

Does Finiflu (Containing Garlic, Onion And Chilli) Provide Symptomatic Relief from Cold and Flu? What is the Evidence Base for this Remedy?

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Abstract

Introduction: It is estimated that adults experience between two and four colds per year and catch roughly double this number. Colds and flus are self-limiting conditions; however, there are a number of treatments to help manage symptoms. The efficacy of Finiflu, containing garlic, onion and chilli, and claims to relieve the symptoms of cold and flu, but it is unclear what clinical data supports its efficacy.

Materials and Methods: Finiflu was registered with the Therapeutic Good Administration in Australia in 2009. The current research focused on three aspects to assess the base evidence for Finiflu. This included: 1) An assessment of the characteristic properties of Finiflu based on information in the public domain, with the intention of determining any gaps in the evidence base for Finiflu; 2) A review of the literature supporting the efficacy of Finiflu for the relief of cold and flu symptoms; and, 3) A review of the literature supporting efficacy of Finiflu's main ingredients for the relief of cold and flu symptoms.

Results: Search results showed the main gaps in the product characteristics related to the pharmacodynamics and pharmacokinetic data. This is needed to determine the efficacy of Finiflu for the claims being made, the optimal posology for Finiflu as well as how the main ingredients in Finiflu are absorbed, distributed, metabolised and excreted by the body. The literature published in the public domain was searched to determine the number of reports supporting the efficacy of Finiflu and its main ingredients. Searches revealed no evidence for Finiflu or its main ingredients, except garlic, which had limited support when used prophylactically.

Discussion: Future evidence is needed to support the efficacy of Finiflu and its main ingredients. Evidence needs to address the efficacy of Finiflu when used acutely to manage the short-term symptoms of cold and flu.

Keywords: Finiflu; Garlic; Onion; Chilli; Cold; Flu; Symptomatic Relief

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Introduction

Background

It is a fact that in the winter, most people will catch a cold as there is no effective cure for cold viruses with adults having 2 to 4 colds per year and children having roughly double this number [1]. Hence it is no surprise that viral respiratory tract infections are the most common ailments in humans [2]. The economic impact of respiratory tract infections, at least in the USA, has been estimated to cost the USA economy \$40 billion per annum [2, 3]. Research by Molinari et al [4] reported that annual influenza epidemics led to the loss of 610,660 life-years, 3.1 million hospitalized days and 31.4 million outpatient visits in the USA. Vaccination before the flu season, therefore, is a widely adopted strategy to prevent flu from spreading [5]. There are, however, a number of natural therapies that could help prevent cold and flu [6] and there are others that help manage the symptoms once colds and flu. One example, only available in Australia, is Finiflu [7].

Finiflu comes in chocolate flavoured squares containing garlic, onion and chilli and claims to provide symptomatic relief from colds and flu. Indeed, the pack states "Assists with the relief of symptoms associated with cold and flu and other mild respiratory conditions." The name also implies it is for 'flu' as this forms part the trademarked name [8]. The pack states the following usage: The symptoms specifically identified on pack are runny nose, congestion, mucous and cough.

In 2009, Finiflu received a class 5 approval from Therapeutic Goods Administration (TGA) in Australia [7]. Class 5 covers the following: ‘Pharmaceutical, medical preparations and substances; vitamins and vitamin supplements; minerals and mineral supplements; nutritional supplements; pharmaceutical preparations containing vitamins, minerals and herbal substances; natural health food and herbal remedy products in this class; compositions and other preparations included in this class for making any of the aforesaid goods.’ Finiflu is not licenced in Europe and it is unclear where else it is licenced globally. Applications for such products will need to show clinical efficacy and safety in patients that have cold and flu symptoms. Thus, clinical trials would need to consider symptoms where it claims to be effective. A new application would need to show clinical evidence for the on-pack claims it is making, which includes a runny nose, congestion, mucous build-up and cough.

Objectives

As this is a relatively new remedy and the data supporting its use are unclear, the objectives of this current report were:

1. To identify the characteristic properties of Finiflu based on information in the public domain. From this it is also possible to identify gaps in the support evidence for Finiflu.
2. To assess the level of evidence supporting efficacy of Finiflu for the relief of cold and flu symptoms.
3. To assess the level of evidence supporting efficacy of Finiflu’s main ingredients for the relief of cold and flu symptoms.

