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(54) Title: HERBAL COMPOSITION

(57) Abstract: The invention relates to herbal composition comprising extracts from Arnica, Comfrey, Witch Hazel, Calendula, Hypericum, and Lavender; formulations containing the herbal composition; and use of the herbal composition for treating a soft and/or hard tissue injury, and symptoms associated with the injury.

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HERBAL COMPOSITION

The invention relates to a herbal composition
for treating a soft and/or hard tissue injury such as
5 bruises.

BACKGROUND

10 Sporting and recreational activities are a major
part of people's lives. They promote fitness, fun and
socialisation. However, there is also a risk of injury
associated with many of these activities that results in
damage to soft and/or hard tissue. Such injuries can also
be sustained during activities of everyday life.

15

A bruise or "contusion" is a traumatic injury to
soft tissue underneath the skin resulting in breakage of
the local capillaries and leakage of red blood cells into
the soft tissue.

20

There are three major types of bruises:
subcutaneous, which is beneath the skin; intramuscular,
which is within the belly of the underlying muscle, and;
periosteal, which is bone bruise. Bruises can last from
25 days to months, with bone bruising being the most severe
and painful.

Apart from being painful, bruises are often
accompanied by discolouration of the skin and swelling.

30

Within hours a bruise will turn into a dark blue
or purple color. As the bruise begins to heal, it changes
colors. The color change is due to the biochemical
breakdown of hemoglobin that is found in the blood. As the
35 different components of the blood are broken down,
different colors will appear in the bruise.

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The swelling associated with a bruise is the result of an excessive build-up of fluid in the damaged soft tissue.

5 Muscle aches and pains are common and are most frequently related to tension, overuse, or muscle injury from exercise or physically demanding work. In these situations, the muscle pain tends to involve specific muscles and starts during or just after the activity.
10 Muscle pain can also involve the connective soft tissue that surrounds the muscle. Connective soft tissue includes ligaments, tendons, and fascia (thick bands of tendons).

15 A strain, which is also called a "pulled muscle", is caused when a muscle becomes overstretched and tears resulting in soft tissue damage. Excessive physical activity or effort, improper warming up before physical activity and poor flexibility can all cause this type of injury.

20 A sprain, which is an injury to the ligaments around a joint, occurs when a ligament is stretched too far or tears. When a ligament is damaged, there is pain and swelling around the joint.

25 Another form of injury often sustained by people during sporting, recreational and everyday life activities is hard tissue damage, such as a broken bone or fracture. It usually takes between two weeks and six months to heal
30 a broken bone or fracture, depending on the age and health of the person afflicted and the severity of the injury.

35 While there may be varying orthodox treatments available to treat a soft and/or hard tissue injury, there is a need to provide the public with a useful, alternative choice of treatment.

SUMMARY

According to a first aspect of the invention,
there is provided a herbal composition comprising extracts
5 from:

Arnica (*Arnica montana*);
Comfrey (*Symphytum spp*);
Witch Hazel (*Hamamelis virginiana*);
Calendula (*Calendula officinalis*);
10 Hypericum (*Hypericum perforatum*); and
Lavender (*Lavender angustifolia*).

The herbal composition may further comprise
extracts from one or more of Aloe (*Aloe sp*), Agrimony
15 (*Agrimonia eupatoria*), Nettles (*Urtica dioica*), Burdock
(*Arctium lappa*), Jamaican Dogwood (*Piscidia erythrina*),
Oats (*Avena sativa*), Licorice (*Glycyrrhiza glabra*),
Chamomile (*Matricaria recutita*), Albizzia (*Albizzia*
lebeck), Devil's Claw (*Harpagophytum procumbens*), Golden
20 seal (*Hydrastis canadensis*), Kava (*Piper mythisticum*),
Corydalis (*Corydalis ambigua*), Marshmallow (*Althea*
officinalis), Poke root (*Phytolacca decandra*), Plantain
spp (*Plantago major and minor*), Raspberry (*Rubus idaeus*),
Prickly ask (*Santhoxylum clava-herculis*), Yellow dock
25 (*Rumex crispus*), Rose (*Rosa spp*), Willow (*Salix spp*),
Shepherd's purse (*Capsella bursa-pastorus*), Horse chestnut
(*Aesculus hippocastanum*), Chickweed (*Stellaria media*),
Fumitory (*Fumaria officinalis*), Blue flag (*Iris*
versicolor), Cleavers (*Galium aparine*), Figwort
30 (*Scrophularia nodosa*), Thuja (*Thuja occidentalis*),
Sarsaparilla (*Smilax officinalis*), Sassafras (*Sassafras*
albidum), Red clover (*Trifolium pretense*), Yarrow
(*Achillea millefolium*), Self heal (*Prunella vulgaris*),
American cranesbill (*Geranium maculatum*), Elder (*Sambucus*
35 *nigra*), Horsetail (*Equisetum spp*), Slippery Elm (*Ulmus*
fulva), Hoheria (*Hoheria populnea*), Sage (*Salvia*
officinalis), Bearberry (*Arctostaphylos uva ursi*), Sweet

