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Australian Government

Department of Health

Therapeutic Goods Administration

TGA internal use only

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Food-therapeutic good interface product assessment¹

Overview	
Product name (include the ARTG # if relevant)	Souvenaid No AUSTL
Source	Internal TGA review (Listing Compliance Section – Complementary and OTC Medicines Branch)
Details of the referral	<p>Part of a project to assess a series of goods presented as being Food for Special Medical Purposes and sold under Standard 2.9.5.</p> <p>Souvenaid website: https://www.souvenaid.com.au/</p> <p>Nutricia's Souvenaid page: https://nutriciamedical.com.au/products/souvenaid/</p> <p>Nutricia's online store: https://www.nutriciastore.com.au/souvenaid-product.html</p>
Manufacturer/supplier	Nutricia
Summary of lab tests	NA
Ingredients	<p>Water, maltodextrin, sugar, fish oil, milk proteins, flavouring (vanilla), uridine 5'-monophosphate disodium salt, choline chloride, acidity regulator (citric acid), stabilisers (microcrystalline cellulose and sodium carboxymethylcellulose), potassium citrate, soy lecithin, calcium hydroxide, sodium L-ascorbate, DL-α tocopheryl acetate, magnesium hydroxide, potassium hydroxide, sodium chloride, sodium selenite, ferrous lactate, sodium citrate, colour (curcumin), pteroylmonoglutamic acid, cyanocobalamin, zinc sulphate, retinyl acetate, nicotinamide, pyridoxine hydrochloride, copper gluconate, manganese sulphate, chromium chloride, calcium D-pantothenate, D-biotin, cholecalciferol, thiamin hydrochloride, sodium molybdate, riboflavin, potassium iodide, phytomenadione.</p>
Summary of any public safety concerns	NA

Assessment against Food-Therapeutic Goods Guidance Tool ²	
Question	Assessment outcome

- ¹ This form is designed to be used for assisting in the assessment of products at the food-therapeutic goods interface. It reflects the questions in the Guidance Tool (version May 2014). If consultation is required with other agencies (other than Customs or the AFP), use the Protocol.
- ² A copy of the diagram from the Guidance Tool is at Attachment 3 of this form.

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Q1 – product solely for oral use?

Yes ☒ → Go to Q2
No ☐ → Go to Q6 to determine if therapeutic goods

Q2 – covered by a s7 declaration that it is therapeutic goods? <https://www.tga.gov.au/orders-goods-are-therapeutic-goods>

Yes ☐ → Most likely a therapeutic good – provide reasoning and details below then go to Q3
No ☒ → Go to Q3

Q2 continued - Details of s7 considered and reasons why they are applicable or not

Product does not appear to contain Trefriw Wells mineral water, isolated HMB, shark cartilage, fibre (in capsule, tablet or pill form) or promoted for cosmetic purposes.

Q3 – covered by s7AA declaration?

Please note, at the present time there are no s7AA declarations. Answer will be no until further notice.

Yes ☐ → Most likely not a therapeutic good. Continue with assessment. Go to Q4
No ☒ → Go to Q4

Goods for which there is a standard?

Q4 - goods for which there is a food standard?

Is the product "goods for which there is a standard" in the Food Standards Code?

Found in Chapter 2 here:

<http://www.foodstandards.gov.au/code/Pages/default.aspx>

Yes ☐ → Product is likely not a therapeutic good, continue with assessment. Go to Q5
No ☒ → Go to Q5

Provide the food standard(s) you have considered and reasons why they are/are not applicable:

Standard 2.9.5 Food for special medical purposes was considered because the product is marketed as a Food for special medical purposes. This standard states:

2.9.5—2 Definitions

- **food for special medical purposes** means a food that is:

(a) specially formulated for the dietary management of individuals: [emphasis added]

(i) by way of **exclusive or partial feeding**, who have **special medically determined nutrient requirements** or **whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food**; and

(ii) whose **dietary management cannot be completely achieved without the use of the food**; and

(b) intended to be used under medical supervision; and

(c) represented as being:

(i) a food for special medical purposes; or

(ii) for the dietary management of a disease, disorder or medical condition.

