Pros-'aleiv®

NDC # 65448-2165-1

PROTOCOL No. 72

www.amtrx.com

DESCRIPTION

Pros-'aleiv® (NDC # 65448-2165-1) is a highly effective, prescription only, herbal poly-peptide extract combination that temporarily but rapidly alleviates the symptoms of urinary retention and incomplete bladder emptying. Pros-'aleiv® may be utilized in acute or chronic conditions of the prostate including acute urinary retention due to benign prostate hypertrophy (BPH) as well as prostate carcinoma. It has further been demonstrated to decrease PSA levels in BPH and patients with prostate cancer.

Pros-aleiv® is formulated using a combination of highly active, herbal poly-peptide extracts combined with and stabilized in a lipid encapsulated hydrophobic matrix. This unique combination is then delivered using a unique, proprietary trans-dermal delivery mechanism. The resulting formulation provides a high potency, convenient, rapid onset therapeutic agent for the temporary relief of urinary retention, flow incontinence and incomplete bladder emptying resulting from benign prostatic hypertrophy or prostate cancer.

ACTIVE INGREDIENTS

The phytopharmaceutical constituents of Pros-aleiv® include dioegenin, beta-sitosterol, sterols, stigmasterol, sycloartenol humulene, humulone, luplin, lupulon, 2-methyl-3-butene-2-ol, homostachydrine, saponin, stachydrine, diadzein, and genistin. these constituents are derived from various herbal poly-peptide extracts which include discosrea villosa, serenoa repens, trifolium prantense, viscum album, similax officianlis, sedicago sativa, medicao sativa, slavia officinalis, cacchaum officinerium, olea europaea, vitex agnus, urtica dioica, cimicifuga racemosa, and angelica sinensis. Additional ingredients include EOH/IPA and distilled water in a base of Evito‰ (proprietary formula consisting of oleic acid, linoleic acid, gamma linolenic acid, stearic acid, hexadecenoic acid, palmitic acid, icosenoic acid, docosenoic acid, tetracosenoic acid, eicosapentaenoic acid, docosahexaenoic acid, mryistic acid, lauric acid, caprylic acid, capric acid, and a, b, g, and d tocopherols).

ACTIONS AND PHARMACOLOGY (Function)

The component poly-peptide extracts were specifically selected because of their phytochemical characteristics which appear to exhibit both progestagenic and estrogenic properties and can occupy both estrogenic and progestagenic receptors. Although the exact mechanism of action of Pros-'aleiv® is not clearly understood, the following theories have been postulated and may explain many of the results clinically observed in patients.

Competitive inhibition:

As we age, hormonal levels begin to decline. In males, both testosterone (commonly recognized male hormone) and progesterone (a minor male hormone) begin to diminish. Additionally, as a result of chronic stress, estrogen levels begin to dramatically increase. Men with BPH have both elevated levels of testosterone and estrogen. Since the prostate has estrogen receptors, and estrogen is a stress response hormone (causing cellular increases in water and calcium influx), it is beneficial to inhibit or moderate estrogen receptors and carrier proteins.

Smooth muscle relaxant:

Several other problems must be considered as potentially obstructive and preventing bladder voiding. The constant BPH static pressure applied by the prostate capsule, the smooth muscle contraction around the upper urethra, and the muscle fibers swelling within the prostatic connective tissue can all contribute to the obstructive nature of BPH. Specific constituents of certain phytopharmaceuticals act as smooth muscle relaxants and can selectively relax the urethra, thereby reducing the dynamic obstruction and significantly reducing internal bladder pressure and the symptom of incomplete bladder emptying.

INDICATIONS AND USAGE

Pros-'aleiv® may be utilized in acute or chronic conditions of the prostate which effect urinary flow including acute urinary retention due to benign prostate hypertrophy (BPH) or mass affect from prostate carcinoma. It may also help alleviate the symptoms of incomplete bladder emptying and assist in reducing the incidence of nocturia. It has further been demonstrated to decrease PSA levels in BPH and patients with prostate cancer.

