagina and its surrounding areas can only be used when absolutely necessary.

□Name□Policresulen Vaginal Suppository

Pin yin: Jujiafenhuangquan Yindaoshuan

□Ingredients□The main component of this product is Policresulen. Its chemical name is: m-cresol sulfonic acid and formaldehyde polymer.

□Character□This product is light red to light red brown suppository.

□Indication□It is used in the treatment of local inflammation or infection and tissue damage of vagina and cervix (eg, discharge due to bacterial, trichomonal and fungal infections, pressure sores from pessaries), condylomata acuminata, protuberance of cervical mucosa (cervical ectopia). For cervical erosion, cervicitis and different kinds of vaginitis.(Bacterial Vaginitis,Trichomonas Vaginitis,monilial vaginitis)pressure ulcer caused by Pessaries.

□Specification□8piece/box

□Usage and Dosage□ Vaginal administration, put the product into the deep part of the vagina, once every 2 days. If the affected part is burned with the Policresulen concentrated solution, a suppository should put in every other day between the two burns. For the convenience of use, the patient had better take the supine position, first wet the suppository with water, and then insert it into the deep part of vagina. Usually, it is better to use medicine before going to bed at night. Use with sanitary napkin together, to prevent pollution of clothes and bedding.

□Adverse Reactions□ Occasional local irritation will be occurred after treatment (such as burning or pain) usually can be tolerated and will soon disappear.

□Contraindications□ During pregnancy, especially in the last three months of pregnancy, any treatment of the cervix should not be used, while the treatment of the vagina and its surrounding areas can only be used when absolutely necessary.

□Precaution□

1. External use only, should not be taken orally.
2. This product should avoid contact with eyes.
3. This product will accelerate and enhance the repair process. If the necrotic tissue falls

off from the focus, sometimes even a large sheet falls off. Do not panic.

4. Stop treatment during menstruation. Avoid sexual life during treatment. Do not use irritating soap to clean the affected area.

5. Cotton fabric and leather shall be washed with water immediately before the preparation is dry, when the solution contacting with them.

6. Spots on the vaginal suppository are the natural phenomena produced by its matrix, which do not affect the use and efficacy of the drug, nor affect its tolerance.

☐Medication for pregnant women and lactating women☐ During pregnancy, especially in the third trimester, any cervical treatment should be avoided, and the Policresulen suppository is no exception. At this time, the potential harm of the drug to the mother and baby should be fully considered. Although the animal test shows that the drug has no teratogenic effect, the results of the human test have not been obtained. It is unclear whether the milk of lactating women will contain the active ingredient of this medicine.

☐Children Medication☐The safety and efficacy of children patients have not been studied.

☐Geriatric Medication☐The safety and efficacy of elderly patients have not been studied.

☐Drug Interactions☐Policresulen can only be used locally. Since the interaction with other drugs cannot be ruled out, it is avoided to use more than two drugs at the same place at the same time.

☐Pharmacology and Toxicology☐

Pharmacological Action

The mechanism of action of policresulen is to kill bacteria, haze bacteria and trichomonad by strong acid and protein coagulation. Selectively cause necrosis or pathological tissue and columnar epithelial protein denaturation. It causes vasoconstriction and plasma protein coagulation to stop bleeding.

Policresulen has a wide range of antibacterial activities, including common gram-positive bacteria, Gram-negative bacteria, fungi and some viruses, of which Gardnerella vaginatis, anaerobic trichomonad and Candida are particularly sensitive. But Doderlein bacterial flora was not affected. At present, the drug has not been reported to cause drug resistance.

Policresulen can selectively coagulate necrotic or diseased tissues and promote tissue regeneration and epithelial re covering. Healthy squamous epithelium is unaffected, while the cytoplasm and nucleus of columnar epithelium may swell after contact with the drug, and then shrink in a few seconds. Local application of policresulen does not produce toxicity.

Toxicity Studying

More than 50 years of clinical experience has proved that the local use of policresulen is non-toxic.

Acute toxicity: The LD50 of mice was 360mg/kg after intravenous administration and 2400mg/kg after oral administration. The LD50 of rats was 400mg/kg intravenously and 3500mg/kg orally. The LD50 of mice is 200 times of the therapeutic dose of human beings, and the LD50 of rats is 300 times of the therapeutic dose of human beings.

Chronic toxicity: Rats and dogs were given 40 times and 9 times of the human

treatment dose for 3 months, no related toxic effect was found.