Materials and Methods

Searches conducted to identify Finiflu’s product characteristics

A number of characteristics were identified as being important to understanding the product such as its intended use and how it should be used most effectively. The criteria collected for Finiflu included:

1. Summary of product.
2. Qualitative and quantitative composition.
3. Delivery form.
4. Product particulars including therapeutic use, posology, contraindications, special warnings and special precautions for use, interactions with other ingredients, pregnancy and lactation,

effects on the ability to drive and use machines, undesirable effects and the potential for overdose

5. Pharmacodynamic, pharmacokinetic data and pre-clinical data.
6. Excipients, incompatibilities, shelf-life, storage, container and disposal.
7. The manufacturer’s details.
8. Authorisation number by the TGA.
9. Date of first authorisation by the TGA.

This information was collated from two sources (listed below) and used to identify the extent of data supporting the use of Finiflu.

- The TGA website - see [https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=69356D333ADEB64AC A2577DD00031B15&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=69356D333ADEB64AC A2577DD00031B15&agid=(PrintDetailsPublic)&actionid=1)
- The Finiflu product website – see <http://Finiflu.com.au/faq.html>.

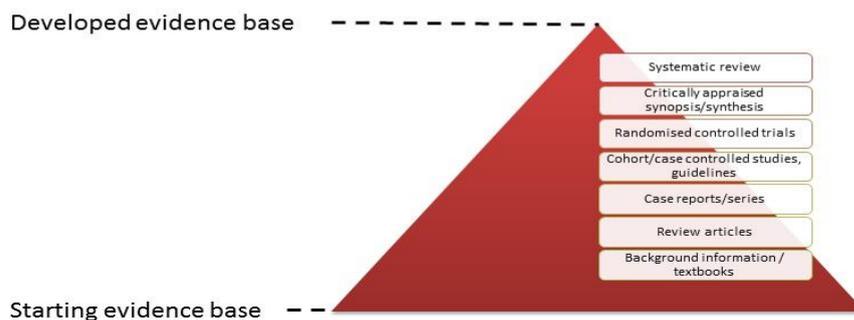
Searches conducted to identify the evidence supporting the use of Finiflu in cold and flu

Finiflu is listed in the Australian Register of Therapeutic Goods (AUST L165924). Hence, literature in the public domain was searched to define the product characteristics of Finiflu and to identify clinical efficacy data supporting the use of Finiflu for the symptoms of cold and flu. Figure 1 is a pyramid that depicts the extent of quality of evidence base that is used to support a product or the ingredients in a product when considered as being efficacious in humans.

To assess the level of support the search focused on ‘review articles’ conducted in ‘humans.’ Results were then filtered using the below search strings:

1. By searching literature in the public domain to identify product characteristics for Finiflu.
2. By searching literature in the public domain to identify evidence supporting the use of its main ingredients (garlic, onion and chilli).

Figure 1: Schematic diagram to demonstrate the levels of clinical evidence.



Databases searched and search terms used

The search primarily used PubMed (see www.pubmed.org) using two pre-defined filters - 'humans' and 'review.' The following search terms and combinations of terms were then used:

1. The product ('Finiflu') or main ingredients ('garlic', 'onion' and 'chilli'); and,
2. The symptoms of cold and flu ('common cold', 'flu', 'congestion', 'cough', 'mucous' and 'runny nose').

Searches were conducted to combine '1' and '2' above and the output was used to answer objectives 1 and 2 below.

Presentation of Data

Data is presented using the following three headings to ensure the objectives are discussed individually:

1. Objective 1: To identify the characteristic properties of Finiflu based on information in the public domain. From this it is also possible to identify gaps in the support evidence for Finiflu ('Characteristic properties of Finiflu').
2. Objective 2: To assess the level of evidence supporting efficacy of Finiflu for the relief of cold and flu symptoms ('Data supporting the efficacy of Finiflu').
3. Objective 3: To assess the level of evidence supporting efficacy of Finiflu's main ingredients for the relief of cold and flu symptoms ('Data supporting the efficacy of Finiflu's main ingredients').

Results

The results are organised by objective and detailed below.

Objective 1: Characteristic properties of Finiflu

The literature was searched as outlined in the Materials and methods section above and is summarised under the 9 headings below.

