

**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.

78 cases of cervical erosion patients were examined by TCT and HPV, excluded the cervical high intraepithelial lesions and human papillomavirus infection. Then treat with Policresulen Vaginal Suppository. The cervical condition and erosion degree were recorded clearly before treatment. Before sleeping, one suppository was put into the deep vagina, once every other day, two boxes as one course of treatment, three courses of treatment were used continuously, and further consultation at one month after stopping treatment.

Chronic cervicitis is a common disease in married women. It refers to the infiltration of a large number of chronic inflammatory cells such as plasma cells and lymphocytes in the cervical stroma, accompanied by squamous metaplasia and hyperplasia of the cervical gland epithelium and stroma. It is a high risk factor for cervical cancer. Chronic cervicitis can be divided into four pathological types: cervical erosion, cervical polyp, cervical hypertrophy and cervical cyst. The most common pathological type is cervical erosion. Some patients may cause infection, bleeding, cervical stenosis, infertility and other symptoms after the treatment of cervical cryotherapy and microwave. Some patients have certain concerns. From January 2013 to December 2015, our hospital adopted the Policresulen Vaginal Suppository to treat cervical erosion with satisfactory effect. The report is as follows:

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 astringe, 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 360mg/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				Second Period of Treatment					
		heal	Obvious Effective	effective	No effect	Total Efficacy rate %	heal	Obvious Effective	effective	No effect	Total Efficacy rate %
Mild	11	4	2	5	0	100	2	2	7	0	100
Moderate	35	0	5	28	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 irritating 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	98	4	98%	100%
Trichomonas	52	50	2	96.2%	100%
Bacterial	28	18	10	64.3%	100%
Senile	20	12	8	60%	100%
Total	200	178	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**

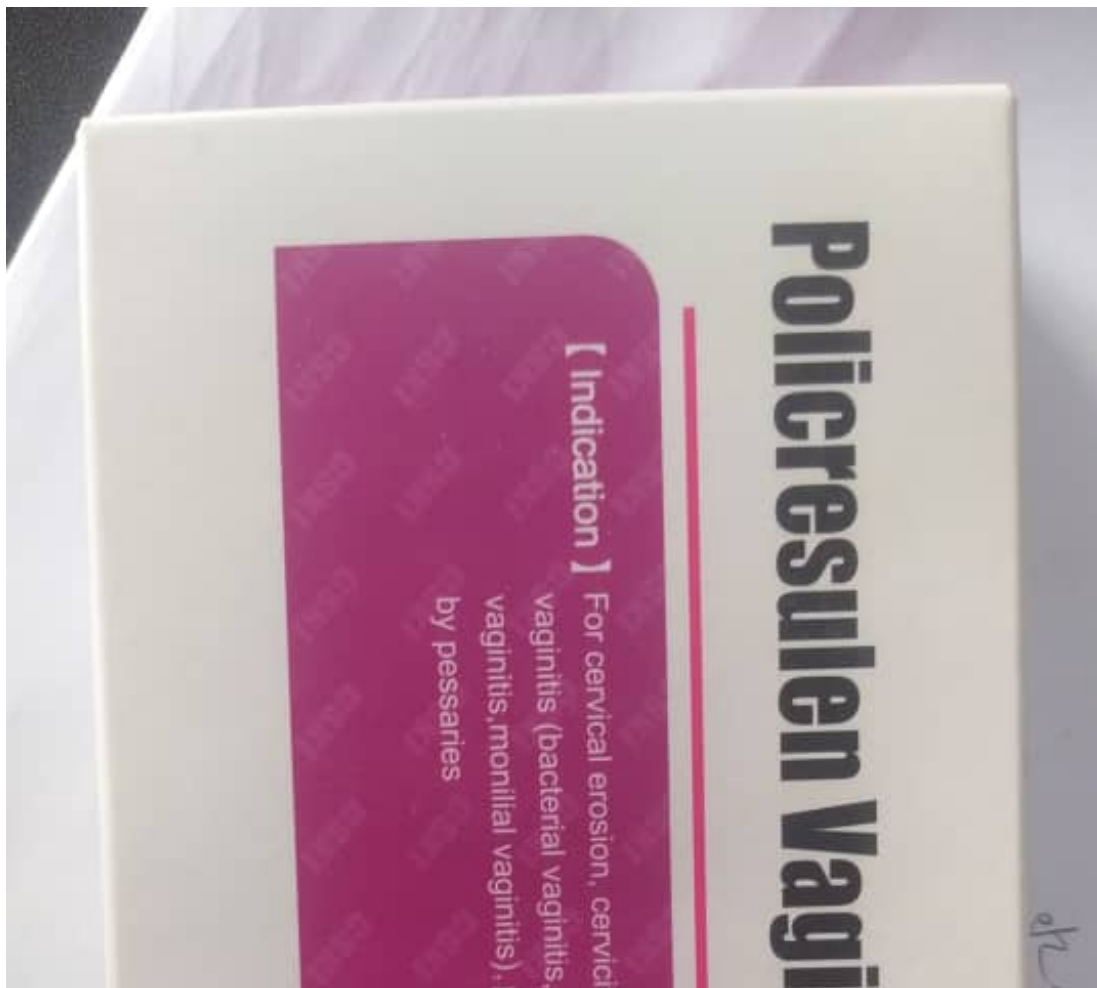
Choices of cases: Among these 50 cases of patients with cervical erosion, 12 cases are mild (Grade I); 20 cases are moderate (Grade II); 15 cases are serious(Grade III); 3 cases are cervical polyp.

