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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

WO 2007/008119 A1

(54) Title: THE USE OF KETOPROFEN IN TREATING HEMORRHOIDS

(57) Abstract: The efficacy of Ketoprofen was investigated in treating Hemorrhoids in its various forms, stages and clinical symptoms. Clinical trials were conducted in Sudan at Sadiq Abu Aagla out-patient clinic. Results from trials Data collected over a total of 6 months including after-treatment follow-up has revealed an outstanding healing effect of a 2.5% preparation of Ketoprofen dissolved in Glycerine. All treated patients fully recovered from all symptoms including pain in a period of 4 -14 days from commence of treatment. There was no relapse noted for any of the hemorrhoids clinical manifestations whatsoever within a period of 6 months after commences of treatment. It was thus concluded that Ketoprofen is a final cure for Hemorrhoids in all its stages and that it eliminates the need for surgery.

# The use of Ketoprofen in Treating Hemorrhoids

By El Fatih Osman Hassan Omran

## Introduction

Hemorrhoids is a common disease in adults of both sexes and is characterized by internal/external disorder and congestion of the ano-rectal veins leading to discomfort, pain, pruritus, mucous discharge, prolapse and bleeding.
Up-to-date, no drug of steroidal or non-steroidal nature or otherwise is known to cure or even relief the pains of hemorrhoids effectively.

## Objective:

The current study investigates the efficacy of Ketoprofen 2.5% in the treatment of hemorrhoids and relieving its pains.

## Materials and Methods:

Studies were started on Jan. 2005 and concluded in July 2005.
Location of trials was ""Sadig Abu Aagla's public clinic. Burri, Sudan. Physician in charge:
Dr. Khalid El Tayeb Bashir

Patients of age groups 30-60 of both sexes were included in this study. Routine examinations were curried out for all positively diagnosed patients before commence of trials and results were recorded. Hemorrhoids manifestations were recorded as per attached tables (1)
Inclusion criteria; Only patients with hemorrhoids symptoms, with or without rectal bleeding were included.
Exclusion criteria: Patients with hemorrhoids symptoms but having other complications were excluded from trials.

Ketoprofen preparation of 2.5% dissolved in glycerol was administered b.d. to 25 patients randomly selected and denominated as group "A" or "Treatment Group". Another group of 25 patients were receiving conventional Hemorrhoids treatments and were denominated as group "B" or "Control group".
Two patients of group "A" and one of group "B" have discontinued trials.
Follow-up observations and examination were made on daily basis on both groups for the first 14 days.
Examinations and collection of data were made on weekly basis then 3 months and 6 months after the start of medication to note incidence of recurrence of any of the clinical symptoms and side-effects if any.

Externally affected areas were thoroughly cleaned with dilute antiseptics (Dettol) before administration of the drug. Clean disposable syringes were used to deliver about 2 c.c. of the drug through the rectal opening to a depth of 3-4 cm to cover the affected internal areas. About another 2 c.c. were applied and thoroughly rubbed over the external affected areas. Group "B" received conventional Hemorrhoids treatments.

**Results and Discussion**

Pre-Treatment incidence of clinical data were recorded as per attached Table (1).
Post-Treatment clinical data were recorded and analyzed as per attached Tables (2 -7).
In all 23 patients of Group "A", the need for a surgical operation was completely eliminated.
All external and internal congested veins were ruptured painlessly discharging the congested blood and completely healed within a maximum of 14 days of treatment.
17 out of 23 patients of Group "A" achieved complete cure and healing within 7 days.
The rest (6 patients) reached to same level of cure in 14 days. Only one patient of group "B" got well after 7 days and 4 after 2 weeks and 3 months. None of the patients of group "A" had recurrence of disease symptoms during the follow-up duration of 6 months while one case of recurrence was noted in group "B".
Patients of group "A" who were suffering from itching/pain experienced immediate relief (within 2-5 minutes) following the first application. The preparation has exhibited a slight burning pain effect in some patients which lasted for about 2-5 minutes after which all pains were relieved.
Patients from group "A" who suffered from congested veins and/or bleeding experienced increase in bleeding at first due to vein rupturing followed by quick healing and complete cessation of bleeding.
In none of the 23 patients of group "A" any adverse side-effects or complications were noted.
None of the 24 patients in the control group (Group B) attained complete healing or a lasting relief of pains.
When data were analyzed statistically, results for pruritus, pain, vein congestion and bleeding were found to be statistically significant.
Those for mucous discharge and prolapse were not statistically different from the control (group "B") which gave similar improvements in patients conditions.

