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(54) Titre : FORMULATION ANTI-SEBORRHEIQUE
(54) Title: ANTI-SEBORRHOEIC FORMULATION

(57) **Abrégé/Abstract:**

An anti-seborrhoeic composition having either or both of a broad spectrum anti-fungal drug and/or a topical antiseptic. The composition can be formulated as a shampoo with a keratolytic or keratoplastic compound. The composition is preferably formulated as a shampoo with miconazole, chlorhexidine and it might include selenium sulphide.





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(21) International Application Number: PCT/AU92/00543 (22) International Filing Date: 12 October 1992 (12.10.92) (30) Priority data: PK 8926 15 October 1991 (15.10.91) AU (71)(72) Applicant and Inventor: MASON, Kenneth, Vincent [AU/AU]; 22 Kana Crescent, Slacks Creek, QLD 4127 (AU). (74) Agent: GRANT ADAMS & COMPANY; G.P.O. Box 1413, 144 Edward Street, Brisbane, QLD 4000 (AU). (81) Designated States: AU, CA, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE).		2121123 Published <i>With international search report.</i>
(54) Title: ANTI-SEBORRHOEIC FORMULATION (57) Abstract An anti-seborrhoeic composition having either or both of a broad spectrum anti-fungal drug and/or a topical antiseptic. The composition can be formulated as a shampoo with a keratolytic or keratoplastic compound. The composition is preferably formulated as a shampoo with miconazole, chlorhexidine and it might include selenium sulphide.		

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Title: "ANTI-SEBORRHOEIC FORMULATION"

FIELD OF THE INVENTION

THIS INVENTION relates to a composition suited to use as an anti-seborrhoeic formulation which can be
5 for the treatment of the clinical disease seborrhoeic dermatitis in animals such as dogs.

BACKGROUND OF THE INVENTION

Seborrhoea is a chronic skin disease that is considered to be a defect in keratinization with
10 increased scale formulation. Dandruff is a mild form. Seborrhoea is divided into three clinical forms. Seborrhoea sicca which is characterised by dry scaling of the skin. Seborrhoea oleosa is characterised by local to diffuse scaling associated with excessive
15 sebum. Seborrhoeic dermatitis is characterised by scaling and greasiness with gross evidence of local or diffuse inflammation. There are breed predilections for Cocker Spaniels, Springer Spaniels, Basset Hounds and, in particular, the most difficult form occurs in West
20 Highland White Terriers. It is considered to be a primary keratinization defect of genetic origin. Although some causes are known, these if found are designated secondary seborrhoeas. Primary idiopathic seborrhoeic dermatitis is currently considered to be a
25 chronic disease that can be ameliorated but not cured.

Standard ameliorating treatments are usually shampoos containing salicylic acid, sulphur, selenium sulphide, tars and antiseptics. These give only very temporary relief from symptoms, usually for a few days
30 at the most.

Human seborrhoeic dermatitis has recently been associated with the yeast Malassezia (Pityrosporum) ovale. Malassezia pachydermatis has been reported to be associated with a dermatitis in dogs. However, dogs
35 with the classic seborrhoeic dermatitis in West Highland

Whites have been treated with ketoconazole tablets orally without producing a reliable cure. Symptoms re-occurred or worsened while on a treatment.

OBJECT OF THE INVENTION

5 It is an object of the invention to provide an anti-seborrhoeic formulation which is effective against seborrhoeic dermatitis achieving a therapeutic response not known before from standard treatment.

NATURE OF THE INVENTION

10 The invention achieves its object in provision of a composition for treatment of seborrhoeic skin disease comprising a broad spectrum anti-fungal drug and/or a topical antiseptic.

Preferably the composition is formulated for
15 topical application and it may include a keratolytic/keratoplastic compound.

Preferably the broad spectrum anti-fungal drug is one of the imidazole/triazole group, for example miconazole.

20 Preferably the topical antiseptic is a phenol-biguanide type such as chlorhexidine, or tricolsan.

Preferably the keratolytic/keratoplastic compound is selenium sulphide.

Preferably the composition is provided in a
25 shampoo base which might be any standard shampoo base and, in particular, a typical anti-dandruff shampoo base is used.

The invention is directed to an anti-seborrhoeic composition for use in the treatment of dogs,
30 said composition comprising: (a) a broad-spectrum antifungal drug selected from imidazoles and triazoles, and (b) a topical antiseptic selected from chlorhexidine and triclosan.

The broad-spectrum anti-fungal drug can be one
35 of ketoconazole, miconazole, econazole or enilconazole. The topical antiseptic can be chlorhexidine and the broad-spectrum anti-fungal drug can be miconazole.

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The invention is also directed to the use of a composition comprising an anti-fungal drug and a topical antiseptic in the manufacture of a medicament for the treatment of seborrhoeic skin conditions in dogs.

5 The invention also pertains to the use of a composition comprising 1% selenium sulphide and 1% chlorhexidine in a shampoo base in the manufacture of a medicament for the treatment of seborrhoeic skin conditions in dogs.

