Arth-aleiv®

NDC# 65448-2155-1

PROTOCOL No. 85

www.amtrx.com

DESCRIPTION

Arth-'aleiv® (NDC # 65448-2155-1) is a highly effective, prescription only, herbal derived, poly-peptide combination that temporarily but rapidly alleviates the symptoms of arthritic joint pain, pain from old fracture sites and at the site of prosthesis implants. Arth-'aleiv® may be utilized in acute or chronic conditions that cause any type of joint or bone pain. It has further been demonstrated to increase the range of motion and flexibility in various joints that have deteriorated due to chronic disease or chronic injury.

Arth-'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 arthritic joint pain, pain from old fracture sites and at the site of prosthesis implants.

The phytopharmaceutical constituents are Dioegenin, Beta-Sitosterol, Sterols, Navelbine, Lectins, IL-1, IL-ll, IL-lll, IL-6, Caffeic acid, Simmondsin, Vassopressin, 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, viscum album, similax officinalis, sedicago sativa, slavia officinalis, cacchaum officinerium, olea europaea, vitexagnus, cimicifuga racemosa, and angelica sinensis, 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, icosenoic acid, docosenoic acid, tetracosenoic acid, eicosapentaenoic acid, docosahexaenoic acid, mryistic acid, lauric acid, caprylic acid, capric acid, a, b, g, and d tocopherols, tocotrieols, and naturally occurring antioxidants and bioflavinoids).

The component extracts were selected because these phytochemicals exhibit numerous properties as Biological Response Modifiers. Each drop delivers the mil-equivalent of 63 milligrams of the active herbal poly-peptide extract.

FUNCTION

Biological Response Modifiers

Arthritic and many other inflammatory responses are caused by an over-response of the immune system.

Interlukins (cytokines) act as a type of biological response modifiers, which can improve the body's response to injury, infection and disease and stimulate the production of IL-1, 2, 3,and 6 and neuropeptide beta-endorphin.

By Competitive inhibition:

Estrogen is a stress hormone found in injured and/or inflamed tissues. Estrogen, by creating oxygen deficiency (hypoxia), stimulates first swelling and then collagen synthesis. Estrogen increase the blood flow to cells, but less than it increases cellular metabolic oxygen demand, as can be seen from the color change of estrogenized tissues. When the level of estrogen is high, metabolically demanding tissues, under conditions restrict blood flow and hypoxia become apoptotic. Estrogen acts through inflammatory mediators, mRMA, DNA, sphingosine, serotonin, and histamine to increase vascular permeability, with concurrent cellular influx of water and calcium. . Because estrogen is a stress response hormone (causing cellular increases in water and calcium retention (influx), it is beneficial to inhibit or moderate estrogen receptors and carrier proteins by binding to the carrier protein and/or a receptor.

DOSAGE AND ADMINISTRATION

Arth-aleiv¤ is administered as required in the area of pain and/or in the area of pain origin and area of sympathetic pain. Apply several drops and smooth into skin for absorption. Normal dosage is 4 - 8 drops applied 2-3 times per day. For external use only. Do not use internally.

CONTRAINDICATIONS

No known sensitivity to active or inactive ingredients.

DRUG INTERACTIONS

No drug interactions have been assessed.

WARNING

Do not use in pregnancy, while breast feeding or in children under the age of 12.

OVERDOSAGE

Subjects have been administered doses of 10,000x with no adverse effects.

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

FAQ'S ABOUT ARTH-'ALEIV®

How is Arth-'aleiv® applied and how do I determine if a patient will benefit from treatment using Arth-'aleiv® ?

Arth-'aleiv® is applied topically to the area over the joint involved, is stored easily, and efficacy is easily established for each individual patient. Simply place a liberal number of drops over the joint involved and wait for up to 5 minutes. If the patient responds to treatment, the patient is a candidate for ongoing treatments using Arth-'aleiv®. The transdermal delivery mechanism of Arth-'aleiv® allows for excellent patient compliance, is applied transdermally, and has no reported tolerability problems.

Does Arth-'aleiv® work for other types of pain besides joint pain?

Arth-'aleiv® appears to be most effective for the relief of pain from arthritis (degenerative joint diseases such as Osteoarthritis, and Rheumatoid Arthritis). But it has also been effective in helping to stop vascular and tension type headaches when applied topically to the occipital region of the calvarium (base of the skull). It has also frequently been shown to be effective in certain ligament and tendon injuries. However, the efficacy of Arth-'aleiv® in relieving the pain of the above mentioned conditions is far less reliable, ranging anywhere from 60% to 80% efficacious.