(2) Despite subsection (1), a food is not **food for special medical purposes** if it is:

(a) formulated and represented as being for the dietary management of obesity or overweight; or

(b) an infant formula product.

Reasons :

(i) This product is **not** for exclusive or partial feeding (it is for supplementation to the normal diet). Product is stated to be in addition to normal dietary intake.

(ii) There is no known additional nutrient requirement for patients with early stage Alzheimer's disease compared to the normal population and there is no limited or impaired capacity for absorption, taking, digestion, metabolising or excreting ordinary food or certain nutrients in ordinary food in early stage Alzheimer's.

(iii) The product is advertised (see website excerpts in Q6(1)) for **treating or alleviating Alzheimer's / memory loss from Alzheimer's directly**, rather than providing dietary management of nutrient requirements secondary to Alzheimer's.

(iv) The product does have nutritional value in the form of macronutrients -carbohydrates and fats, and a small amount of protein- and vitamins and minerals.

(v) The product is presented in the form of a 125mL drink.

(vi) If required, dietary management of those with early stage Alzheimer's disease should be able to be achieved without the use of this product, through the use of food in the ordinary sense.

Due to the above, I do not consider this product to fit under Food Standard 2.9.5

Also considered was **Standard 2.9.3 Formulated meal replacements and formulated supplementary foods** as Souvenaid is of similar presentation to products sold as formulated supplementary foods. This standard states:

2.9.3—2 Definitions

formulated supplementary food means a food specifically formulated as, and sold on the basis that it is, a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements.

Reasons:

As stated above in point (ii) of the reasoning considered under 2.9.5, there is no known additional nutritional requirement in early stage Alzheimer's disease. The product is marketed to treat Alzheimer's disease which would be considered a high level health claim- this claim is not contained in the 'Conditions for permitted high level health claims' table in Schedule 4. Also, a requirement for these foods is a higher protein and energy component.

Due to the above, I do not consider this product to fit under Food Standard 2.9.3.

Q5 -
"tradition of

Q5(a) – What kind of goods is the product?

Liquid containing carbohydrates, fats, some protein, vitamins and minerals.

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use" as food
in Australia
or NZ?

Q5(b) – What is the form in which the
product is presented?

Liquid in the form of a drink.

Q5(c) – Is there a use of the product as
"food for humans" in Aus/NZ in that
form?

Yes ☐ → Go to Q5(d)
No ☒ → Go to Q6

There is use of similar products sold as food under Standard 2.9.3
Formulated meal replacements and formulated supplementary foods,
though a requirement for these foods is a higher protein and energy
component. However this product itself does not have a use as food
for humans. It is entirely manufactured to become this product, and as
such does not satisfy "use as food for humans"

Q5(d) – Is there a "tradition" of the use
as food for humans in Aus or NZ?

Yes ☐ → **Most likely not a therapeutic good – provide
details below. Continue with assessment.**
No ☒ → Go to Q6

This specific product does not have a "tradition" of use as a food.

Defined as 'therapeutic goods' under the Act?

Q6(1) –
determine
what use the
product
appears to be
for. Is the
product:

(a) Represented *in*
any way to be for
therapeutic use?

Consider all aspects
including the label,
webpage, directions of
use, therapeutic
claims, tradition of use
of the product etc.
Include text from the
label and webpage
highlighting relevant
passages

Text from Nutricia store website

*Souvenaid® is a food for special medical purposes that nutritionally
supports memory function during the early stages of Alzheimer's
disease. [Learn more about Souvenaid®](#)*

INDICATION

- For the **dietary management of Alzheimer's disease**. To be
used as a supplement to the normal dietary intake.

IMPORTANT NOTICE

- Not suitable as sole source of nutrition**
- Not for intravenous use
- Not suitable for patients with allergies to fish oil, milk or soy
- Not suitable for patients with Galactosaemia
- Souvenaid does contain carbohydrate and as with other
foods containing carbohydrate, it is advisable for people
with diabetes to monitor their blood glucose levels as per
normal

DIRECTIONS FOR USE

- Souvenaid® is designed to be **taken as one bottle (125ml)
once a day, in addition to the normal dietary intake**
- The length of use of Souvenaid® by an individual should be
determined by their healthcare professional
- Shake well before use
- Ready to drink and best served chilled

STORAGE

- Store in a cool, dry place
- Once opened, store in the refrigerator
- Discard unused contents after 24 hours

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PRODUCT TYPE

- Oral Nutritional Supplements

AGE GROUP

- Adult

Text from Souvenaid website accessed 13/06/2019

WHAT IS SOUVENAIID®?