DOSAGE AND ADMINISTRATION

Pros-'aleiv® is administered daily to an area of the body consisting of minimal subcutaneous tissue and a capillary dense region with high vascular supply. Apply several drops and smooth into skin for absorption. Normal dosage is 12 – 15 drops applied 2 - 3 times per day. Each drop delivers the mil-equivalent of 63 milligrams of active components of the various highly active, herbal poly-peptide extracts. Pros-'aleiv® is for trans-dermal use only. Not for internal use.

CONTRAINDICATIONS

No known sensitivity to active or inactive ingredients.

DRUG INTERACTIONS

No drug interactions have been assessed.

OVERDOSAGE

Subjects have been administered doses of 10,000x with no adverse effects. No adverse effects from any of the constituent ingredients can be found in the medical literature.

Packaging: 1 oz bottle
Storage: 15-30 deg C (59-86 deg F)
Manufactured exclusively for Balance Dermaceuticals"
Made in U.S.A.

Further Information about Pros-'aleiv®

Pros-'aleiv® has been highly effective in alleviating the symptoms of BPH. It has been used in acute settings in a number of emergency rooms in North Carolina and has effectively prevented the use of Foley catherization in all cases where it was utilized. In acute cases, Pros-'aleiv® has induced spontaneous voiding within 25 minutes of application. Generally however, onset of action may range anywhere from 5 minutes to 40 minutes depending on dose used as well as level of urinary retention. Most patients use Pros-'aleiv® on a regular basis to maintain good urinary flow and preserve good prostate function.

Dosage of Pros-'aleiv® varies depending on the acuity of the clinical situation. For maintenance purposes, usually 5 drops of Pros-'aleiv® applied tid on EACH forearm is sufficient to maintain good urinary flow and alleviate the sensation of retention. This maintenance dose amounts to a total of 30 drops applied daily. Each bottle contains a 30 day supply based upon this maintenance dosage. For acute urinary retention, the dose is doubled to 10 gtts on EACH forearm and repeated every 15 minutes until voiding resumes. Generally speaking, most patients with acute symptoms experience improvement in symptoms within 30 to 45 minutes of initiating treatment with Pros-'aleiv®.

There are currently over 12 million males estimated to be suffering from BPH in the US alone. Pros-'aleiv® offers an efficacious, cost effective, natural option to help reduce the symptoms of urinary retention in patients suffering from BPH and Prostate Cancer. No laboratory workup is necessary although a baseline PSA level with repeat levels may be appropriate and provide objective methods of assessing efficacy.

REFERENCES

Cristoni A, Di Pierro F, Bombardelli E. Botanical derivatives for the prostate. *Fitoterapia*. 2000 Aug; 71 Suppl 1:S21-8. Scientific Department, Indena S.p.A., Viale Ortles 12, 20139, Milan, Italy.

Dvorkin L, Song KY. Herbs for benign prostatic hyperplasia. *Ann Pharmacother*. 2002 Sep; 36(9): 1443-52.

Wilt T, Ishani A, Mac Donald R. Serenoa repens for benign prostatic hyperplasia. *Cochrane Database Syst Rev*. 2002;(3): CD001423.

Zarkovic N, Vukovic T, Loncaric I, Miletic M, Zarkovic K, Borovic S, Cipak A, Sabolovic S, Konitzer M, Mang S. An overview on anticancer activities of the Viscum album extract Isorel. *Cancer Biother Radiopharm*. 2001 Feb; 16(1): 55-62.

FORMULA

www.balancederm.com NDC 65448-2165-1

Balance® DERMACEUTICALS PHYSICIAN'S FORMULA

Pros-áleiv®

Disp: 30 cc (900 gtts) - Use as directed

Use ONLY Under Medical Supervision

Ingredients:
An herbal poly-peptide extract including angelica sinensis, cacchaum officinerium, cimicifuga racemosa, discosrea villosa, humulus lupulus, medicao sativa, olea europaea, sedicago sativa, serenoa repens, similax officinalis, slavia officinalis, trifolium prantense, urtica dioica, viscum album, and vitex agnus, EOH/IPA, distilled water, in a base of EVITO™ (proprietary formula consisting of oleic acid, linoleic acid, gamma linolenic acid, stearic acid, hexadecenoic acid, palmitic acid, eicosenoic acid, docosenoic acid, tetracosenoic acid, eicosapentaenoic acid, docosahexaenoic acid, myristic acid, lauric acid, caprylic acid, capric acid & a, b, g & d tocopherols).

