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**Application of Garmastan for  
prevention and treatment of  
mammary gland rhagades**

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# GARMASTAN

- Contains the active substance *guaiazulene*, obtained from the essential oil of the guaiacum tree (*Gvajacum officinale*, *G. sanctum*)
- Garmastan is especially indicated for breast-feeding women
- Widely used in the obstetrics practice in Germany, Austria, Hungary and Romania
- Available at the Bulgarian pharmaceutical market since March, 2001



# **OBJECTIVE OF THE CLINICAL STUDY**

**REPORTING THE  
EFFICACOUSNESS AND SIDE  
EFFECTS AFTER THE LOCAL  
APPLICATION OF GARMASTAN  
FOR PREVENTION AND  
TREATMENT OF MAMILLA AND  
AREOLA RHAGADES**



# **MATERIALS AND METHODS**

- **A six-month clinical study in the period March 1 - August 31, 2001 with patients from Second Clinic of Obstetrics - Pleven**
- **Number of subjects – 44 women between the 1<sup>st</sup> and 20<sup>th</sup> day after child delivery, divided into TWO groups:**



## PREVENTION

- **I<sup>st</sup> group /n=24/**
- **With a higher risk of epithelial lesions**
- **Women who deliver for the first time, with a light complexion, flat and concave breast nipples, microthelia and hypogalactia**

## TREATMENT

- **II-nd group /n=20/**
- **Women with rhagades**
- **Pronounced or less pronounced rhagades**



# **Schemes for the application of GARMASTAN**

- **First group – as a PREVENTION /N=24/:**  
Garmastan is applied in a thin layer, three times a day;
  - **The application starts on the first day after child delivery for a period of 10 days**
- **Second group – as a TREATMENT /N=20/:**  
Treatment of the lesions formed between the third and fifth day after child delivery
  - **3 – 6 applications of Garmastan daily;**
  - **An average duration of the treatment – 12 days**



# RESULTS

- **REPORTING THE EFFECT AND THE SIDE EFFECTS AFTER THE APPLICATION OF GARMASTAN ACCORDING TO THE OBJECTIVE OBSERVATION AND SUBJECTIVE COMMENTS OF THE PATIENTS**





# **RESULTS – I<sup>st</sup> group**

## **prevention /n=24/**

- **After three applications of Garmastan daily the skin of the breast nipples and areolas has become smooth and elastic in 75 % of the cases /n=18/**
- **In 3 of the cases /1 with microthelia and 2 with hypogalactia/ were observed slight lesions of the mamilla which necessiated 6 applications of Garmastan daily**
- **3 other women delivering a child for the first time, blondes, with painful and swollen breast nipples, also had to apply Garmastan 6 times daily instead of 3**





# RESULTS

## I<sup>st</sup> group prevention /n=24/

- In 6 of the above mentioned cases was reported a fast healing and antiphlogistic effect of the lesion



# **RESULTS –**

## **II<sup>nd</sup> group /n=20/; treatment with GARMASTAN**

- Rhagades of the mamilla and areola - less or more pronounced;
- The observation started in the clinic and continued after dehospitalisation;
- The hydrophilic ointment is easily absorbed, without causing any pain in the sensitive areas. It is odourless, does not contain animal or artificial fats. The gauze pad with Garmastan was easily removed;
- Before breast-feeding the breasts were washed with plain water;



# RESULTS

## **II<sup>nd</sup> group /n=20/; treatment with GARMASTAN**

- The epithelial lesions of the breast nipples and areolas did not become a reason for weaning;
- After dehospitalisation of the women was reported a tendency /n=6/ or entire disappearance of the subjective complaints (spontaneous pain or pain during breast-feeding);
- **Objective study:** normal or complete epithelization of rhagades;
- In 9 of the cases the application of Garmastan continued at home without any additional complications;



# RESULTS

- **NO SIDE EFFECTS WERE REPORTED AFTER LOCAL APPLICATION OF GARMASTAN (including cases of hypersensitivity)**



# **RESULTS**


## **of the microbiological analysis**

- **In 7 of the cases with serious and secreting rhagades**
- **From the site of the lesion and the nasopharynx of the babies were isolated the following micro-organisms:**



# **Microbiological analysis of the lesion**

<b>Type of the micro-organism</b>	<b>Number of patients</b>
<b>Staphylococcus epidermidis</b>	<b>2</b>
<b>Staphylococcus aureus</b>	<b>2</b>
<b>Escherichia coli + Candida species</b>	<b>1</b>
<b>Lack of bacterial growth</b>	<b>2</b>



**Microbiological analysis  
from the nasopharynx of 3 babies was  
isolated an identical bacterial flora:**

Type of the micro-organism	Number of patients
Staphylococcus epidermidis	2
Staphylococcus aureus + Candida species	1





## **RESULTS FROM THE TREATMENT WITH GARMASTAN**

- **The healing of rhagades followed a physiological mechanism, with a subsiding and disappearance of the inflammatory symptoms, without antibiotics and only with the application of Garmastan**



## DISCUSSION

- In 75% of the cases in the group with a high risk (group I) was achieved an efficient prevention of rhagades with 3 applications of Garmastan daily;
- In 25% of the cases (6 cases) arose the need of increase of the application to 6 times daily because of the appearance of slight lesions (3) or subjective complaints (tense or painful breast nipples – 3 of the cases)
- ***In order to be fully efficacious the product has to be applied after each breast-feeding (6 times daily) which is also the company recommendation***



## **DISCUSSION**

- **The fast epithelizing and antiphlogistic effect of Garmastan is due to its active ingredient guaiazulene ;**
- **The properties of the azulenes – a group of organic compounds of natural origin, have been known for a long time. They are widely used in the dermatological practice;**
- **The antiphlogistic action of guaiazulene is due to the blockage of the arachidonic cascade and therefore of the leucotrienic and prostate gland secretion (mediators of inflammation);**



## DISCUSSION

- ***THE RESULTS OF THE CLINICAL STUDY PROVE THAT GARMASTAN STIMULATES THE NATURAL HEALING PROCESS AND HAS AN ANTI-INFLAMMATORY ACTION***

# CONCLUSION

- ***Garmastan*** - A NEW ALTERNATIVE FOR PREVENTION AND TREATMENT OF RHAGADES – A COMMON PROBLEM IN THE OBSTETRICS PRACTICE!

✓ EFFICACIOUS

✓ HARMLESS

✓ HYPOALLERGENIC

✓ NO SIDE EFFECTS

✓ FAST RELIEF OF SUBJECTIVE COMPLAINTS

✓ EASY APPLICATION