Souvenaid® is an innovative product clinically proven to nutritionally support memory performance in patients with early Alzheimer's disease.^{1,2,3}

What makes Souvenaid® so unique is its patented formula known as Fortasyn™ Connect, a combination of nutrients which provide the nutritional building blocks to improve memory performance. This innovation is backed by 20 years of evidence based research, supported by an extensive ongoing research program and has robust demonstration of memory benefit.

Souvenaid® is taken once daily and comprises of a unique combination of omega-3 polyunsaturated fatty acids, uridine monophosphate and choline, together with phospholipids, B vitamins and other nutrients, at levels difficult to achieve from dietary intake alone.

HOW DOES SOUVENAIID® WORK?

There is a growing body of evidence showing that people with early Alzheimer's disease have low levels of several nutrients – omega-3 fatty acids, B vitamins and antioxidants are just some – despite eating a normal diet.¹⁻² These nutrients play an important role in brain health and memory function.

Souvenaid® has been designed to supply specific nutrients to aid the naturally occurring processes in the brain, that are involved in maintaining the brain's integrity. The unique combination of nutrients that Souvenaid® contains, work together to produce a greater effect than when taking them individually. Although, found naturally in food, the amount of these specific nutrients found in Souvenaid® would be difficult to achieve through a normal diet.

SOUVENAIID® – CLINICALLY PROVEN

Souvenaid's® efficacy was originally established in 2 clinical trials, Souvenir I and Souvenir II, which demonstrated memory improvement in patients with mild to moderate Alzheimer's disease taking Souvenaid® once-daily over 12 and 24 weeks, respectively.^{3,4} A third trial was then conducted which is known as LipiDidiet. It included patients with mild-to-moderate Alzheimer's disease and found that Souvenaid® improved everyday thinking, functional ability and memory performance in the people who drank it every day for 2 years.⁵

HOW SHOULD I TAKE SOUVENAIID®?

DIRECTIONS

Souvenaid® is intended to be taken as one bottle (125ml) once a day. It should be taken under the direction of your healthcare professional. It may help to take Souvenaid® at the same time each day. For example: In the morning with breakfast. This should make it easier to remember to take it each day as it will become a habit. If you forget to take it at the usual time, there is no need to wait until the same time the next day to consume it. You can drink it when you remember or are reminded.

SERVING

In order to benefit from taking Souvenaid®, it is recommended that one bottle of Souvenaid® should be consumed once a day for a minimum of 6 months.

Souvenaid® is a ready to drink beverage and can be taken straight from the bottle, through a straw or poured into a glass depending on your preference.

It tastes best served chilled so we suggest keeping a few bottles in the fridge.

If you want to turn your daily Souvenaid® into a delicious creation, check out our [great range of recipes](#).

STORAGE

Souvenaid® can be stored in a cool dry place and is stable for 12 months when kept under these conditions.

Once opened, a bottle of Souvenaid® should be closed, kept in the fridge and consumed within 24 hours. We recommend drinking an

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entire bottle of Souvenaid® at once to ensure that the correct amount is taken each day.

HOW SAFE IS SOUVENAIID®?

Souvenaid® contains nutrients that are naturally present in food. Results from three clinical studies showed Souvenaid® was very well tolerated and had a positive safety profile.¹⁻⁴

SOUVENAIID® & OTHER MEDICATION

Souvenaid® has been tested as an add-on therapy to standard medications for Alzheimer's disease. No adverse events were reported as a result of taking Souvenaid® along with these medications.⁴

Many patients who have been involved in clinical trials with Souvenaid® were also taking medications for other conditions. The use of Souvenaid® in combination with these other medications was not associated with any side effects in these patients.