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violet (*Viola odorata*), Tormentil (*Potentilla tormentilla*), Ladies mantle (*Alchemilla mollis/vulgaris*), New Zealand Flax (*Phormium spp*), Flax (*Linum usitatissimum*), Woundwort (*Stachys palustris*), Hops
5 (*Humulus lupulus*), Pilewort (*Ranunculus ficaria*), Heartsease (*Viola tricolour*), Ginger (*Zingerber officinalis*), Oak (*Quercus spp*), Ground ivy (*Glechoma hederacea*), Rosemary (*Rosmarinus officinalis*), Crampbark (*Viburnum opulus*), Eyebright (*Euphrasia officinalis*),
10 Couchgrass (*Agropyron repens*), Corn silk (*Zea mays*), Thyme (*Thymus spp*), Meadowsweet (*Filipendula ulmaria*), Mullein (*Verbascum spp*), Wild yam (*Dioscorea villosa*), and California poppy (*Eschscholzia California*).

15 A second aspect of the invention provides a method of treating a soft and/or hard tissue injury or symptoms associated with the injury which comprises administering a therapeutically effective amount of the herbal composition as defined above to a subject in need
20 thereof.

 A third aspect of the invention provides use of the herbal composition as defined above for the manufacture of medicament for treating a soft and/or hard
25 tissue injury or symptoms associated with the injury.

 A fourth aspect of the invention provides use of the herbal composition as defined above for treating a soft and/or hard tissue injury or symptoms associated with
30 the injury.

 A fifth aspect of the invention provides the herbal composition as defined above for use in treating a soft and/or hard tissue injury or symptoms associated with
35 the injury.

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The herbal composition may conveniently be administered together with one or more carriers. Thus, a seventh aspect of the invention provides the herbal composition as defined above together with one or more carriers.

The herbal composition is suitably administered topically.

10 DETAILED DESCRIPTION

In the subject specification, except where the context requires otherwise due to express language or necessary implication, the words "comprise" or variations such as "comprises" or "comprising" are used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

20 It must be noted that, as used in the subject specification, the singular forms "a", "an" and "the" include plural aspects unless the context clearly dictates otherwise. Thus, for example, reference to "an extract" includes a single extract, as well as two or more extracts; and so forth.

The term "extract" as used herein should be taken in the broadest possible sense. "Extracts" may include tinctures, fluid extracts or solid extracts, tars, cold pressed oils, infused oils, infusions, decoctions, tars, essential oils, and mucilage, for example.

The herbal composition may include one or more different kinds of extracts. For example, extracts in the form of a tincture, an infused oil and an essential oil. Furthermore, the different herbs may be processed to form

extracts by different means. Similarly, the herbal composition may comprise a mixture of two or more types of extracts of a particular herb.

5 Tinctures may be formed from water-based infusions and decoctions. Alternative bases for the extract may include acettracts (to form a vinegar extract), glycetracts (to form a glycerine extract), mels (to form a honey extract), oxymels (honey and vinegar), or syrups (to
10 form a sugar extract).

 Tinctures are prepared by methods well known in the art. Briefly, however, a fresh plant tincture is made by first obtaining a herb dried by air as known in the
15 art. The dried herbs are then further dried in an oven at a temperature of between 60°C and 70°C. The oven dried herbs are then suspended in a solution in a storage container. In a preferred form, the solution is a mixture of alcohol and water. To make up a 1:5 tincture, 75 gms of
20 oven dried herb is suspended in 375 ml of the solution (weight of herb x 5 to get 1:5 ratio) in a storage container. The storage container is allowed to stand for about 6 weeks and is shaken periodically. The mixture is then filtered and the solution withdrawn provides the
25 tincture used.

 Other methods of extracting herbs are well known in the field. For example, cold percolation techniques may be used to prepare tinctures.

30 The tinctures may also be purchased from herbal suppliers such as MediHerb Pty Ltd, 124 McEvoy Street, Warwick, Queensland 4370, Australia in a ready-to-use formulation.

