Title: TOPICAL FORMULATION FOR THE TREATMENT OF ANO-RECTAL DISEASES

Abstract: The present invention refers to a topical pharmaceutical formulation in the form of a cream, a ointment, suppositories, a paste, an enema, respectively, useful for the treatment of hemorrhoids and anal fistula resp. fissures. Said formulation is composed of D-panthenol, L-cysteine, N-acetyl-D, L-homocystein thiolactone, hydrocortisone acetate, idochlorhydroxyquin and lidocaine. The above formulation has the following pharmacological actions: It activates various essential enzymatic systems especially on the cells whose damaged. It shows a preventive curative anti-necrotic action and maintains the redox potential. The formulation has a detoxicating and anti-allergic influence. The formulation has an anti-bacterial, an anti-fungal and a local anesthetic action.
A NEW PHARMACEUTICAL FORMULA FOR
TREATMENT OF ANO-RECTAL DISEASES

Technical Field:
Pharmaceutical formula for medical treatment of Ano-rectal diseases this topical pharmaceutical formula used in the treatment of external and internal hemorrhoids with all degrease & treatment of low and high rectal fistula also used in the treatment of anal fissures. The pharmaceutical forms of the above formula can be used in the form of cream, ointment, enema, paste.

Background Art
The most topical pharmaceutical preparations present the market of pharmacy present now used for symptomatic relief of the anorectal diseases so this preparations contains antiallergic, antipruritic, anti-inflammatory, Vasoconstrictors, astringent, anti bacterial, demulcent, etc.
Example .Bismuth sub Gallat 2.25%, Zinc Oxide 10.75%, Balsam Peru 1.87%, Bismuth Oxide 0.87%.
All the above chemical substances have soothing, astringent effect for treatment simple anorectal inflammations and irritations it relives hemorrhoid pain.

Our new invention topical pharmaceutical formula made mainly from nutritional components with high safety profile with minimal side effects.
Our new topical pharmaceutical formula used not only for symptomatic relive of the above anorectal diseases but also it use for complete treatment of this diseases.
Disclosure of the Invention

The new topical pharmaceutical formula used for medical treatment of hemorrhoid anal fissures, rectal fistula in the form of cream ointments, suppositories, enema, paste.

This formula composed of:
L- Cysteine (from 2% to 20%), N- Acetyl - D, L-Homocysteinethiolactone (from 2% to 20%), D- Panthenol (from 1% to 10%), Iodochlorhydroxyquin (from 0.1% to 3%), Lidocaine (from 1 to 6%), Hydrocortisone acetate (from 0.5% to 3%).

Properties:

Our topical pharmaceutical formula affords prompt relief from unpleasant symptoms of hemorrhoid, Anal fissures, rectal fistula i.e. pain smarting, itching, skin tension.

The properties of each above substances in our formula:

A. N- Acetyl - D, L-Homocysteinethiolactone & L- Cysteine activate various essential enzymatic systems of the vital cells especially the cells whose damaged by infectious or toxic substances results in necrosis.

So the above two amino acids have preventive curative anti necrotic action also they act as physiological carriers of sulphydryl groups so they are of decisive importance to various intermediary processes of the metabolism and for the maintenance of redox potential.

They have detoxicating influence and antiallergic influence.

The above two amino acids potentiat the blood circulation and relief ischemia in this area.
B. D-Panthenol have an important role in healing of tissues and is easily absorbed to make the skin and soft tissues soft, clean, moist.

Also, D-Panthenol increases the absorption of the above amino acid so increase the bioavailability of the active ingredients so increases the therapeutic effect.

C. Hydrocortisone used as anti-inflammatory and allergic and Antipruritic.

D. Iodochlorhydroxy quin is an antibacterial anti-fungal.

E. Lidocaine is along active local anesthetic.

Indications:

Treatment of external & internal hemorrhoids with different degrees & anal fissures & low and high rectal fistula also used as prophylaxis between attack to prevent recurrences.

In hemorrhoidal complication like anal purities pre-operative and post-operative treatments of hemorrhoidectomy.
CLAIMS

1- A new topical pharmaceutical formula composition with ranges of concentration of each component:
L-Cysteine (from 2% to 20%), N-acetyl - D₃L- Homocysteine thiolactone (from 2% to 20%), D-Panthenol (from 1% to 10%),
Hydrocortisone acetate (from 0.5% to 3%), Iodochlorohydroxyquin (from 0.1% to 3%), Lidocaine (from 1% to 6%).

2- As in number (1) the use of the upper topical pharmaceutical formula the uses for treatment of external and internal hemorrhoids with deferent degrees & the treatment of low and high rectal fistula & in the treatment of anal fissures.

3- As in number (1) the new topical use of L-Cystein & N-Acetyl - D₃L- Homocysteinenethiolactone in concentration ranges (from 2% to 20% ) in anorectal area.

4- As in number (1) the use of upper pharmaceutical formula in the form of cream, ointment, suppositories, enema, paste.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC®: A61K 31/167 (2006.01); A61K 31/255 (2006.01); A61K 31/195 (2006.01); A61K 31/573 (2006.01); A61K31/47 (2006.01); A61K 31/164 (2006.01)

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)
1PC®: 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 practicable, search terms used)
WPI, EPODOC, PAJ, medline, CAS, TXTE, TXTG, TXTF

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<th>Category</th>
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<th>Relevant to claim No.</th>
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<tr>
<td>A</td>
<td>JP 6092833 A (SHISEIDO CO LTD) 5 April 1994 (05.04.1994) abstract, on-line translation of the JPO.</td>
<td>1-4</td>
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<tr>
<td>A</td>
<td>Marigliano F., &quot;Results in using the combination corticosteroid and iodochlorhydroxyquinoline in proctology&quot;, Hospital, Nov. 1967, Vol 72, Nr. 5, pages 1551-1554 abstract (Medline: NLM4242960).</td>
<td>1-4</td>
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Further documents are listed in the continuation of Box C. See patent family 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 application or patent 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
24 March 2006 (24.03.2006)

Date of mailing of the international search report
19 April 2006 (19.04.2006)

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Form PCT/ISA/21 0 (second sheet) (January 2004)
Continuation of first sheet

Continuation No. 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:

Claims Nos.: 2-4 because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 2-4 are directed to a therapeutic method of treatment of the human/animal body, the search has been carried out and is based on the alleged effects of the compound/composition.

Continuation No. IV:
Text of the abstract
(Continuation of item 5 of the first sheet)

The present invention refers to a topical pharmaceutical formulation in the form of a cream, an ointment, suppositories, a paste, an enema, respectively, useful for the treatment of hemorrhoids and anal fistula resp. fissures. Said formulation is composed of D-panthenol, L-cysteine, N-acetyl-D, L-homocystein thiolactone, hydrocortisone acetate, iodochlorhydroxyquin and lidocaine.
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