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(71) Applicant

**Rex Ellis Newnham,**

**P.O. Box 61, Thornbury**

**3071, Victoria, Australia**

(72) Inventor

**Rex Ellis Newnham**

(74) Agents

**Forrester Ketley and Co.,**

**Forrester House, 52**

**Bounds Green Road,**

**London N11 2EY**

(54) **Treatment of arthritis**

(57) A composition for treatment of arthritic conditions comprises from 2 to 500 parts by weight of a boron-containing compound, the dried herbs

Guaicum, Berberis and *Harpagophytum recumbens*, each in an amount up to an equivalent of 150 parts by weight of the dried herb, Rhustox or Byronia. Excipients and fillers may be included. The boron compound can be sodium tetraborate.

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## SPECIFICATION

**A composition for the treatment of arthritis**

The present invention relates to compositions for alleviating the discomforts of arthritis, including rheumatoid arthritis and osteoarthritis.

It is believed that the onset of arthritis is, at least in part, due to a mineral deficiency in boron and, to a lesser extent, in magnesium. Close analysis of the food intake of arthritis-sufferers suggests this to be the case, and treatment with a mixture of boron- and magnesium-containing compounds supports this finding. Such findings are described in my Australian Patent Specification No. 514,161.

This patent specification describes a composition comprising an inorganic boron-containing compound in combination with an inorganic magnesium-containing compound, useful for treating arthritic conditions when orally administered.

The present invention seeks to provide an improved composition.

According to the present invention, there is provided a composition for the treatment of arthritis comprising: from 2 to 500 parts by weight of at least one boron-containing compound; Guaiacum in an amount up to an equivalent of 150 parts by weight of the dried herb; Berberis in an amount up to an equivalent of 150 parts by weight of the dried herb; *Harpagophytum recumbens* in an amount up to an equivalent of 150 parts by weight of the dried herb; and an effective amount of Rhustox or Bryonia, or mixtures thereof.

Preferably, the balance of the composition consists of excipients and/or fillers.

Excipients are a combination of one or more ingredients used to bind the composition together, to enable rapid dissolution of the ingredients when ingested, and to lubricate the composition during the step of moulding the composition into a tablet or the like. The preferred ingredients are gum arabic (acting as a binder), starch (to enable rapid disintegration of the tablet after ingestion), and magnesium stearate (acting as a mould lubricant). The fillers which may be present may be functional, such as a magnesium compound, for example magnesium phosphate, magnesium oxide, magnesium carbonate and the like or inert, such as lactose, calcium carbonate or the like.

Mixtures of Rhustox and Bryonia are preferred, instead of only one of these substances, and they are present in small but effective amounts, preferably less than about 1 ppm each, based on the total weight of the composition as measured in milligram quantities.

Conveniently, the amount of excipient present ranges from 40 to 100 parts by weight, most preferably 55 to 65 parts by weight, and the amount of filler employed is an amount sufficient to provide a tablet of desired weight.

The pharmaceutical composition is normally provided in a dry form. The Guaiacum, Berberis and *Harpagophytum recumbens* may each be

provided as a fluid extract, the fluid carrier for the extract being evaporated from the solids to leave an equivalent amount of functional ingredient of the dried herb. Moist herbs may also be used but this adds to the cost of providing a dry composition.

Rhustox is a homeopathic substance which has been found to be effective for the relief of those arthritic attacks which occur after periods of rest. Bryonia is a homeopathic substance which has been found to be effective in relief of those arthritic attacks which occur after periods of activity. Both are added to the dry ingredients of the composition as a 6x solution and the solvent is evaporated, leaving the effective ingredients in a concentration up to about 1 ppm based on the total weight of the composition.