SOUVENAIID® & OTHER MEDICAL CONDITIONS

- Souvenaid® is not suitable as a sole source of nutrition and should be used in addition to normal dietary intake.
- People who have an allergy to milk protein, fish oil or soy may not be able to consume Souvenaid®.
- Souvenaid® is not suitable for people with galactosaemia.
- Souvenaid® is free from gluten-containing ingredients (<20mg/kg).
- Souvenaid® is low lactose (<300mg/kg).
- People with diabetes can consume Souvenaid®. However, Souvenaid® does contain carbohydrates and, as with other foods containing carbohydrate, it is advisable for people with diabetes to monitor their blood glucose levels in consultation with their diabetes medical team.

SOUVENAIID® – THE MEMORY DRINK

ARE MEMORY LAPSES AN EARLY SIGN OF ALZHEIMER'S DISEASE?

MAYBE NOT? WHAT YOU NEED TO KNOW!

The truth is that the symptoms of Alzheimer's disease, and of the related condition of mild cognitive impairment (MCI), are very different to an occasional bout of forgetfulness. Unlike people with normal lapses in memory, those with Alzheimer's simply can't retain information, even when prompted. Their memory issues can't be reversed by a change of medication, more sleep or other treatment. Instead, their memory progressively worsens and the condition starts to affect other cognitive functions, such as language and reasoning. MCI, meanwhile, impacts memory but doesn't involve the significant loss of other cognitive functions.

Throughout our lives we continually lose and replace important brain connections known as synapses without noticing. In a healthy brain the amount of new synapses that are formed matches the amounts that are lost. What we consume in our daily diet plays an important part in the process because the brain needs key nutrients – omega-3 fatty acids, phospholipids, choline, uridine monophosphate and B vitamins – in the right combination and at the right level to replace the synapses.

Read More- As we get older, our body may become less efficient at extracting and using key nutrients we get from our food. The availability of these key nutrients may therefore be poor despite eating a healthy, balanced diet.

Furthermore, as we age, the process of losing and replacing brain connections may become unbalanced so that synapse loss outweighs replacement, often leading to forgetfulness.

In the case of Alzheimer's disease (compared with the normal aging process), the rate at which synapses are lost accelerates to the point that their renewal cannot keep up and the balance is lost; this is where we start to see significant issues with memory.

Research has shown that people with memory loss in early Alzheimer's disease often have low levels of these key nutrients, despite eating a normal diet.^{1,2} Souvenaid® has been designed to provide these essential nutrients at levels otherwise difficult to achieve through diet alone.

HOW DOES SOUVENAIID® WORK?

Souvenaid is an innovative product clinically proven to nutritionally support memory loss in people with early Alzheimer's disease.³⁻⁵ It does this by providing important nutrients which are the building

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blocks required to maintain connections in the brain and this cannot be achieved from dietary intake alone. It takes time for these nutrients to be taken up and used by the body, so there is no noticeable effect straight away. Therefore, it is important to keep taking Souvenaid® every day to ensure a continuous and adequate supply of important nutrients for the brain.

WHERE CAN I BUY SOUVENAIID® FROM?

There are 3 easy ways to buy Souvenaid®.

- Buy it directly from our [online store](#) and have it delivered directly to your door step.
- Purchase from your local pharmacy
- Call us direct on [1800 319 420](#)

WHAT IF I STILL HAVE QUESTIONS?

If you feel that you still have questions, please take a look at our [Frequently Asked Questions](#), [send us an email](#) or call our Souvenaid® team on [1800 319 420](#)

THE BRAIN EXPLAINED

The average adult human brain weighs around approximately 1.4kg and is about the size of a medium cauliflower. It contains around 100 billion nerve cells, called neurones, which are connected by 100 trillion connections, known as synapses. Synapses are found where nerve cells connect with other nerve cells.

Neurones can be seen as the building blocks of the brain network and synapses as the links in the network. Electrical signals, together with chemical reactions that are passed between the neurones and the synapses allow the brain to carry out its many important functions, like for example memory.

Did you know the brain can be divided into 4 areas known as 'lobes'? Although they have strong connections with each other, they can largely be defined by the cognitive processes that they carry out.