1. Summary of product entry: Finiflu chocolate squares.
2. Qualitative and quantitative composition: Allium cepa, 166.66 mg/g; capsicum Powder 4.16 mg/g; Garlic Clove Powder, 8.33 mg/g.
3. Delivery form: Oral form.
4. Product particulars:
 - Therapeutic use - assists with the relief of symptoms associated with colds and flu and other mild respiratory conditions. Therapeutic uses stated include runny nose, congestion, mucous and cough.
 - Posology and method of administration - the advice is that the product is taken orally with two squares of chocolate taken every two hours with a maximum of sixteen tablets taken in one day. For use from 2 years of age. Not to be used in children under two years of age without medical advice. Finiflu can also be used in the elderly. The general advice is to consult a health care professional if there is any doubt about using Finiflu or, if following use, symptoms persist.

- Contra-indications - before taking this product, diabetics should consult their healthcare professional.
- Special warnings and special precautions for use - if symptoms persist consult your healthcare practitioner.
- Interaction with other medicinal products and other forms of interaction - if you are on any other medication it is best to consult with a healthcare professional before taking this medicine.
- Pregnancy and lactation - if pregnancy, consult a healthcare professional before taking Finiflu.
- Effects on ability to drive and use machines - Finiflu does not contain any alcohol or other sedating ingredients that will affect the ability to drive and use machines.
- Undesirable effects – following use there may be an increased urge to blow the nose, burp and even slight diarrhoea. These mild effects will only last while you are taking the course of Finiflu and all are normal reactions.
- Overdose – nothing reported.

5. Pharmacodynamic and pharmacokinetic data

- Pharmacodynamic properties - Finiflu contains ingredients which have been traditionally used to assist with the relief of symptoms associated with colds and flu and other mild respiratory conditions. Garlic and onion contain a potent component known as allicin, which, according to the TGA and manufacturer's website, acts as a mucolytic, expectorant, antiseptic, anti-inflammatory and antimicrobial.
- Pharmacokinetic properties - nothing reported.
- Pre-clinical safety data - nothing reported on the absorption, distribution, metabolism and excretion.

6. Excipients, incompatibilities, shelf-life, storage, container, disposal

- List of excipients - nothing reported.
- Incompatibilities - nothing reported.
- Shelf-life - 2 years.
- Special precautions for storage - to be stored below 30°C.
- Nature and contents of container - nothing reported.
- Special precautions for disposal - nothing reported.

7. Product manufacturer

- BR Industries Pty Ltd, PO Box 198, BUNBURY, WA, 6231, Australia

8. Authorisation number

- Entry code 165924; included in the Australian Register of Therapeutic Goods AUST L165924.

9. Date of first authorisation

- 8th October 2009.

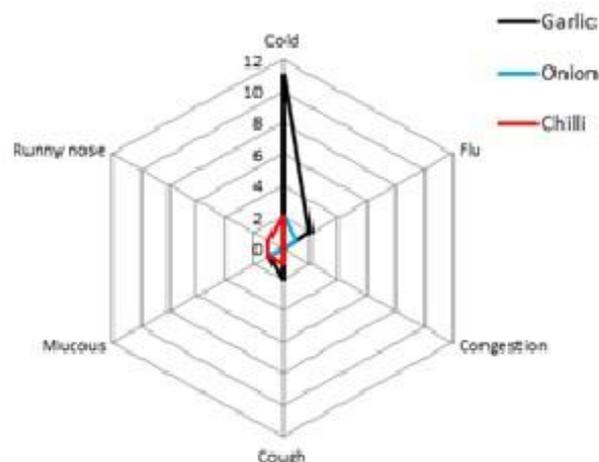
Objective 2: Data supporting the efficacy of Finiflu

- A product licenced would have a strong evidence base with randomised controlled trials to support the efficacy of a product. This approach was used to search the 'evidence base' for Finiflu and only one short review was identify [9]. Suggesting that Finiflu has a 'starting evidence base.'

Objective 3: Data supporting the efficacy of Finiflu's main ingredients

- The above literature search was repeated for Finiflu's main ingredients and the quantitative results are presented in Figure 2. Data is organised by the therapy area (cold and flu) and cold and flu symptoms – runny nose, cough, congestion and runny nose. Results show that there is limited evidence for all three main ingredients – 16 articles identified for garlic, 4 for onion and 5 for chilli. Further quantification reveals that 1 of 36 of the garlic, 3 of 4 for onion and 3 of 5 for chilli were based on cold and flu per se rather than presenting data specific to the management of symptoms (see Figure 2).