The skin tolerance test of policresulen was carried out on the back of hair removing rats. In the first 10 days of the 14 day observation, the application of different concentrations of policresulen (4%, 11% and 36%) only caused temporary skin redness, which lasted until the third application at most.

Reproductive toxicity: The study on pregnant rats and rabbits shows that there was no embryotoxicity or teratogenicity effect on animals. teratogenicity

Mutagenicity/carcinogenicity: there is no relevant study on the carcinogenesis of this product. Ames test proves that policresulen has no mutagenic effect there is no relevant research on the carcinogenesis of this product. Ames test proves that policresulen has no mutagenicity effects. Although there is no research report on carcinogenesis of this product, no mutagenic or carcinogenic effect has been found in clinical application for many years.

□Pharmacokinetic□ Data are still lacking

□Shelf Life□ 36 months

□Storage□Shading, airtight, stored below 25 °C

□Package□ Medical polyethylene PVC composite packaging. 8 capsules per box. 8 medical plastic fingertips.

□Validity Period□ 36 months

□Executive Standard□National Food and Drug Administration Standard YBH02122009

□Approval No. □National Drug Approval No. H20093211

□Production Enterprise□

Name: Heilongjiang Tianlong Pharmaceutical Co., Ltd.

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Medicine Keep out of reach of children.

□Pharmacology and Toxicology□

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Content of Labeling

Policresulen Vaginal Suppository

Product Description

Policresulen vaginal suppository is a topical haemostatic and antiseptic. The main composition is policresulen. Clinically adapt to cervical erosion, cervicitis and all kinds of vaginal inflammatory (such as leukorrhagia caused by bacteria, trichomonad and mould), vulva itch, pressure ulcers caused by using pessary. Policresulen is a high acid substance with strong negative charge, which can selectively apply on pathological and necrotic tissues with positive charge. Through the solidification made by high acid and protein, it can make germs and protozoan astringent, atrophy and dissolve. Widely play a role of anti bacteria and sterilize.

Product features

- Have no effect on the normal squamous cell. Maintain PH value of the inside vagina effectively. Make it more favorable for the recreate of physiological flora and not favorable for the living of pathogenic bacteria.
- Also, the medicine has a wide anti bacteria spectrum. It can work on germ, mould, trichomonad and even some virus.
- Astringe to stop bleeding. So, after using the medicine, symptoms like contact bleeding and leukorrhagia can be relieved rapidly.
- Have no damage to intrauterine device. No need to take it out during the treatment. Not leaving any scar or make cervical narrow.
- No effect on the normal elastic of cervical canal. Can be accepted by patients widely.
- Application scope is wide, especially for nonparous patients and patients who use intrauterine device and suffer stubborn vaginal inflammatory and who also have psychological fear to physical treatment.
- No toxin, not lead to allergic and drug-resistant. No need any device and worth to promoting and applying.

Toxicology Research

The clinical experience of 50years proves that topical use of policresulen vaginal suppository is non-toxic.

Acute toxicity LD50 intravenous medication for mice is 380mg/kg, oral medication is 2400mg/kg; LD50 of rat intravenous and oral medication is 400mg/kg and 3500mg/kg. LD50 of mice is 200 times treatment dosage of human; LD50 of rat is 300 times treatment dosage of human.

Chronic toxicity Give rat and dog medication separately for 3 months according to 40 times and 9 times of the dosage of human treatment, finding no relative toxic effect.

Genital toxicity The research on pregnant rat and rabbit proves that policresulen has no embryotoxicity or teratogenesis effect.

Mutagenesis/carcinogenicity There are no relatively researches on carcinogenicity of the product. And Ames test proves that policresulen has no mutagenesis effect.

Clinical Observation of Curative Effect

★ **Policresulen vaginal suppository curing cervical erosion has a favorable curative effect.**

Choice of cases: 60 cases are cervical erosion patients, among those, 11 cases are mild, 35 cases are moderate and 14 cases are serious. All except for CIN and cervical cancer.

Curative methods: Start the treatment after 3-5days when menstruation is clean. Use the suppository 1time per two days, 4 times as one circle. Use antibiotic simultaneously for those who have complicated adnexitis and relatively serious vaginitis.