IMPORTANCE OF NUTRITION

The connections in the brain, called synapses, are continuously re-formed throughout life. This means that existing synapses are replaced every 3-6 months with new ones. In a healthy brain the amount of new synapses that are formed matches the amounts that are lost. What we consume plays an important part in the process because the brain needs key nutrients – omega-3 fatty acids, phospholipids, choline, uridine monophosphate and B vitamins – in the right combination and at the right level to replace the synapses.

While a healthy brain can replace the synapses as quickly as they're required, this doesn't occur in someone with Alzheimer's disease. Instead, the loss of synapses occurs at a faster rate than they can be replaced, causing memory loss and the decline of other cognitive functions.

With nutrients being important in this process of synapse replacement, eating plans such as the Mediterranean diet – rich in fruits, vegetables, olive oil, beans, wheat and rice but limited in red meats and poultry – have been found to assist brain health in older adults.

While scientists don't have a definitive answer to why synapses aren't replaced at the optimal rate in people with Alzheimer's, it's known that those in the early stages of the condition typically have low levels of those key nutrients, even if they eat a healthy diet.^{1,2}

Souvenaid® is formulated to provide Alzheimer's patients with these nutrients, in a way they could never achieve simply by eating. Souvenaid® includes all the nutrients at levels needed to make new synapses

WHAT IS ALZHEIMER'S DISEASE?

Alzheimer's disease is the most common form of dementia, affecting up to 70% of all people with dementia. It is expected an estimated 447,115 Australians in 2019 will be living with dementia. Worldwide dementia affects almost 50 million people, which is predicted to increase to 131.5 million people by 2050.¹

Alzheimer's is a physical brain disease characterised by the impairment of brain functions such as impaired memory, language, thinking and behaviour. It is a progressive disease caused by the gradual degeneration of brain cells. Alzheimer's disease can broadly be categorised into two areas:²

Sporadic Alzheimer's disease can affect adults at any age, but occurs most often after age 65. This is the most common form of Alzheimer's disease and affects people who may or may not have a family history of the disease.

Familial Alzheimer's disease is a much less common form in which the disease is passed directly from one generation to another.

A person is usually said to have early onset Alzheimer's when they develop the condition in their 20s and by their 40s are severely affected by their symptoms. But Alzheimer's more commonly appears in older adults, with the risk of developing the condition doubling every five years after the age of 60.³

RISK FACTORS

Although the causes of Alzheimer's disease are still not yet fully understood, scientists are starting to gain a greater understanding of the risk factors that increase the likelihood of developing the disease. These include age, family history, heart health and lifestyle factors, such as diet or physical activity.^{1,2}

AGE

The greatest risk factor for developing Alzheimer's disease is advancing age. Studies have shown that the occurrence of Alzheimer's increases from about the age of 65. After age 65, the risk of Alzheimer's disease doubles every five years. After age 85, the risk reaches nearly one-third.

FAMILY HISTORY

People with a first degree relative, such as a parent or a sibling, who has developed Alzheimer's disease, have an increased risk of developing the disease. This risk is higher if two or more first degree relatives have been affected.

HEART HEALTH

Some of the strongest evidence links your brain health to heart health. Therefore maintaining healthy cholesterol levels and blood glucose levels is important, especially if you have cardiovascular disease or diabetes.

RISK FACTORS YOU CAN CHANGE

Although there are no definitive protective factors for dementia, there are several lifestyle factors that could reduce your risk of developing dementia. These include:

- Maintaining a healthy level of physical activity
- Staying mentally active
- Adopting a healthy diet
- Enjoying a socially active lifestyle

IDENTIFYING SYMPTOMS OF ALZHEIMER'S DISEASE

DIFFERENCE BETWEEN EARLY ALZHEIMER'S DISEASE AND FORGETFULNESS

We all forget things from time to time and this forgetfulness tends to increase with age. It can be difficult to judge whether this forgetfulness is a part of normal ageing. Typically it is the 'depth' of the memory loss that differs in 'normal forgetfulness' versus that due to Alzheimer's disease. A person with 'normal forgetfulness' can usually still remember other facts associated with the thing they have forgotten. For example, they may briefly forget their neighbour's name but the person they are talking to is their neighbour. A person with Alzheimer's disease will often forget not only their neighbour's name, but also the context in which they know them.