**Conclusion:**
The following post-treatment results were obtained:
1- The preparation was found to be extremely effective in complete and lasting healing of hemorrhoids when applied twice daily for a treatment duration of 7 - 14 days.
2- It was found to be extremely effective in giving spontaneous and lasting relief of hemorrhoids pains within 2-5 minutes.
3- The preparation was found to moderately improve/cure prolapse associated with hemorrhoids, pregnancy or delivery.
4- No adverse side-effects were noted during treatment and follow-up periods.
5- It was found to be tolerably painful compared to severe pains due to hemorrhoids.
6- It was found to sooth pruritus and stop mucous discharge associated with hemorrhoids.
Congested hemorrhoid veins were observed to painlessly rupture, discharge and completely heal within 7- 14 days.

**(Table (1) Pre-Treatment Incidence of symptoms**

**Counts of patients showing symptoms**

| TREATMENTS. | PRURITUS | PAIN | MUCOUS DISCHARGE | CONGESTED VEINS | PROLAPSE | BLEEDING |
|---|---|---|---|---|---|---|
| GROUP "A" | 6 | 20 | 5 | 18 | 7 | 8 |
| GROUP "B" | 7 | 19 | 4 | 19 | 6 | 8 |

**Post-Treatment incidence of symptoms**

**Table (2) Incidence of Pruritus**

**Counts of patients showing symptoms**

| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | After 6 months |
|---|---|---|---|---|---|
| GROUP "A" | 6 | 1 | 0 | 0 | 0 |
| GROUP "B" | 7 | 1 | 2 | 3 | 4 |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 7 | 1.4 | 6.8 |
| GROUP "B" | 5 | 17 | 3.4 | 5.3 |
| | | | | |
| DAY1 | 2 | 13 | 6.5 | 0.5 |
| DAY7 | 2 | 2 | 1 | 0 |
| DAY14 | 2 | 2 | 1 | 2 |
| AFTER 3 MONTHS | 2 | 3 | 1.5 | 4.5 |
| AFTER 6 MONTHS | 2 | 4 | 2 | 8 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 10 | 1 | 10 | 8 | 0.047420656 | 7.708649719 |
| Columns | 43.4 | 4 | 10.85 | 8.68 | 0.029811279 | 6.388233942 |
| Error | 5 | 4 | 1.25 | | | |
| | | | | | | |
| Total | 58.4 | 9 | | | | |

## Table (3) incidence of pain

| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | AFTER 6 MONTHS |
|---|---|---|---|---|---|
| GROUP "A" | 20 | 0 | 0 | 0 | 0 |
| GROUP "B" | 19 | 6 | 5 | 5 | 6 |
| | | | | | |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 20 | 4 | 80 |
| GROUP "B" | 5 | 41 | 8.2 | 36.7 |
| | | | | |
| DAY1 | 2 | 39 | 19.5 | 0.5 |
| DAY7 | 2 | 6 | 3 | 18 |
| DAY14 | 2 | 5 | 2.5 | 12.5 |
| AFTER 3 MONTHS | 2 | 5 | 2.5 | 12.5 |
| AFTER 6 MONTHS | 2 | 6 | 3 | 18 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 44.1 | 1 | 44.1 | 10.13793103 | 0.033406805 | 7.708649719 |
| Columns | 449.4 | 4 | 112.35 | 25.82758621 | 0.004064709 | 6.388233942 |
| Error | 17.4 | 4 | 4.35 | | | |
| | | | | | | |
| Total | 510.9 | 9 | | | | |