Observation of Curative Effect:

Grading	N	First Period of Treatment				Total Efficacy rate %	Second Period of Treatment				Total Efficacy rate %
		heal	Obvious Effective	effective	No effect		heal	Obvious Effective	effective	No effect	
Mild	11	4	2	5	0	100	2	2	7	0	100
Moderate	35	0	5	26	2	94	1	8	26	0	100
Serious	14	0	0	10	4	71	0	3	10	1	93
Total	60	4	7	43	6	88	3	13	43	1	98

Conclusion: Policresulen vaginal suppository has obvious curative effects for cervical erosion. No scar after cervical treatment. Has no intasing to uterine. No pain on the abdomen and no change of menstrual volume. No vagina bleeding. Especially fit for nonparous women.

★ **200 cases clinical observation on policresulen vaginal suppository curing vaginitis**

Application method: 3 days after menstruation is clean. Use the suppository for 1 piece at the next day, 6 pcs as one circle. Review after menstruation. Trichomonas vaginitis needs to review 3 times.

Observation on curative effect:

Types of vaginitis	Cases	Obvious Effective	Effective	Obvious Effective Rate	Effective rate
Mycotic	100	96	4	96%	100%
Trichomonas	52	50	2	96.2%	100%
Bacterial	28	18	10	64.3%	100%
Serise	20	12	8	60%	100%
Total	200	176	24	88%	100%

Conclusion: The characteristics of policresulen vaginal suppository are selectively working on the necrotic tissues and pathological tissues. It can condensation pathogen organism and make it easier to be eliminated. And at the same time, not affect the normal squamous. Policresulen can destroy all kinds of pathogen microorganism; simultaneously protect the growth of physiological flora. Reduce vulva itching rapidly, and the syndrome of leukorrhagia. Furthermore, it can also take effect on astringing to stop bleeding and promote healing of wound.

★ **50 cases for policresulen vaginal suppository curing acute cervicitis**

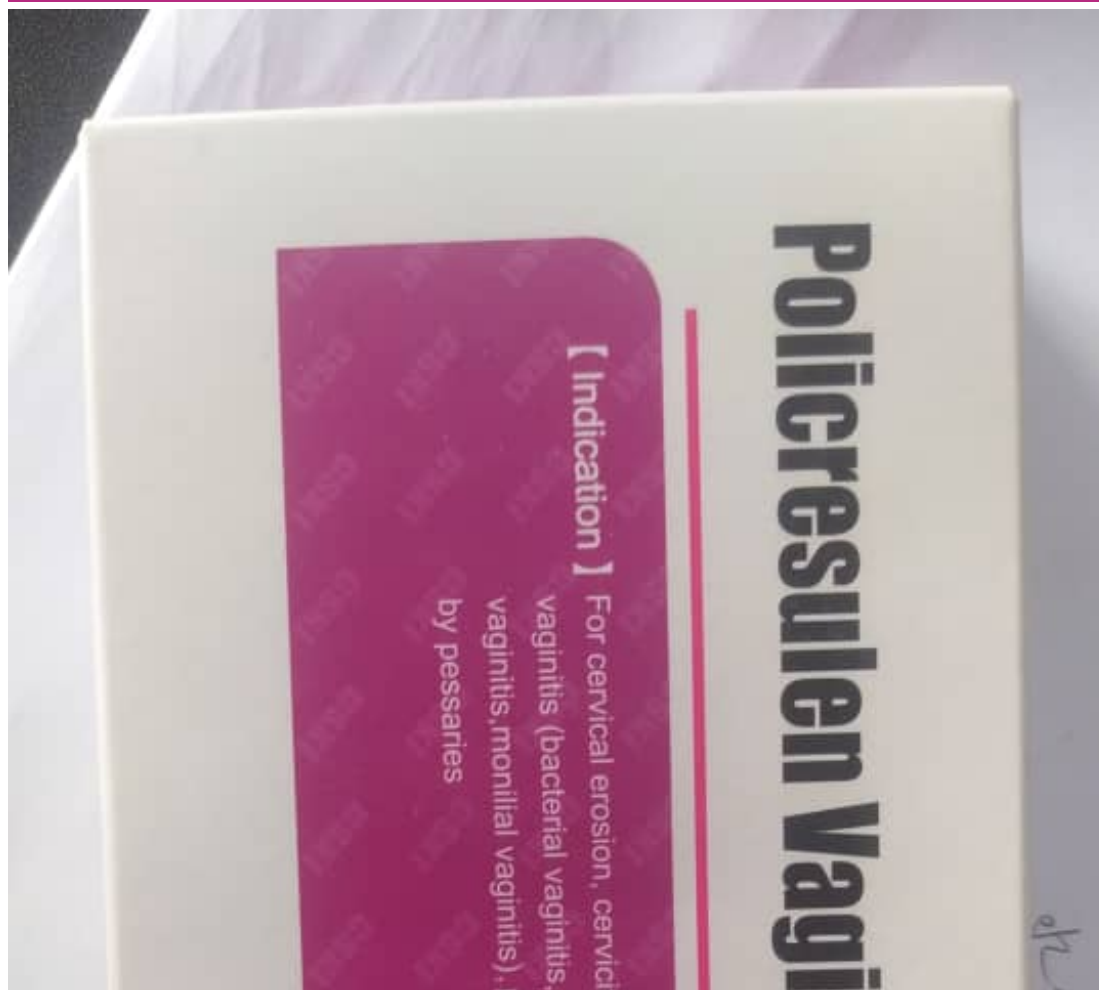
Choices of cases: Among these 50 cases of patients with cervical erosion, 12 cases are mild (Grade I); 20 cases are moderate (Grade II); 15 cases are serious (Grade III); 3 cases are cervical polyp.