35 An infused oil may be made by infusing or macerating the herb in an oil. Infusing or macerating a

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herb in an oil solubilises the herb, making the resulting infused oil particularly suitable for topical application.

5 The oil used to prepare the infused oil may be a fixed or vegetable oil. A fixed oil is a non-volatile animal or plant based oil.

10 Examples of fixed, fruit and vegetable oils include almond oil (including sweet almond oil), coconut oil, corn oil, peanut oil, olive oil (including extra virgin olive oil), safflower oil, sesame oil, soybean oil, castor oil, wheat germ oil, jojoba oil and cod-liver oil.

15 Cold pressed oils are particularly preferred. Methods for preparing cold pressed oils are well known in the field. Generally, the process involves a simple crushing and filtering process.

20 Methods for preparing essential oils are well known in the field. Steam-distillation is an example of one method that is used. Generally, steam-distillation involves passing steam throughout a particular part of the herb plant, which evaporates its oils. The steam is then condensed and the oils separate from the water. This
25 method yields a high quality oil.

A tar is a very strong decoction, which is further reduced by evaporation.

30 Mucilage is a gelatinous substance, which is extracted from the herb plant, such as the root.

35 The extracts may be prepared from any part of the herb plant such as, for example, foliage, leaves, the root, flowers, bark, stems or rhizome, seeds, and fruit. However, particular parts of the herb plant are usually used to prepare the extracts.

An Arnica extract is usually made from the flowers. In a preferred embodiment of the invention, the Arnica extract is prepared as a tincture. The herbal
5 composition preferably comprises from about 1 ml to about 100 mls of Arnica extract, more preferably from about 50 mls to about 70 mls of Arnica extract, and most preferably about 60 mls of Arnica extract.

10 A Comfrey extract is usually made from the root. In a preferred embodiment of the invention, the Comfrey extract is prepared as a tincture. However, fresh mucilage extracted from the root may also be used. The herbal
15 composition preferably comprises from about 1 ml to about 100 mls of Comfrey extract, more preferably from about 50 mls to about 70 mls of Comfrey extract, and most preferably about 60 mls of Comfrey extract.

A Witch Hazel extract is usually made from the
20 leaves. In a preferred embodiment of the invention, the Witch Hazel extract is prepared as a tincture. However, the Witch Hazel extract may also be prepared as an infusion or decoction. The herbal composition preferably
25 comprises from about 1 ml to about 60 mls of Witch Hazel extract, more preferably from about 30 mls to about 50 mls of Witch Hazel extract, and most preferably about 40 mls of Witch Hazel extract.

A Calendula extract is usually made from the
30 flowers. In a preferred form of the invention, the Calendula extract is infused in an oil. However, the Calendula extract may also be prepared as a tincture. The herbal composition preferably comprises from about 1 ml to
35 about 60 mls of Calendula extract, more preferably from about 30 mls to about 50 mls of Calendula extract, and most preferably about 40 mls of Calendula extract.

A Hypericum extract is usually made from the flowers and aerial parts of the plant. In a preferred embodiment of the invention, the Hypericum extract is infused in an oil. However, the Hypericum extract may also be prepared as a tincture. The herbal composition preferably comprises from about 1 ml to about 60 mls of Hypericum extract, more preferably from about 30 mls to about 50 mls of Hypericum extract, and most preferably about 40 mls of Hypericum extract.

10

A Lavender extract is usually made from the flowers. In a preferred embodiment of the invention, the Lavender extract is prepared as an essential oil. However, the Lavender extract may also be prepared as a tincture. The herbal composition preferably comprises from about 1 ml to about 60 mls of Lavender extract, more preferably from about 30 mls to about 50 mls of Lavender extract, and most preferably about 40 mls of Lavender extract.

20

Table 1 illustrates a herbal composition of a preferred embodiment of the invention.