10 BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described with reference to the graph of FIG. 1 which illustrates the results of a trial of a particular composition in accordance with the invention.

15 PREFERRED EMBODIMENTS

In tests of a composition in accordance with the invention, 41 dogs were diagnosed with seborrhoeic

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dermatitis. These 41 dogs contained a disproportional high number of West Highland White dogs as compared with the normal dog population. This is to be expected given the breed predisposition to this disease. A double
5 blind randomised clinical trial was designed around two shampoo treatments. Cross over from one treatment group to the other was allowed if the first treatment failed.

The dogs were treated with either an industry standard 1% selenium sulphide shampoo (Selsun Blue or
10 Seleen) originating from Abbots Laboratories or the following composition in accordance with the invention; a shampoo containing 0.25% selenium sulphide, 2.0% chlorhexidine and 2.0% miconazole. All ingredients are measured by weight. The response was then measured on
15 an objective scale by looking for improvement in the clinical symptoms at two and four weeks.

FIG. 1 depicts graphically the results of the trial which indicates that the shampoo combination according to the invention, the graph labeled I, had
20 results far superior to the standard treatment with a 1% selenium sulphide shampoo indicated by the graph labelled II.

Imidazole and Triazole drugs are known potent
fungicide chemicals used in medicine and in agriculture.
25 Examples are ketoconazole, miconazole, econazole and enilconazole.

One of the most potent systemic imidazole is ketoconazole. By itself, as a tablet, it has failed to provide a reliable cure in tests on seborrhoeic West
30 Highland White dogs. Partial response in some dogs was followed by recrudescence of the seborrhoea while still on treatment.

Chlorhexidine is a phenol-related biguanide antiseptic, it is a broad spectrum anti-microbial. It
35 has been used as a topical wash, rinse and in a shampoo

in veterinary and human medicine for over 30 years. Despite being widely used, it has not gained a reputation for value in seborrhoeic dermatitis.

5 Selenium sulphide in a shampoo base is widely used as an anti-seborrhoeic and anti-dandruff in man and dogs. However, it gives only temporary relief. It has keratoplastic and keratolytic properties. It thus works by suppressing and breaking up scale.

10 Various combinations of the above active ingredients have been tried in a shampoo base on dogs with seborrhoeic dermatitis. It has been found that combinations of 1.0% selenium sulphide and 1.0% chlorhexidine; 1.0% selenium sulphide, 1% chlorhexidine and 1.0% miconazole; and 0.25% selenium sulphide, with
15 2% chlorhexidine and 2.0% miconazole were all much more effective than the standard 1.0% selenium sulphide alone. A 2% shampoo with imidazoles such as ketoconazole, miconazole, econazole and enilconazole
20 have been achieved with the composition described above with reference to FIG. 1.

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WHAT IS CLAIMED IS:

1. An anti-seborrhoeic composition for use in the treatment of dogs,
said composition comprising:
 - 5 (a) a broad-spectrum antifungal drug selected from imidazoles and triazoles, and
 - (b) a topical antiseptic selected from chlorhexidine and triclosan.
2. An anti-seborrhoeic composition as claimed in claim 1 wherein the
10 broad-spectrum anti-fungal drug is one of ketoconazole, miconazole, econazole or enilconazole.
3. An anti-seborrhoeic composition as claimed in claim 2 wherein the
15 topical antiseptic is chlorhexidine and the broad-spectrum anti-fungal drug is miconazole.
4. An anti-seborrhoeic composition as claimed in claim 3 comprising by
weight 2.0% miconazole and 2.0% chlorhexidine.
- 20 5. An anti-seborrhoeic composition as claimed in any of claims 1 to 4 wherein the composition is formulated as a shampoo.
6. An anti-seborrhoeic composition as claimed in claim 5 which
contains a keratolytic or keratoplastic compound.
25
7. An anti-seborrhoeic composition as claimed in claim 6 characterised
in that the keratolytic or keratoplastic compound is selenium sulphide.
8. An anti-seborrhoeic composition as claimed in claim 7 comprising by
30 weight 0.25% selenium sulphide, 2.0% chlorhexidine and 2.0% miconazole.
9. An anti-seborrhoeic composition as claimed in claim 7 comprising by
weight 1% selenium sulphide, 1% chlorhexidine and 1% miconazole.

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10. The use of a composition comprising an anti-fungal drug and a topical antiseptic in the manufacture of a medicament for the treatment of seborrhoeic skin conditions in dogs.

5 11. The use as claimed in claim 10 wherein the topical antiseptic is a phenol-biguanide type and the anti-fungal drug is one of the imidazole/triazole group.

10 12. The use as claimed in claim 11 wherein the topical antiseptic is chlorhexidine and the anti-fungal drug is miconazole.

13. The use as claimed in claim 10 wherein the composition is a composition as claimed in any of claims 1 to 9.

15 14. The use of a composition comprising 1% selenium sulphide and 1% chlorhexidine in a shampoo base in the manufacture of a medicament for the treatment of seborrhoeic skin conditions in dogs.

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FIG 1