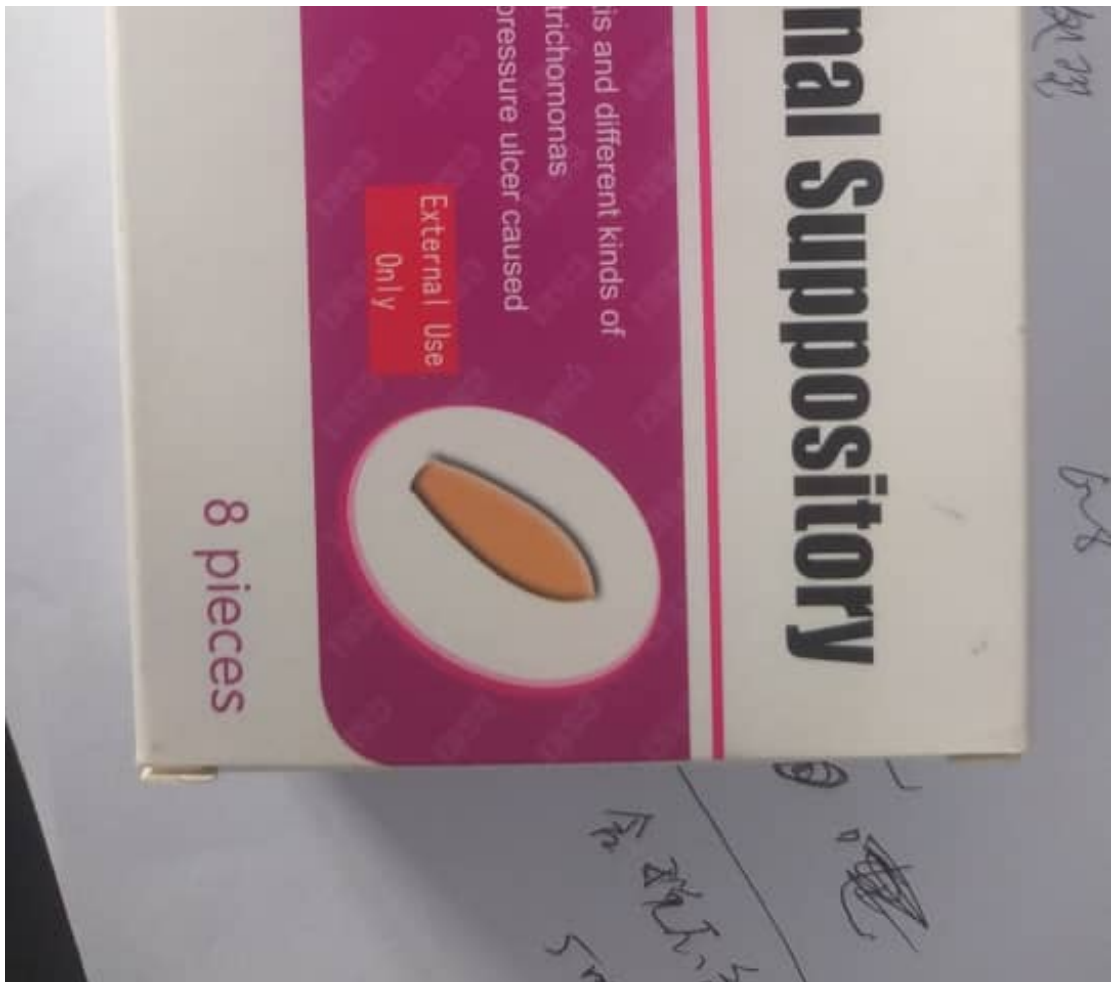
Application method: Use policresulen vaginal suppository, 1 piece per day, continues to use for 6-12 days.