## Table (3) incidence of pain

| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | AFTER 6 MONTHS |
|---|---|---|---|---|---|
| GROUP "A" | 20 | 0 | 0 | 0 | 0 |
| GROUP "B" | 19 | 6 | 5 | 5 | 6 |
| | | | | | |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 20 | 4 | 80 |
| GROUP "B" | 5 | 41 | 8.2 | 36.7 |
| | | | | |
| DAY1 | 2 | 39 | 19.5 | 0.5 |
| DAY7 | 2 | 6 | 3 | 18 |
| DAY14 | 2 | 5 | 2.5 | 12.5 |
| AFTER 3 MONTHS | 2 | 5 | 2.5 | 12.5 |
| AFTER 6 MONTHS | 2 | 6 | 3 | 18 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 44.1 | 1 | 44.1 | 10.13793103 | 0.033406805 | 7.708649719 |
| Columns | 449.4 | 4 | 112.35 | 25.82758621 | 0.004064709 | 6.388233942 |
| Error | 17.4 | 4 | 4.35 | | | |
| | | | | | | |
| Total | 510.9 | 9 | | | | |

**Table (4) Incidence of Mucous Discharge**

**Counts of patients showing symptoms**

| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | AFTER 6 MONTHS |
|---|---|---|---|---|---|
| GROUP "A" | 5 | 1 | 0 | 0 | 0 |
| GROUP "B" | 4 | 2 | 1 | 0 | 0 |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 6 | 1.2 | 4.7 |
| GROUP "B" | 5 | 7 | 1.4 | 2.8 |
| | | | | |
| DAY1 | 2 | 9 | 4.5 | 0.5 |
| DAY7 | 2 | 3 | 1.5 | 0.5 |
| DAY14 | 2 | 1 | 0.5 | 0.5 |
| AFTER 3 MONTHS | 2 | 0 | 0 | 0 |
| AFTER 6 MONTHS | 2 | 0 | 0 | 0 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 0.1 | 1 | 0.1 | 0.285714286 | 0.621308295 | 7.708649719 |
| Columns | 28.6 | 4 | 7.15 | 20.42857143 | 0.006330074 | 6.388233942 |
| Error | 1.4 | 4 | 0.35 | | | |
| | | | | | | |
| Total | 30.1 | 9 | | | | |

**Table (5) Incidence of Prolapse**

| | Counts of patients showing symptoms | | | | |
|---|---|---|---|---|---|
| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | AFTER 6 MONTHS |
| GROUP "A" | 7 | 6 | 5 | 5 | 4 |
| GROUP "B" | 6 | 6 | 6 | 5 | 5 |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 27 | 5.4 | 1.3 |
| GROUP "B" | 5 | 28 | 5.6 | 0.3 |
| | | | | |
| DAY1 | 2 | 13 | 6.5 | 0.5 |
| DAY7 | 2 | 12 | 6 | 0 |
| DAY14 | 2 | 11 | 5.5 | 0.5 |
| AFTER 3 MONTHS | 2 | 10 | 5 | 0 |
| AFTER 6 MONTHS | 2 | 9 | 4.5 | 0.5 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 0.1 | 1 | 0.1 | 0.285714286 | 0.621308295 | 7.708649719 |
| Columns | 5 | 4 | 1.25 | 3.571428571 | 0.122619629 | 6.388233942 |
| Error | 1.4 | 4 | 0.35 | | | |
| | | | | | | |
| Total | 6.5 | 9 | | | | |

**Table (6) Incidence of Bleeding**

| | Counts of patients showing symptoms | | | | |
|---|---|---|---|---|---|
| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | AFTER 6 MONTHS |
| GROUP "A" | 8 | 2 | 1 | 0 | 0 |
| GROUP "B" | 8 | 6 | 6 | 5 | 5 |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 11 | 2.2 | 11.2 |
| GROUP "B" | 5 | 30 | 6 | 1.5 |
| | | | | |
| DAY1 | 2 | 16 | 8 | 0 |
| DAY7 | 2 | 8 | 4 | 8 |
| DAY14 | 2 | 7 | 3.5 | 12.5 |
| AFTER 3 MONTHS | 2 | 5 | 2.5 | 12.5 |
| AFTER 6 MONTHS | 2 | 5 | 2.5 | 12.5 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 36.1 | 1 | 36.1 | 15.36170213 | 0.017256402 | 7.708649719 |
| Columns | 41.4 | 4 | 10.35 | 4.404255319 | 0.090047369 | 6.388233942 |
| Error | 9.4 | 4 | 2.35 | | | |
| | | | | | | |
| Total | 86.9 | 9 | | | | |