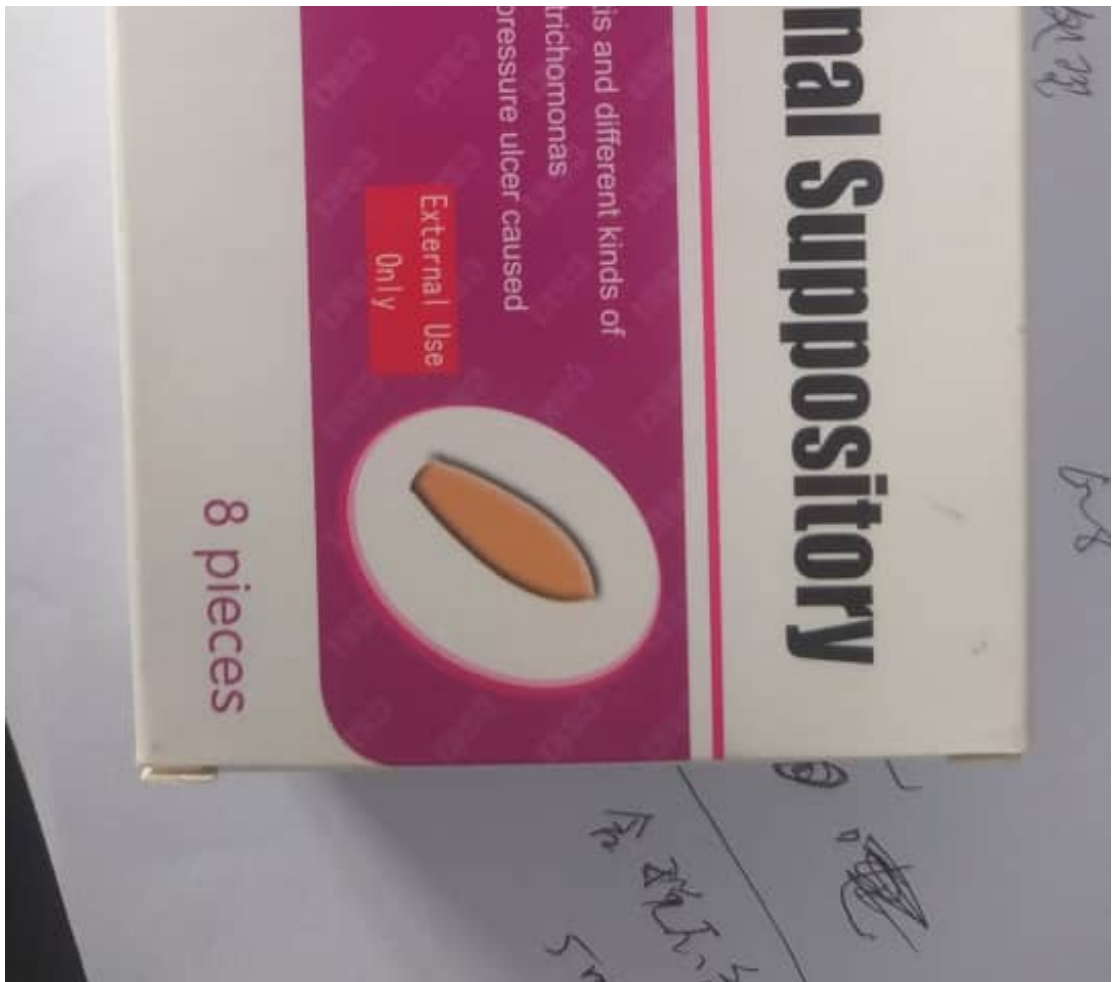
Application method: Use policresulen vaginal suppository, 1 piece per day, continues to use for 6-12 days.

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 mucosa 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

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.

JUJIAFENHUANGQUAN YINDAOSHUAN			
policresulen vaginal suppository suppository			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:84149-0042
Route of Administration	VAGINAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
POLICRESULEN (UNII: 6I19M5GB0G) (POLICRESULEN - UNII:6I19M5GB0G)		POLICRESULEN	90 mg in 1 U	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84149-0042-3	8 U in 1 BOX; Type 0: Not a Combination Product	03/01/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		03/01/2024		

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(84149-0042)

Revised: 5/2024

Heilongjiang Tianlong Pharmaceutical Co Ltd