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(54) Title: A FORMULATION, E.G. FOR USE IN THE TREATMENT OF FLU AND COLDS

(57) Abstract: A formulation comprising a therapeutic and synergistic combination of Echinacea and Vitamin D (preferably Vitamin D3), preferably further comprising any one or more of selenium, Vitamin C and a multivitamin formulation, preferably for use as a medicament, preferably formed as a nasal preparation, preferably for use in the treatment of flu, colds, mild chest infections and/or mild lung infections, preferably for use in a dual therapy treatment, preferably for use in a dosage regime in which it is taken twice daily.



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TITLE

A FORMULATION, E.G. FOR USE IN THE TREATMENT OF FLU AND COLDS

FIELD OF THE INVENTION

This invention relates to a formulation, e.g. for use in the treatment of flu and colds.

BACKGROUND

Flu is a prevalent illness, very common in Winter seasons but also at other times of the year. No treatments are considered to be very effective and antibiotics have no effect against viruses, although they may prevent and treat secondary bacterial infections. During global pandemics, hundreds of thousands, if not many millions of patients, may suffer fatal consequences. During normal flu outbreaks, the cost to economies is considerable in terms of lost production and heavy demands on hospitals.

Echinacea has been considered by some, especially herbalists, to be a remedy for infections; however, results are often conflicting and can be unconvincing.

THE INVENTION

One aspect of the invention provides a formulation as claimed in claim 1.

Another aspect of the invention provides a formulation as claimed in claim 2.

Other aspects/examples of the invention provide, respectively:

- 1. A formulation comprising Echinacea and Vitamin D for use in the treatment of flu, colds and mild chest and lung infections.
- 2. A formulation comprising Echinacea and Vitamin D3 for use in the treatment of flu, colds and mild chest and lung infections.
- 3. A formulation comprising Echinacea, selenium and Vitamin D for use in the treatment of flu, colds and mild chest and lung infections.
- 4. A formulation comprising Echinacea, selenium and Vitamin D3 for use in the treatment of flu, colds and mild chest and lung infections.

- 5. A formulation comprising Echinacea, selenium and Vitamin D and Vitamin C for use in the treatment of flu, colds and mild chest and lung infections.
- 6. A formulation comprising Echinacea, selenium and Vitamin D3 and Vitamin C for use in the treatment of flu, colds and mild chest and lung infections.
- 5 • 7. A formulation comprising Echinacea, selenium and Vitamin D3, Vitamin C and a multivitamin formulation for use in the treatment of flu, colds and mild chest and lung infections.

Embodiments of the invention may have any one or more of the following features:

- in which the Vitamin D comprises Vitamin D3.
- comprising selenium.
- 10 • comprising Vitamin C.
- for use as a medicament.
- formed as a nasal preparation.
- for use in the treatment of flu, colds, mild chest infections and/or mild lung infections.
- for use in a dual therapy treatment.
- 15 • for use in a dosage regime in which it is taken twice daily.
- comprising a multivitamin formulation.
- for use in a dosage regime in which the formulation and a multivitamin supplement are taken twice daily.
- in a presentation adapted for use in a dual therapy treatment comprising a multivitamin
20 formulation.

Embodiments of the invention provide a formulation for use in the treatment of flu, colds, mild chest and lung infections, that may also assist in reducing bacterial antibiotic resistance development, and economic burdens of flu.

25 Examples of the inventive formulation have proved effective to the inventor on numerous occasions in self experimentation where flu symptoms were progressing with mild aches and pains, mild fevers and

fatigue. Early treatment, in particular, terminated progression of the illness with rapid recovery, but therapeutic effects have also been seen in more advanced stages; however, in cases of pneumonia and worsening or severe asthma, patients should consult medical advice with some urgency.

The following is given by way of a preferred example, but formulations with substantial variations in the
5 ranges of ratios of each of the ingredients (with any ingredient varied respectively in the range from 4 times to a quarter of, but better if in the range from twice to half of, the values given in the following example) were tried successfully, and found to have a synergistic and therapeutic action.

The formulation of Echinacea purpurea (800 mg), Vitamin D3 (25 micro grammes), Vitamin C (500mg) and selenium (100mg) and if desired, a multi vitamin supplement (international standard daily dose
10 formulation) was taken twice daily - at morning and evening with effective results often within one or two days. The dosing should continue for a minimum of 5 days or a maximum of 2 weeks. Should symptoms persist or if worsening symptoms occur, medical advice should be sought if considered necessary, especially if symptoms of pneumonia or asthma in asthmatics worsen. No side effects have been observed by the inventor.

15 The following appear to the inventor to be the actions concerned. Echinacea and vitamin D3 seem to have a synergistic effect against flu. Lack of sunlight during winter may contribute to vitamin D3 deficiency and a resulting immune weakness. When selenium is added, this has a substantial further synergistic effect. It seems to act to prevent flu viral mutations within the body that can result in new strains evolving, constantly evading the immune response. Vitamin C was observed to add a further
20 synergistic effect. It also seemed to be particularly therapeutic in helping to prevent lung and chest infections developing as a secondary infection to the flu infection.

With many antibiotics losing effectiveness as resistant bacterial strains develop, the inventive formulations may provide a first line therapy prior to antibiotic use should this become necessary. In this way, the development of resistance could be combated.

25 A nasal preparation of this formulation can be used for colds where substantial mucous and debris in the nasal passages may prevent the usual medicinal compounds from penetrating effectively. A nasal cold formulation is of benefit for a dual therapy approach.