Table 1

Common Name	Approved Name	Herb Part	Preparation
Arnica	Arnica Montana	Flowers	Tincture
Comfrey	Symphytum spp	Root	Fresh mucilage
Witch Hazel	Hamamelis virginiana	Leaves	Tincture
Calendula	Calendula officinalis	Flowers	Infused oil
Hypericum	Hypericum perforatum	Flowers	Infused oil
Lavender	Lavender angustifolia	Flowers	Essential oil

25

In addition to the above-mentioned herb extracts, the herbal composition may further comprise one or more additional herb extracts, which may also assist in treating a soft and/or hard tissue injury or symptoms associated with the injury. Examples include herb extracts of one or more of Aloe (*Aloe sp*), Agrimony (*Agrimonia eupatoria*), Nettles (*Urtica dioica*), Burdock (*Arctium*

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lappa), Jamaican Dogwood (*Piscidia erythrina*), Oats (*Avena sativa*), Licorice (*Glycyrrhiza glabra*), Chamomile (*Matricaria recutita*), Albizzia (*Albizzia lebeck*), Devil's Claw (*Harpagophytum procumbens*), Golden seal (*Hydrastis canadensis*), Kava (*Piper myristicum*), Corydalis (*Corydalis ambigua*), Marshmallow (*Althea officinalis*), Poke root (*Phytolacca decandra*), Plantain spp (*Plantago major and minor*), Raspberry (*Rubus idaeus*), Prickly ask (*Santhoxylum clava-herculis*), Yellow dock (*Rumex crispus*), Rose (*Rosa spp*), Willow (*Salix spp*), Shepherd's purse (*Capsella bursa-pastorus*), Horse chestnut (*Aesculus hippocastanum*), Chickweed (*Stellaria media*), Fumitory (*Fumaria officinalis*), Blue flag (*Iris versicolor*), Cleavers (*Galium aparine*), Figwort (*Scrophularia nodosa*), Thuja (*Thuja occidentalis*), Sarsaparilla (*Smilax officinalis*), Sassafras (*Sassafras albidum*), Red clover (*Trifolium pretense*), Yarrow (*Achillea millefolium*), Self heal (*Prunella vulgaris*), American cranesbill (*Geranium maculatum*), Elder (*Sambucus nigra*), Horsetail (*Equisetum spp*), Slippery Elm (*Ulmus fulva*), Hoheria (*Hoheria populnea*), Sage (*Salvia officinalis*), Bearberry (*Arctostaphylos uva ursi*), Sweet violet (*Viola odorata*), Tormentil (*Potentilla tormentilla*), Ladies mantle (*Alchemilla mollis/vulgaris*), New Zealand Flax (*Phormium spp*), Flax (*Linum usitatissimum*), Woundwort (*Stachys palustris*), Hops (*Humulus lupulus*), Pilewort (*Ranunculus ficaria*), Heartsease (*Viola tricolour*), Ginger (*Zingerber officinalis*), Oak (*Quercus spp*), Ground ivy (*Glechoma hederacea*), Rosemary (*Rosmarinus officinalis*), Crampbark (*Viburnum opulus*), Eyebright (*Euphrasia officinalis*), Couchgrass (*Agropyron repens*), Corn silk (*Zea mays*), Thyme (*Thymus spp*), Meadowsweet (*Filipendula ulmaria*), Mullein (*Verbascum spp*), Wild yam (*Dioscorea villosa*), and California poppy (*Eschscholzia California*).

35

In a 500 ml cream base, the herbal composition may comprise from about 1 ml to about 100 mls, more

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preferably from about 20 mls to about 60 mls, and most preferably about 30 mls of each of the above-mentioned additional herb extracts.

5 The term "soft tissue" is used herein in the broadest sense and includes structural tissue, areolar tissue, adipose tissue, aponeurosis, ligaments, tendons, fascia, muscles, cartilage, and the like.

10 Bruises, contusions, haematomas, strains or pulled muscles, and sprains, are examples of "soft tissue injuries".

15 The term "hard tissue" is used herein to refer to bone.

 An example of a "hard tissue injury" is a fracture to a bone. There are several types of bone fractures, including the "greenstick" fracture, which is
20 an incomplete fracture in which the bone bends, the "transverse" fracture, which is a fracture that goes across the bone's axis causing it to break, and the "simple" fracture, which is fracture that breaks the bone but does not break the skin. Another type of fracture is
25 the "stress" fracture, which is a hairline crack in the bone that develops because of repeated or prolonged forces against the bone.

30 Typical symptoms associated with a soft or hard tissue injury include, but are not limited to, skin discoloration, swelling, aches and pain.

35 Not wishing to be bound by a particular theory or hypothesis the inventor believes that the surprising and unexpected effects seen with the herbal composition results from synergism between the individual components. As each of the above-mentioned additional herb extracts

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has its own individual therapeutic action, the synergy between the individual components in the herbal composition can be further enhanced by addition of one or more of these additional herb extracts in the herbal composition.