How does Arth-'aleiv® work?

The major active ingredient of Arth-'aleiv® appears to be a multiple complex of herbal polypeptide extracts which elicit a specific pharmacological reaction at the molecular level on the pain receptor sites. The actual development of Arth-'aleiv® however was purely accidental and as a result, the exact mechanism of action has not yet been elucidated.

How does Arth-'aleiv® cross the skin so quickly and effectively?

Arth-'aleiv® uses a transdermal delivery mechanism to conduct the herbal polypeptide complex across the dermis. Arth-'aleiv® is applied topically and is delivered in a special solublized proprietary carrier base (Evito™) which is responsible for this transdermal mechanism of delivery. This carrier base permits the almost immediate absorption of all the active constituents of Arth-'aleiv®, leading to the rapid biological availability of these polypeptide complexes which are presumed to cause a competitive inhibition resulting in the blocking of pain receptor sights and subsequently inhibit pain temporarily.

Does Arth-'aleiv® have any toxic effects?

Arth-'aleiv® is primarily composed of phyto-pharmaceutical (plant derived) polypeptides. The basic herbs in Arth-'aleiv® have been used medicinally for centuries without toxicity. In human exposure, subjects have been excessively dosed with the Arth-'aleiv® concentrated extract (which is marketed after being diluted by a factor of 10,000 to make the Arth-'aleiv®) without ANY adverse affects what so ever.

However, it's use in pregnancy has not been established so as with all herbal products, DO

REFERENCES

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E.G.Kocisi, et al., Carcinogensis 1994 Nov; 15(11): 2637-43.

Heiny BM, Albrecht V, Beuth J: *Anticancer Research* 18(1B): 583-586, 1998.

McCaig, et al., 1998, Yang et al., 1999.

NOT USE DURING PREGNANCY. Also, the use of Arth-'aleiv® has not been documented in anyone under the age of 12. Although no adverse affects have ever been reported, due to the potent nature of some of the herbal constituents of Arth-'aleiv®, DO NOT USE IN CHILDREN UNDER THE AGE OF 12.

What are the active ingredients of Arth-'aleiv®?

The active polypeptides isolated in Arth-'aleiv® have been determined to range from 9 to 46 sequences long. Of these, some components exhibited marginal activity while others exhibited exceptionally high activity. Specific ingredients were chosen for their individual active components, while others were chosen for their ability to mask the formula and inhibit duplication. Arth-'aleiv® contains the active polypeptides from the following natural substances:

DISCOSREA VILLOSA, SENEROR REISS, ALPINA OXYPHYLLA, VISCUM ALBUM, SIMPLAX OFFICINALIS, TRIFOLIUM PRATENSE, MEDICAO STIVEA, SALVIA OFFICINALIS, SACCHARUN OFFICINALIUM, DIMETHYLSULFOXIDE, ETOH as a PRESERVATIVE, in a base of EVITO™ (a blend of all natural ingredients combined into a 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, a,b, g & d Tocopherols, Tocotrieols, and naturally occurring antioxidants and bioflavinoids in an organic marine lipid concentrate.

Where can I obtain a bottle of Arth-'aleiv® & how long does a bottle last?

Depending on frequency of usage, one bottle of 30 cc of Arth-'aleiv® lasts anywhere from 3 weeks to 2 months. Arth-'aleiv® is only available by prescription through medical doctors (MD's or DO's) or through a pharmacy. Dentists and Podiatrists (DDS's and DPM's) may also obtain Arth-'aleiv® upon request.

If Arth-'aleiv® only provides relief that is temporary, why would I use it instead of my prescribed drugs?

1.) All the prescriptive oral drugs have negative side effects and contraindications. They are 2 major classes of drugs used for arthritis: NSAID's (non-steroidal, anti-inflammatory drugs) and Narcotics. Both MAY effect your stomach, kidney and liver. 2.) It takes anywhere from 30 minutes to 2 hours before the drugs start working and relieve any pain or discomfort. 3.) The drugs prescribed for joint pain do not cure arthritis and are only designed to provide temporary relief of pain.

There are no contraindications to Arth-'aleiv® as there are with NSAID's such as peptic ulcer disease or renal impairment. The potential for chronic dependence and addiction as well as hepatic dysfunction are not issues with Arth-'aleiv® as compared to the use of Narcotics for pain control.

In comparison, Arth-'aleiv® works almost immediately to relieve pain, with the onset of action being 5 minutes or less. Arth-'aleiv® has in fact, even been used in emergency room settings when IM injections of NSAID's and/or narcotics have not been effective. Lastly, continuous usage over time does not reduce the efficacy of Arth-'aleiv® and in actuality, seems to facilitate an improvement in the range of motion of the afflicted joints.