As would be standard practice, a complete list of contra-indications and possible side-effects to any of these ingredients should be sought by any patient or manufacturer and all recommendations on use

adhered to. All individual ingredients have been in widespread use and studies are prevalent on their individual effects should further information be sought. Medical advice and supervision should be sought as considered necessary. The inventor derives his findings from improvements observed from experimentation on self and friends over three or more years for each person with little if any side effects observed; (however, the inventor accepts no responsibility or liability whatsoever for any side effects or adverse effects that may occur;) as indicated in more detail, as follows.

As noted above, there is a synergistic effect between the Vitamin D and any one or more of the other claimed ingredients. Whereas Vitamin D on its own gives a slight therapy for various medical conditions, and this is not as great as, for example, Vitamin C, the present inventor on the basis of personal research and experience worked out that the use of Vitamin D in conjunction with the other claimed ingredient/s should have a synergistic effect, and when testing this found the effect was in fact much greater than he had thought likely. There are many substances which could have been used with the other claimed ingredients, and all are related to ameliorating various medical conditions, or simply improving general healthiness, so that it is not obvious to try any particular one of them. Indeed, over a long period, i.e. from at least 20 years ago, the other ingredients have been known and yet nobody has thought to combine them with Vitamin D, and made public mention of this. Further, it is known to the inventor that Vitamin D has been tried as one of a large number of trace organic substances used in the diet to improve health generally, as part of a dietary supplement, but not in any way for use in treatment of any illness, and moreover not one that is specifically used and synergistically or even therapeutically effective in conjunction with any of the other ingredients in such a supplement, which must therefore be considered as contributing each in its own individual way to general healthiness. Consequently, the effectiveness of using Vitamin D in a synergistic and therapeutic quantity came as quite a surprise, far exceeding the inventor's expectations, and even more so for the particular named maladies, which seem to have closely related characteristics. This is exemplified in the following table, extracted from the inventor's records of experiments:

TABLE

Tried out on self and friends, over a period of 10 years, overlapping periods:

	<u>Series</u>	<u>Echinacea</u>	<u>Vitamin D</u>	<u>Selenium</u>	<u>Vitamin C</u>	<u>Multivitamins</u>	<u>No. of illnesses</u>	<u>Spread of years</u>
							4	10
5	A	X					8	5
	B		X				6	4
	C			X			4	3
	D				X		4	3
	E					X	3	3
10	F	X	X				5	4
	G	X	X	X			4	4
	H	X	X	X	X		3	3
	I	X	X	X	X	X	4	3

NOTES

15 Series Course of illness, once ill; normally about 2 weeks to recover

FV (Flu vaccine) (Prevents or reduces on some occasions, if taken before ill, but does not affect recovery time)

A Recovery slow, variable and uncertain; but variably somewhat better than with no medication

B Illness symptoms no change; no noticeable reduction in recovery time

20 C Illness symptoms no change; no noticeable reduction in recovery time

D Slightly improved general health; illness symptoms slightly reduced; minor reduction in recovery time

E Slightly improved general health; illness symptoms slightly reduced; minor reduction in recovery time

25 F Substantially and consistently improved recovery time, order of 1 week; mildly reduces symptoms

G Substantially and consistently improved recovery time (about 3 days), even compared with F; moderately reduces symptoms

30 H Decidedly and consistently improved recovery time (around 2 days); even better on symptoms; compared with G

I Noticeably and consistently improved recovery time (1 or 2 days); somewhat better on symptoms; compared with H

CLAIMS

1. A formulation comprising a therapeutic combination of Echinacea and Vitamin D.
2. A formulation comprising a therapeutic and synergistic combination of Echinacea and Vitamin D.
3. A formulation as claimed in claim 1 or 2, in which the Vitamin D comprises Vitamin D3.
- 5 4. A formulation as claimed in any preceding claim, comprising selenium.
5. A formulation as claimed in any preceding claim, comprising Vitamin C.
6. A formulation as claimed in any preceding claim, for use as a medicament.
7. A formulation as claimed in any preceding claim, formed as a nasal preparation.
8. A formulation as claimed in any preceding claim, for use in the treatment of flu, colds, mild chest
10 infections and/or mild lung infections.
9. A formulation as claimed in any preceding claim, for use in a dual therapy treatment.
10. A formulation as claimed in any preceding claim, for use in a dosage regime in which it is taken twice daily.
11. A formulation as claimed in any preceding claim, comprising a multivitamin formulation.
- 15 12. A formulation as claimed in any one claims 1 to 10, for use in a dosage regime in which the formulation and a multivitamin supplement are taken twice daily.
13. A formulation as claimed in any preceding claim, in a presentation adapted for use in a dual therapy treatment.
14. A formulation as claimed in claim 1 and substantially according to any example hereinbefore
20 described.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2014/058681

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According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61K A61P		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data, BIOSIS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Jamieson Natural Sources: "ZINC LOZENGES WITH ECHINACEA, VITAMINS C & D HONEY LEMON", 24 August 2012 (2012-08-24), XP002722102, Retrieved from the Internet: URL: http://www.jamiesonvitamins.com/files/2655%20-%20Zinc%20Lozenges%20with%20Vitamin%20C%20&%20D,%20Echinacea%20-%20Honey%20Lemon_0.pdf [retrieved on 2014-03-21] the whole document ----- -/-	1-4,6, 8-14
☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.		
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Information on patent family members

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