Figure 2: Diagram demonstrating the evidence base for main ingredients of Finiflu for the symptomatic relief of cold and flu symptoms.



Discussion

The current research sought to quantify the level of support for Finiflu. This was done in three ways: defining its product characteristics and defining the level of support for Finiflu and its actives in the public domain. These are discussed separately below.

Objective 1: Characteristic properties of Finiflu

A review of the product characteristics identified a gap in the support of the pharmacodynamics and pharmacokinetics of Finiflu. This means there is no apparent data to support the use of Finiflu for the symptomatic relief of cold and flu. Furthermore, the lack of pharmacokinetic data means it is unclear if the ingredients in Finiflu are absorbed, then how they distributed, metabolised and excreted from the body. Also, the lack of data means it is unclear how frequently Finiflu should be taken to obtain the best effects with the fewest number of chocolate squares.

Objective 2: Data supporting the efficacy of Finiflu

This literature identified no new studies supporting the use of Finiflu. This also included case reports following its real-world usage. Hence, the manufacturer should consider working with users to assess collate data on the efficacy and safety of Finiflu in the real-world and then using these as an evidence base.

Objective 3: Data supporting the efficacy of Finiflu's main ingredients

A PubMed search identified 25 articles reporting the use of garlic, onion and chilli in cold and flu. The majority of this evidence was for the use of garlic (16 of 25 articles), which means it is unclear what role onion and chilli have in the management of cold and flu. However, even in those articles reporting beneficial effects with garlic, few reports presented evidence on the symptoms of cold and flu (7 of 25 articles).

Of the three ingredients in Finiflu, garlic had the best supported in terms of relief from the symptoms of cold and flu. The systematic review by Lissiman et al. [1] identified six randomised, controlled trials reporting benefits with garlic. One of these trials was placebo controlled involving 146 subjects who ingested garlic (180 mg of allicin) or placebo once per day for 12 weeks. Note that this differs from Finiflu where garlic clove powder weight was reported (i.e., a maximum of 16 tablets in one day equals 266.4 mg of garlic clove powder). The key findings were that garlic led to significantly fewer occurrences of the common cold (24 versus 65

occurrences [garlic versus placebo]). Garlic also led to fewer lost days to illness (111 versus 366 days, respectively). And, garlic had no benefit in terms of time to recover from a common cold (4.63 versus 5.63 days, respectively). The main side effects of garlic were odour and rash.

The applicability of the data by Lissiman et al. [1] needs to be discussed in further detail. There are two important points to consider – the duration of treatment. Indeed, Lissiman et al. [1] administered garlic prophylactically over the course of 12 weeks whereas Finiflu is intended to be used to treat acute symptoms of the common cold, a disease that is self-limiting persisting for up to 10 days [10]. The second point relates to the posology of the data presented by Lissiman et al. [1] where garlic was administered once per day (180 mg of allicin) whereas the posology of Finiflu means that 16.65 mg of garlic clove powder by weight (the allicin content was not reported but 1,000 mg of fresh garlic has been reported to release 3.7 mg of allicin [11] which could mean that as little as 1 mg of allicin is ingested in ant one chocolate square) is administered every 2 hours up to 16 times in one day. This effectively means that a very low-dose of allicin is administered and a sustained low dose is maintained throughout the day. This is in contrast to Lissiman et al. [1] where a bolus, high dose of allicin is administered daily. How this different dosing regime affects the management of symptoms is unclear and whether this low dose of allicin in Finiflu also needs to be established. The comparison of Lissiman et al. [1] and Finiflu posology raises a number of other points that require further clarification in future work. These include: i) how the formulation of Finiflu is absorbed, distributed, metabolised and excreted by the body; ii) what is the optimal dosing for Finiflu; iii) does the delivery of a low dose versus a single high dose have any bearing on common cold symptoms or the side effects reported; and, iv) whether the combination of garlic, onion and chilli have any synergistic effects in terms of overall efficacy.

Conclusions

Previous work [9] concluded that evidence for Finiflu, as well as its individual ingredients, is quite limited. This means that further research is needed to establish the efficacy of Finiflu and to also validate findings previously reported, as is the case for garlic.

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