The term "subject" as used herein refers to any animal that sustains a soft and/or hard tissue injury and requires treatment with the herbal composition to treat the soft and/or hard tissue injury or symptoms associated with the injury. The subject may be an animal, such as a mammal, preferably a human, or may be a non-human primate or non-primates such as used in animal model testing. While it is particularly contemplated that the herbal composition is suitable for use in treatment of humans, it is also applicable to veterinary treatment, including treatment of companion animals such as dogs and cats, and domestic animals such as horses, ponies, donkeys, mules, llama, alpaca, pigs, cattle and sheep, or zoo animals such as primates, felids, canids, bovids, and ungulates.

Generally, the terms "treating", "treatment" and the like are used herein to mean affecting a subject, tissue or cell to obtain a desired pharmacological and/or physiological effect. The effect may be prophylactic in terms of completely or partially treating the soft and/or hard tissue injury or symptoms associated with the injury. "Treating" as used herein covers any treatment of a soft and/or hard tissue injury or symptoms associated with the injury suffered by an animal such as a mammal, more particularly a human, and includes treating the effects, i.e. cause regression, of a soft and/or hard tissue injury or alleviating, relieving or ameliorating the symptoms associated with the injury.

As used herein, the term "effective amount" means an amount of the herbal composition to treat a soft and/or

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hard tissue injury or symptoms associated with the injury in order to yield a desired therapeutic response.

The term "therapeutically effective amount" means
5 an amount of the herbal composition to yield a desired therapeutic response. For example, treating a soft and/or hard tissue injury or symptoms associated with the injury.

The herbal composition may conveniently be
10 administered together with one or more carriers. Carriers include substances that are useful in preparing a formulation comprising the herbal composition, may be in co-administration with the herbal composition while allowing the individual components to perform their
15 intended function, and are generally safe, non-toxic and are neither biologically or otherwise undesirable. In addition, carriers will include those suitable for veterinarian use as well as human use. Examples of carriers include dispersing agents, suspending agents,
20 emulsifying agents, stabilising agents, wetting agents, binding agents, lubricants, disintegrants, solvents, media, delay agents, fillers, aqueous and oily bases, non-
aqueous vehicles, and the like.

25 In addition, the herbal composition may contain preserving agents, colouring agents, fragrances, thickening and/or gelling agents, buffers and the like. Those skilled in the art will be able to identify further additives that may be desirable for cosmetic reasons, for
30 example.

As it will be appreciated by those skilled in the art to which the invention relates, the herbal composition may be converted into customary formulations. Examples of
35 formulations include, but are not limited to, solutions, emulsions, suspensions, powders, granules, natural and synthetic materials impregnated with the individual

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components of the herbal composition, pastes, ointments, creams, plasters, washes, lotions, transdermal patches, and sprays (atomiser, or aerosol). In a preferred form of the invention, the herbal composition is converted into a formulation suitable for topical administration.

The choice of carriers and/or additives may be dictated to some extent by the intended dosage form of the herbal composition and the mode of administration of the herbal composition.

Formulations comprising the herbal composition may be produced by a number of techniques standard in the art, for example, by mixing the herb extracts with one or more carriers and/or additives until all components are well blended. The formulations may be stored in suitable containers, receptacles, vessels and the like.

For topical administration to the skin, the herbal composition may be formulated as an ointment, cream, compress, poultice, moisturiser, plaster, wash, lotion, or as a transdermal patch. Ointments and creams may, for example, be formulated with an aqueous or oily base with the addition of suitable thickening and/or gelling agents. Examples of oily bases include, but are not limited to, a vitamin E cream or lotion, glucate cream, extra virgin olive oil, sweet almond oil, jojoba oil, apricot oil, peanut oil, fruit and vegetable oils, beeswax, lanolin and honey. Lotions and washes may be formulated with an aqueous or oily base, and will in general also contain one or more emulsifying agents, stabilising agents, dispersing agents, suspending agents, thickening agents, or colouring agents.

A topical formulation in the form of a cream may be prepared by adding about 60 mls of Arnica extract in the form of a tincture; about 60 mls of Comfrey extract in

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the form of fresh mucilage extracted from the root; about 40 mls of Witch Hazel extract in the form of a tincture; about 40 mls of Calendula extract in the form of an infused oil; about 40 mls of Hypericum extract in the form of an infused oil; and about 20 mls of Lavender extract in the form of an essential oil; to about 500 mls of a suitable cream base. These ingredients may be blended by mixing, agitation and/or heating, as known in the art. The cream based topical formulation may then be apportioned into suitable containers for use.