Manufactured Exclusively for
Balance Dermaceuticals®Ltd.
www.balancederm.com

Warnings:
Do not use if under the age of 18.
Keep out of reach of children.

FOR MEDICAL USE ONLY.

Indications:
For the temporary relief of urinary retention or difficulty in urination.

Directions:
Shake well before use. Keep out of extreme temperatures. Use as directed by your physician. Maintenance: apply 10 drops on forearms, 3 times a day. Acute retention: apply 20 drops & repeat every 30 minutes until unrestricted urination.

For external use only.

SAB Microbiological Laboratories
MANUFACTURED BY
V-SAB MEDICAL LABS INC.
CORNELIUS, NC 28031

% DV (Daily Value) Percentage of U.S. Recommended Daily Allowance (RDA) for adults and children four or more years of age.

REFERENCES

Pharmaceutical Grade
INGREDIENTS**

All ingredients in the Balance Dermaceuticals® therapeutic product line are of the highest possible quality available. All ingredients are pharmaceutical grade or higher, when applicable. Certain ingredients, herbs as an example, do not have a designation of pharmaceutical grade. However, of these ingredients that are included in the Balance Dermaceuticals® therapeutic product line, all are tested extensively and analyzed to ensure the highest possible quality, potency and purity. This ensures that you are provided with the most efficacious therapeutics and protocols available in the medical marketplace today.

All Balance Dermaceuticals® therapeutics are manufactured in FDA registered and inspected laboratories and adhere to GMP (Good Manufacturing Processes) standards. All protocols, products and therapeutics not only meet but consistently exceed USP standards. The manufacturing facilities take great measures to ensure unparalleled integrity of every product manufactured and Balance Dermaceuticals® prides itself on demanding superior quality throughout every step of the manufacturing process. Written standard operating procedures (SOP) prepared in accordance with GMP for nutritional supplement USP XXIV production are meticulously followed in order to adhere to strict in-process quality control standards.

Every raw material ingredient is inspected and undergoes stringent quality control measures prior to production. All raw products used are obtained from the most reliable and well-reputed sources. Processing and storage of raw materials as well as harvesting time and transportation methods have all been addressed. Extraction methodologies used are unique to each separate component and are based on maintaining stability of active constituents. As a result, cold process extraction methods are predominantly utilized when possible with chemical and heat extraction methods used only when absolutely necessary.

During initial stages of production, stringent testing and sampling is conducted before any further production cycles are allowed to continue. Accuracy is paramount and meticulous records are kept of each component and the quantity used in every batch of product. The testing laboratories supervised by PhD's, precisely monitor the production cycle of all products. The chemical analysis lab carefully ensures dissociation constants and disintegration factors as well as dissolution and pH testing. The microbiology lab conducts microbial testing on all applicable products to exceed the USP microbiological limit requirements for nutritional therapeutics.

The physical analysis lab checks the weight, hardness and thickness for consistency on all tablets, guaranteeing consistent integrity of each formulation. Potency is verified by high performance liquid chromatography or inductive coupled plasma atomic emission spectrometry, ensuring that the products will not contain less than 100% of the label claim. All finished products are tested for quality assurance purposes, using advanced technologies such as assay analysis and electrophoresis testing and have independent certificate of analysis.

The manufacturing facilities are maintained at constant temperature and humidity levels to ensure optimal freshness of all products produced. The Balance Dermaceuticals® products contain no yeast, wheat, gluten, soy protein, milk, corn, sodium, sugar, starch, artificial coloring, preservatives, or flavoring unless otherwise specifically noted.

Use ONLY Under Medical Supervision.
All ingredients are pharmaceutical grade or higher.** The quality and purity of each protocol is assured. Certificate of analysis is available upon request.

Manufactured in FDA inspected laboratories, using strict GMP Standards.
These statements have not been evaluated by the Food and Drug Administration.

This protocol is not intended to diagnose, treat, cure or prevent any disease.

Manufactured exclusively for Balance Dermaceuticals®

Revised 5/31/2002

Balance® DERMACEUTICALS PHYSICIAN'S FORMULA