**Table (7) Incidence of Congestion**

**Counts of patients showing symptoms**

| TREATMENT | DAY1 | DAY7 | DAY14 | AFTER 3 MONTHS | AFTER 6 MONTHS |
|---|---|---|---|---|---|
| GROUP "A" | 18 | 2 | 0 | 0 | 0 |
| GROUP "B" | 19 | 19 | 18 | 17 | 17 |

Anova: Two-Factor Without Replication

| *SUMMARY* | *Count* | *Sum* | *Average* | *Variance* |
|---|---|---|---|---|
| GROUP "A" | 5 | 20 | 4 | 62 |
| GROUP "B" | 5 | 90 | 18 | 1 |
| | | | | |
| DAY1 | 2 | 37 | 18.5 | 0.5 |
| DAY7 | 2 | 21 | 10.5 | 144.5 |
| DAY14 | 2 | 18 | 9 | 162 |
| AFTER 3 MONTHS | 2 | 17 | 8.5 | 144.5 |
| AFTER 6 MONTHS | 2 | 17 | 8.5 | 144.5 |

ANOVA

| *Source of Variation* | *SS* | *df* | *MS* | *F* | *P-value* | *F crit* |
|---|---|---|---|---|---|---|
| Rows | 490 | 1 | 490 | 18.49056604 | 0.01264496 | 7.708649719 |
| Columns | 146 | 4 | 36.5 | 1.377358491 | 0.381952193 | 6.388233942 |
| Error | 106 | 4 | 26.5 | | | |
| | | | | | | |
| Total | 742 | 9 | | | | |

# C L A I M

Ketoprofen is generally used for killing pains specially rheumatic pains connected with arthritis .
It is not known to have an effect on Hemorrhoids.
It's **indication** for treating hemorrhoids is considered here to be a first report to this effect.
The claim is "**The USE of ketoprofen for treating Hemorrhoids**" in all its forms, stages and its related symptoms.
Hence protection required is for the **Indication of Ketoprofen for Treating Hemorrhoids.**

## AMENDED CLAIMS
## received by the International Bureau on 07 December2005 (07.12.05)

Ketoprofen is generally used for killing pains specially rheumatic pains associated with Arthritis.
It is not known to have an effect on Hemorrhoids.
It's manufacture and use for treating Hemorrhoids is here considered to be a first report to this effect.

**CLAIM (1):**

(THE USE OF KETOPROFEN FOR MANUFACTURING MEDICAMENTS FOR THE TREATMENT OF HEMORRHOIDS IN ALL IT'S STAGES ,FORMS AND MANIFESTATIONS INCLUDING BLEEDING, DISCHARGE, PAIN, PRURITUS, CONGESTION OF THE VEINS AND PROLAPSE).
Hence the protection required is for : The Use of Ketoprofen for the Manufacturing of Medicaments intended for the Treatment of Hemorrhoids in all its stages, forms and manifestations including bleeding, discharge, pain, pruritus, congestion of the veins and prolapse.

**CLAIM (2):**

THE USE OF 2.5% KETOPROFEN DISSOLVED IN PURE GLYCEROL FOR MANUFACTURING A MEDICAMENTS FOR TREATING HEMORRHOIDS AS MANIFESTED BY ITS VARIOUS FORMS AND SYMPTOMS IN ACCORDANCE WITH CLAIM (1)
Hence the protection required is for the Preparation of Ketoprofen with Glycerol for the treatment of Hemorrhoids in accordance with CLAIM(1).

# INTERNATIONAL SEARCH REPORT

International Application No
PCT/SD2005/000008

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K31/192 A61P29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, SCISEARCH, MEDLINE, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 5 894 019 A (HESSE ET AL)<br>13 April 1999 (1999-04-13)<br>claims | 1 |
| A | US 5 602 183 A (MARTIN ET AL)<br>11 February 1997 (1997-02-11)<br>the whole document | 1 |
| A | WO 00/30630 A (LINDEN BIOTECHNOLOGY, INC; XIA, ZHI-TAO) 2 June 2000 (2000-06-02)<br>the whole document | 1 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 27 October 2005 | 04/11/2005 |

| Name and mailing address of the ISA | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040, Tx. 31 651 epo nl,<br>Fax: (+31–70) 340–3016 | Venturini, F |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SD2005/000008

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: –
because they relate to subject matter not required to be searched by this Authority, namely:

Although claim 1 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/SD2005/000008

| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
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