Observation on results:



Conclusion: Policresulen vaginal suppository makes pathological epithelial tissue and protein on columnar epithelial coagulate and fall off. The treatment has no harm to the healthy tissues and plays a function on diminishing inflammation, stopping bleeding, promoting the healing of wound, bulge of cervical mucus and shedding condylooma. Offering immune therapy and antiviral therapy on patients with recurrences of cervicitis can get the best curative effect. And it is worth for spreading.





Instruction for

Usage of Policresulen Vaginal Suppository

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JUJIAFENHUANGQUAN YINDAOSHUAN			
policresulen vaginal suppository suppository			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84149-0102
Route of Administration	VAGINAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	POLICRESULEN (UNII: 6I19M5GB0G) (POLICRESULEN - UNII:6I19M5GB0G)	POLICRESULEN	1 g in 90 mg
Inactive Ingredients			
	Ingredient Name		Strength

WATER (UNII: 059QF0KO0R)

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84149-0102-3	5 mg in 1 BOTTLE; Type 0: Not a Combination Product	03/06/2024	

Dr. Arif

Arif

Policresulen Vaginal Supposito

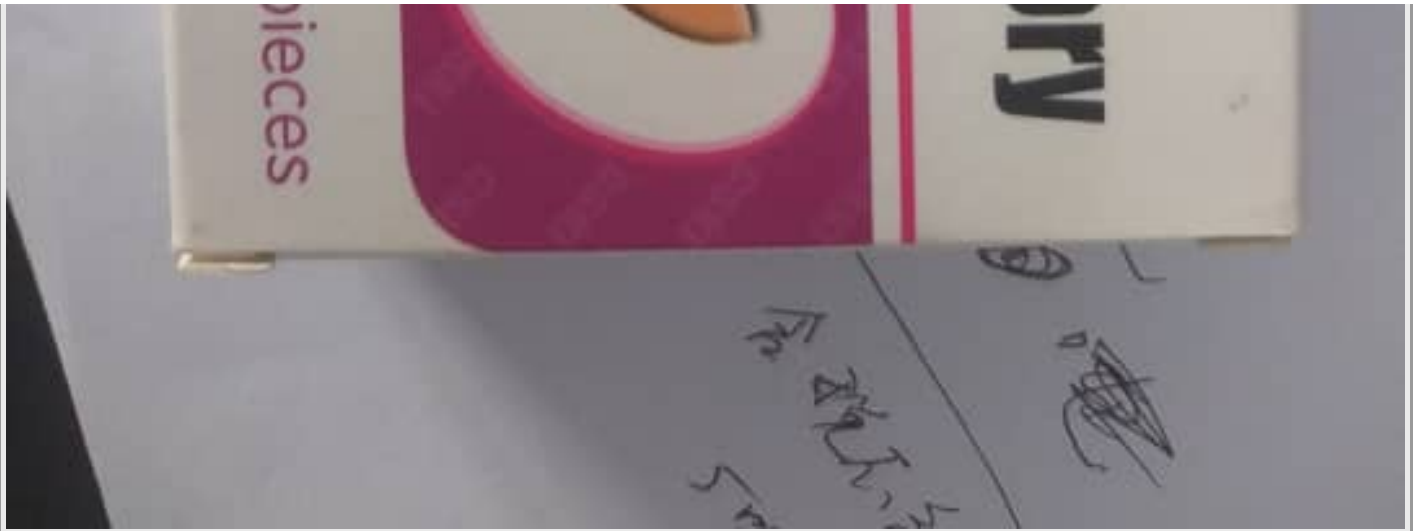
[Indication]

For cervical erosion, cervicitis and different kinds of vaginitis (bacterial vaginitis, trichomonas vaginitis, monilial vaginitis), pressure ulcer caused by pessaries

External Use
Only



8 p



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/06/2024	

Labeler - Heilongjiang Tianlong Pharmaceutical Co Ltd (527931986)

Registrant - Heilongjiang Tianlong Pharmaceutical Co Ltd (527931986)

Establishment

Name	Address	ID/FEI	Business Operations
Heilongjiang Tianlong Pharmaceutical Co Ltd		527931986	manufacture(84149-0102)

Revised: 3/2024

Heilongjiang Tianlong Pharmaceutical Co Ltd