Arth-Phase™ is a 100% natural health product developed to provide the rapid relief of joint pain. In preliminary clinical studies, substantial results were achieved in relieving the symptoms of pain and discomfort in patients suffering from Rheumatoid Arthritis, Osteoarthritis, pain in old fracture sites, pain from past surgeries of joints including the back and hips, and a variety of other chronic and debilitating degenerative joint diseases.

In the preliminary clinical study, of the 720 patients who tried Arth-'aleiv®, 99.3% or 715 experienced pain relief within 1 to 7 minutes after application. The great majority of these

REFERENCES

patients ranked their pain relief as 50% or more improved within the first 7 minutes. The duration of pain relief appears to last anywhere between 2.5 and 5 hours. Doses may be repeated as often as desired. Arth-'aleiv® is applied topically to the area over the joint involved, is stored easily, and is 100% guaranteed to work. The trans-dermal delivery mechanism of Arth-'aleivv allows for excellent patient compliance. It is applied in drops, has a pleasant smell, and has no reported tolerability problems.

FURTHER INFORMATION OF INTEREST

Arth-'aleiv®, Abstract Title

The Role Of Specific Poly-Peptide Sequences On Pain Receptors As An Alternative To Traditional NSAID And / Or Narcotic Usage In Relieving Chronic Arthralgias Of Various Etiologies.

Background

Chronic joint pain due to degenerative joint diseases have made the use of OTC (over the counter) and prescription NSAIDs (non-steroidal, anti-inflammatory drugs) very prevalent in modern society. Unfortunately, the consequence of chronic NSAID usage has led to many complications including inhibition of prostaglandin synthesis leading to gastric ulcers as well as renal impairment and liver compromise. Narcotic analgesics that offer an alternative option to control pain have addictive properties and potential for abuse as well as hepatic implications. Unfortunately, both options offer only limited therapeutic benefits due to dose dependent restrictions, leaving most patients in some form of chronic pain and functional deficit.

Purpose

A prospective study assessing the efficacy of Arth-'aleiv® in temporarily relieving joint pain (arthralgias).

Method

Three clinical sites were utilized to initially access the efficacy of Arth-'aleiv® over a four month period. Log sheets were maintained to record patient trials consisting of the trans-dermal application of a unique complex of poly-peptide sequences known collectively as Art Arth-'aleiv®. A total of 917 patient trials were recorded. These trials simply consisted of local application of Arth-'aleiv® over the joint causing pain and recording specific information and answers to a few questions. Each patient was evaluated within the first 10 minutes after application. Each patient trial recorded had the following information: Name, age, social security numbers to authenticate the trial, area of pain (location of pain in their body), previous diagnosis of the etiology of pain, level of intensity of pain based on a scale of 1 to 10, joint where Arth-'aleiv® was applied, number of drops applied, number of minutes before pain relief experienced, and finally the extent of pain relief as graded on a scale of 1 to 10.

Results

In the preliminary clinical study, 197 patient trials of the 917 completed were eliminated from the final analysis due to establishment of pain resulting from muscular etiology. Of the 720 remaining patients who tried Arth-'aleiv® for joint related pain, 99.3% or 715 experienced pain relief within 1 to 7 minutes after application. The great majority of these patients ranked their pain relief as 50% or more improved within the first 7 minutes. The duration of pain relief appeared to last between 2 and 4 hours.

Conclusion

Arth-'aleiv® (NDC# 65448-2155-1) is a 100% natural medical product developed to provide the rapid relief of joint pain. In preliminary clinical studies, substantial results were achieved in relieving the symptoms of pain and discomfort in patients suffering from Rheumatoid Arthritis, Osteoarthritis, pain in old fracture sites, pain from past surgeries of joints including the back and hips, and a variety of other chronic and debilitating degenerative joint diseases.

REFERENCES

FORMULA

www.balancederm.com NDC 65448-2155-1

Balance® DERMACEUTICALS PHYSICIAN'S FORMULA

Arth-áleiv®

Disp: 30 cc (1200 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 pregnant, or under the age of 12. **Keep out of reach of children.**

FOR MEDICAL USE ONLY.

Indications:
For the temporary relief of joint discomfort (arthritis, degenerative joints, old fracture sites or any other pains related to bones).

Directions:
Shake well before use. Keep out of extreme temperatures. Use as directed by your physician or apply 5 to 20 drops on affected joint, depending on joint size. Repeat as frequently as needed.

For external use only.

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