The following is an example of a presently preferred composition for tablets weighing about 500 mg:

85	Sodium tetraborate	24 mg
	Guaiacum	25 mg
	Berberis	25 mg
	<i>Harpagophytum recumbens</i>	25 mg
	Excipient	60 mg
90	Filler	Balance to make 500 mg
	Rhustox	<1 ppm
	Bryonia	<1 ppm

The solids are impregnated with a 6x solution of Rhustox and a 6x solution of Bryonia, evaporated and dried. The composition, normally in tablet form, is administered orally, typically to provide a dosage of from 50 to 100 mg of the boron-containing compound. Daily dosages may range from as little as 25 mg to 3,000 mg of the boron-containing compound, preferably in the range of from 50 to 100 mg.

When administered to animals, sheep and goats would normally receive the same dosage as humans. Cattle, on the other hand, would receive dosages of 25 mg of the boron-containing compound per 60 kg of body weight. With cattle, the solids are normally mixed with a chaff or other feed.

## CLAIMS

1. A composition for the treatment of arthritis comprising: from 2 to 500 parts by weight of at least one boron-containing compound; Guaiacum in an amount up to an equivalent of 150 parts by weight of the dried herb; Berberis in an amount up to an equivalent of 150 parts by weight of the dried herb; *Harpagophytum recumbens* in an amount up to an equivalent of 150 parts by weight of the dried herb; and an effective amount of Rhustox or Bryonia, or mixtures thereof.

2. A composition according to claim 1 in which there is provided an excipient including a first ingredient for binding the composition into a tablet, a second ingredient for disintegrating the tablet on ingestion, and a third ingredient for lubricating the composition for pressing into a tablet.
3. A composition according to claim 2 in which the first ingredient is gum arabic.
4. A composition according to claim 2 or 3 wherein the second ingredient is starch.
5. A composite according to any one of claims 2 to 4 wherein the third ingredient is magnesium stearate.
6. A composition according to any one of claims 2 to 5 in which the excipient is present in an amount of from 40 to 100 parts by weight.
7. A composition according to claim 6 in which the composition contains 55 to 65 parts by weight of excipient.
8. A composition according to any one of the preceding claims which includes a filler.
9. A composition according to any one of the preceding claims in which the boron-containing compound is sodium tetraborate decahydrate.
10. A composition according to claim 9 comprising substantially 5% sodium tetraborate decahydrate.
11. A composition according to any one of the preceding claims comprising substantially 5% of the dried herb *Guaiaecum*.
12. A composition according to any one of the preceding claims comprising substantially 5% of the dried herb *Berberis*.
13. A combination according to any one of the preceding claims comprising substantially 5% of the dried herb *Harpagophytum recumbens*.
14. A combination according to any one of the preceding claims comprising 8% to 20% of an excipient comprising gum arabic, starch and magnesium stearate.
15. A tablet according to claim 14 in which the excipient is present in an amount of from 11% to 13%.
16. A composition according to any one of the preceding claims in which Rhustox and Bryonia are each present in an amount of up to 1 ppm based on the total weight of the composition.
17. A tablet comprising a composition according to any one of the preceding claims.
18. A tablet according to claim 17 comprising a filler in such an amount as to provide a tablet of substantially 500 milligrams.
19. A process for forming a pharmaceutical composition, the process comprising:
- blending solids comprising from 2 to 500 parts by weight of at least one boron-containing compound; the equivalent of from 1 to 150 parts by weight of the dried herb *Guaiaecum*; the equivalent of from 1 to 150 parts by weight of the dried herb *Berberis*; the equivalent of from 1 to 150 parts by weight of the dried herb *Harpagophytum recumbens*; and from 40 to 100 parts by weight of an excipient comprising gum arabic, starch and magnesium carbonate; and
  - impregnating the solids with a 6x solvent solution of Rhustox and a 6x solvent solution of Bryonia, in a quantity sufficient to provide up to 1 ppm per weight each of Rhustox and Bryonia, based on the total weight of the composition, upon evaluation of the solvent for Rhustox and the solvent for Bryonia.
20. A process according to claim 18 in which the or a said boron-containing compound is sodium tetraborate decahydrate.
21. A composition substantially as described herein.
22. A tablet substantially as described herein with reference to the Example.
23. Any novel feature or combination of features described herein.