In use, the herbal composition would be administered to a subject as needed, as desired, or as advised by a medical practitioner, pharmacist, attendant physician, medical herbalist, naturopath, or veterinarian. The selection of additional herb extracts may also be made on the specific needs of the subject. The herbal composition is suitably applied directly to the affected area, but not to an affected area with broken skin.

As will be appreciated, the dose administered, the period of administration, and the general administration regime may differ between subjects depending on variables such as their tolerance to certain active ingredients, weight, metabolism, the mode of administration chosen, the severity of the symptoms, and the age and/or general health of the subject. In general, when the herbal composition is converted into a formulation suitable for topical administration, the general administration regime for topical treatment is application to the affected areas about 3 times daily.

Treatment is preferably commenced at the time the soft and/or hard tissue injury is sustained and preferably continues until the injury or symptoms associated with the injury are no longer present.

The invention will now be further elucidated by reference to the following non-limiting examples.

EXAMPLES

5

• Subject A

Personal details:

Female, aged 42.

10

Injury:

Impact injury to left knee resulting in the development of a large haematoma and swelling. The subject suffered pain in the affected leg when walking.

15

• Subject B

Personal details:

Female, aged 45.

20

Injury:

After suffering a fall onto a hard surface, the subject sustained a fracture to both coccyx and sacrum and considerable bruising to the lumber and buttock regions.

25

• Subject C

Personal details:

Male, aged 41.

30

Injury:

Repeated knee injuries from playing basketball over 25 years. Suffered constant swelling and pain during and after playing sporting activities.

35

• Subject D

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Personal details:

Male, aged 13.

Injury:

5 Sustained impact injury to right hand during a cricket game.

- Subject E

10 **Personal details:**

Woman, aged 40.

Injury:

15 After an extended exercise programme, the subject suffered swollen and aching feet, knees and hips.

Treatment

20 Each subject was treated with a herbal composition according to the invention.

The herbal composition was prepared as a topical formulation in the form of a cream by mixing the following ingredients:

25 about 60 mls of Arnica extract in the form of a tincture;

about 60 mls of Comfrey extract in the form of fresh mucilage;

30 about 40 mls of Witch Hazel extract in the form of a tincture;

about 40 mls of Calendula extract in the form of an infused oil;

about 40 mls of Hypericum extract in the form of an infused oil;

35 about 20 mls of Lavender extract in the form of an essential oil; and

about 500 mls of a gluconate cream base.

Results

Subject A applied the cream very soon after
5 sustaining the injury. The swelling caused by the injury
considerably reduced within one hour, and almost no pain
was felt after application of the cream. On the following
day, there was no swelling, no pain, and only a slight
yellow discoloration was visible. There was no sign of any
10 discoloration within 3 days. There have also been no
reported ongoing symptoms from the injury.

Subject B applied the cream to the injury. There
was a noticeable decrease in the swelling and little sign
15 of bruising. With rest and continued repeated applications
of the cream, the injury healed well. There have been no
reported complications resulting from the injury.

After regularly applying the cream for a period
20 of two weeks, Subject C was able to participate in
sporting activities without suffering swelling or pain
afterwards.

Subject D repeatedly applied the cream as
25 required resulting in a substantial improvement in 24
hours. All signs of the injury were gone within 60 hours.

Subject E liberally applied the cream to the
affected areas before bedtime. In the morning, there was
30 no sign of swelling or pain and the subject was able to
walk normally without restriction or pain.

Overall, the examples show that the use of a
herbal composition of the present invention worked well
35 and quickly to treat soft and hard tissue injuries and
symptoms associated with such injuries.

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Wherein the foregoing description reference has been made to specific component or integers of the invention which known equivalents then such equivalents are herein incorporated as if individually set forth.

5

Although this invention has been described by example and with reference to possible embodiment thereof, it is to be understood that modifications or improvements may be made thereto without departing from the scope of the invention.

10

CLAIMS:

1. A herbal composition comprising extracts from:
Arnica (*Arnica montana*);
5 Comfrey (*Symphytum spp*);
Witch Hazel (*Hamamelis virginiana*);
Calendula (*Calendula officinalis*);
Hypericum (*Hypericum perforatum*); and
Lavender (*Lavender angustifolia*).
- 10 2. A herbal composition according to claim 1,
wherein the herbal composition comprises from about 1 ml
to about 100 mls of Arnica extract.
- 15 3. A herbal composition according to claim 1 or
claim 2, wherein the herbal composition comprises from
about 1 ml to about 100 mls of Comfrey extract.
- 20 4. A herbal composition according to any one of the
preceding claims, wherein the herbal composition comprises
from about 1 ml to about 60 mls of Witch Hazel extract.
- 25 5. A herbal composition according to any one of the
preceding claims, wherein the herbal composition comprises
from about 1 ml to about 60 mls of Calendula extract.
- 30 6. A herbal composition according to any one of the
preceding claims, wherein the herbal composition comprises
from about 1 ml to about 60 mls of Hypericum extract.
- 35 7. A herbal composition according to any one of the
preceding claims, wherein the herbal composition comprises
from about 1 ml to about 60 mls of Lavender extract.
8. A herbal composition according to any one of the
preceding claims, wherein the herbal composition comprises
from about 50 mls to about 70 mls of Arnica extract.

9. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises from about 50 mls to about 70 mls of Comfrey extract.
- 5
10. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises from about 30 mls to about 50 mls of Witch Hazel extract.
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11. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises from about from about 30 mls to about 50 mls of Calendula extract.
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12. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises from about 30 mls to about 50 mls of Hypericum extract.
- 20
13. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises from about 30 mls to about 50 mls of Lavender extract.
- 25
14. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises about 60 mls of Arnica extract.
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15. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises about 60 mls of Comfrey extract.
- 35
16. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises about 40 mls of Witch Hazel extract.
17. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises about 40 mls of Calendula extract.

18. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises about 40 mls of Hypericum extract.

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19. A herbal composition according to any one of the preceding claims, wherein the herbal composition comprises about 40 mls of Lavender extract.

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20. A herbal composition according to any one of the preceding claims, wherein the herbal composition further comprises extracts from one or more of Aloe, Agrimony, Nettles, Burdock, Jamaican Dogwood, Oats, Licorice, Chamomile, Albizzia, Devil's Claw, Golden seal, Kava, Corydalis, Marshmallow, Poke root, Plantain spp, Raspberry, Prickly ask, Yellow dock, Rose, Willow, Shepherd's purse, Horse chestnut, Chickweed, Fumitory, Blue flag, Cleavers, Figwort, Thuja, Sarsaparilla, Sassafras, Red clover, Yarrow, Self heal, American cranesbill, Elder, Horsetail, Slippery Elm, Hoheria, Sage, Bearberry, Sweet violet, Tormentil, Ladies mantle, New Zealand Flax, Flax, Woundwort, Hops, Pilewort, Heartsease, Ginger, Oak, Ground ivy, Rosemary, Crampbark, Eyebright, Couchgrass, Corn silk, Thyme, Meadowsweet, Mullein, Wild yam, and California poppy.

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21. A herbal composition according to claim 20, wherein the herbal composition comprises from about 1 ml to about 100 mls of extracts from one or more of Aloe, Agrimony, Nettles, Burdock, Jamaican Dogwood, Oats, Licorice, Chamomile, Albizzia, Devil's Claw, Golden seal, Kava, Corydalis, Marshmallow, Poke root, Plantain spp, Raspberry, Prickly ask, Yellow dock, Rose, Willow, Shepherd's purse, Horse chestnut, Chickweed, Fumitory, Blue flag, Cleavers, Figwort, Thuja, Sarsaparilla, Sassafras, Red clover, Yarrow, Self heal, American cranesbill, Elder, Horsetail, Slippery Elm, Hoheria, Sage,

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Bearberry, Sweet violet, Tormentil, Ladies mantle, New Zealand Flax, Flax, Woundwort, Hops, Pilewort, Heartsease, Ginger, Oak, Ground ivy, Rosemary, Crampbark, Eyebright, Couchgrass, Corn silk, Thyme, Meadowsweet, Mullein, Wild yam, and California poppy.

22. A herbal composition according to claim 21, wherein the herbal composition comprises from about 20 mls to about 60 mls of extracts from one or more of Aloe, Agrimony, Nettles, Burdock, Jamaican Dogwood, Oats, Licorice, Chamomile, Albizzia, Devil's Claw, Golden seal, Kava, Corydalis, Marshmallow, Poke root, Plantain spp, Raspberry, Prickly ask, Yellow dock, Rose, Willow, Shepherd's purse, Horse chestnut, Chickweed, Fumitory, Blue flag, Cleavers, Figwort, Thuja, Sarsaparilla, Sassafras, Red clover, Yarrow, Self heal, American cranesbill, Elder, Horsetail, Slippery Elm, Hoheria, Sage, Bearberry, Sweet violet, Tormentil, Ladies mantle, New Zealand Flax, Flax, Woundwort, Hops, Pilewort, Heartsease, Ginger, Oak, Ground ivy, Rosemary, Crampbark, Eyebright, Couchgrass, Corn silk, Thyme, Meadowsweet, Mullein, Wild yam, and California poppy.

23. A herbal composition according to claim 22, wherein the herbal composition comprises about 30 mls of extracts from one or more of Aloe, Agrimony, Nettles, Burdock, Jamaican Dogwood, Oats, Licorice, Chamomile, Albizzia, Devil's Claw, Golden seal, Kava, Corydalis, Marshmallow, Poke root, Plantain spp, Raspberry, Prickly ask, Yellow dock, Rose, Willow, Shepherd's purse, Horse chestnut, Chickweed, Fumitory, Blue flag, Cleavers, Figwort, Thuja, Sarsaparilla, Sassafras, Red clover, Yarrow, Self heal, American cranesbill, Elder, Horsetail, Slippery Elm, Hoheria, Sage, Bearberry, Sweet violet, Tormentil, Ladies mantle, New Zealand Flax, Flax, Woundwort, Hops, Pilewort, Heartsease, Ginger, Oak, Ground ivy, Rosemary, Crampbark, Eyebright, Couchgrass, Corn

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silk, Thyme, Meadowsweet, Mullein, Wild yam, and California poppy.

24. A herbal composition according to any one of the preceding claims, wherein the extract is in the form of a tincture, an infused oil, an essential oil, or a mixture thereof.

25. A herbal composition according to claim 24, wherein the extract is in the form of a tincture.

26. A herbal composition according to claim 25, wherein the tincture is formed from water-based infusions and/or decoctions.

27. A herbal composition according to claim 24 or claim 25, wherein the base for the tincture is an acetate extract to form a vinegar extract, a glycerate extract to form a glycerine extract, a mel to form a honey extract, an oxymel to form a honey and vinegar extract, or a syrup to form a sugar extract.

28. A herbal formulation comprising a herbal composition according to any one of claims 1 to 27 together with one or more carriers.

29. A herbal formulation according to claim 28, wherein the herbal formulation is in the form of an oral formulation or a topical formulation.

30. A herbal formulation according to claim 29, wherein the herbal formulation is in the form of a topical formulation.

31. A herbal formulation according to claim 31, wherein the topical formulation is a cream.

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32. A method of treating a soft and/or hard tissue injury or symptoms associated with the injury which comprises administering a therapeutically effective amount of a herbal composition according to any one of claims 1 to 27, or a herbal formulation according to any one of claims 28 to 31, to a subject in need thereof.

33. A method according to claim 32, wherein the soft tissue injury is an injury of one or more soft tissues selected from structural tissue, areolar tissue, adipose tissue, aponeurosis, ligaments, tendons, fascia, muscles, and cartilage.

34. A method according to claim 32 or claim 33, wherein the soft tissue injury is one or more of a bruise, contusion, haematoma, strain or pulled muscle, and sprain.

35. A method according to claim 32, wherein the hard tissue injury is an injury to a bone.

36. A method according to claim 32 or claim 35, wherein the hard tissue injury is a fracture to a bone including a greenstick fracture, a transverse fracture, a simple fracture, a stress fracture.

37. A method according to claim 32, wherein symptoms associated with a soft or hard tissue injury includes skin discoloration, swelling, aches and pain.

38. A method according to any one of claims 32 to 37, wherein the subject is an animal, mammal or human.

39. A method according to any one of claims 32 to 38, wherein the herbal composition or herbal formulation is in the form of a topical formulation.

40. A method according to claim 39, wherein the

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topical formulation is applied to the soft and/or hard tissue injury at least once daily.

41. A method according to any one of claims 32 to 40,
5 wherein the treatment is commenced when the soft and/or hard tissue injury is sustained.

42. A method according to any one of claims 32 to 41,
10 wherein the treatment continues until the soft and/or hard tissue injury or symptoms associated with the injury are no longer present.

43. Use of the herbal composition according to any one of claims 1 to 27, or a herbal formulation according
15 to any one of claims 28 to 31, for the manufacture of medicament for treating a soft and/or hard tissue injury or symptoms associated with the injury.

44. Use of the herbal composition according to any one of claims 1 to 27, or a herbal formulation according
20 to any one of claims 28 to 31, for treating a soft and/or hard tissue injury or symptoms associated with the injury.

45. A herbal composition according to any one of
25 claims 1 to 27, or a herbal formulation according to any one of claims 28 to 31, for use in treating a soft and/or hard tissue injury or symptoms associated with the injury.