STAGES OF ALZHEIMER'S DISEASE

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Alzheimer's disease is a complex condition that can affect people in different ways. There are, however, stages that many people will progress through and these reflect the movement of the disease through the brain. The symptoms that someone is experiencing will therefore often change, depending on the stage of their disease.

EARLY (OR MILD)

In the very early stages, day-to-day memory problems dominate but these can be subtle so it can be hard to tell if they are due to the normal ageing process. Early warning signs to look out for include:

- Losing or misplacing things
- Becoming confused in familiar places
- Taking longer to carry out everyday tasks
- Changes in mood

MODERATE

In this stage of Alzheimer's disease, the problems with memory become more pronounced and other cognitive processes also start to become affected. People may:

- Tell the same stories or ask the same question repeatedly
- Have difficulty recognising family members or friends
- Have word-finding difficulties or non-fluent speech
- Show a lack of concern over their appearance
- Experience changes in mood and personality

SEVERE

In this stage, the disease spreads to engulf most parts of the brain and the person has what is termed 'a global dementia'. All areas of cognition are severely affected but there are also problems with physical functioning. People at this stage of disease may:

- Be unable to remember their own name or recognise close family members
- Suffer from bladder and bowel incontinence
- Experience visual/auditory hallucinations
- Develop repetitive or ritualistic behaviours
- Need help with even the most basic activities of daily living

If you recognise signs of memory loss in a loved one that keeps on getting worse, to the point you are concerned, it is strongly recommended that you make an appointment to see a doctor for an assessment. The earlier that Alzheimer's disease is diagnosed, the more can be done to manage it.

GETTING A DIAGNOSIS OF ALZHEIMER'S DISEASE

Finding out you or a family member have been diagnosed with Alzheimer's can leave you with many emotions. For some people it can be upsetting or may come as a shock. For others, receiving an 'official' medical diagnosis can simply confirm what has long been suspected.

The below diagram shows the usual route to diagnosis for a patient in the early stages of Alzheimer's disease. Typically a patient or sometimes their family members report memory problems to their GP. The GP will ask a series of questions and may conduct a short test of mental ability. On the basis of this, the doctor will decide whether to refer a patient on to a specialist.

HOW TO GET A DIAGNOSIS?

GP

Report memory complaints to a GP. On the basis of an examination, some questions and a brief memory assessment, referral to a specialist may be made.

SPECIALIST

A specialist and their team may perform a thorough set of examinations. This may include in depth memory testing and brain scans.

DIAGNOSIS

Doctors will rule out other possible causes of **dementia-like conditions**. To make a **diagnosis of Alzheimer's disease**, doctors use specific standardised tests and procedures.

TALKING TO YOUR DOCTOR

Whether you are attending an appointment for yourself or for someone you are supporting, you may find the following tips useful:

- Before your visit, think about any symptoms that you want to raise during your consultation.
- Go with someone who will support you and who can write down any important points the professional makes.
- Ask the doctor to write down any medical terms, particularly if English is not your first language.
- Ask what you can expect to happen further on in the future – this can be very useful to help you make plans.
- Request any information they have about contacting local support groups.

FREQUENTLY ASKED QUESTIONS

What is Souvenaid? Souvenaid® is food for special medical purposes for the **dietary management of patients diagnosed with mild/early Alzheimer's disease**. It must be used under medical supervision. It is a **once daily 125mL drink which contains a unique, patented combination of nutrients designed to support memory performance**. Souvenaid® taken daily has benefits in the dietary management of mild Alzheimer's disease.

Who is Souvenaid for? Souvenaid® is for **people who are in the early stages of Alzheimer's disease**. The clinical benefit of Souvenaid® has so far only been demonstrated in people during the **early stages of Alzheimer's disease**. Souvenaid® must be used under medical supervision.

What does Souvenaid contain? Souvenaid® contains a unique combination of nutrients, called Fortasyn™ Connect, at levels difficult to achieve from normal dietary intake alone. This combination of nutrients in Souvenaid® **supports brain health** and includes fish oil, phospholipids, choline, uridine monophosphate, vitamin E, vitamin C, vitamin B12, vitamin B6 and folic acid. The **unique combination of nutrients is designed to support memory performance in people living with Alzheimer's disease**.

How does Souvenaid work? There is a growing body of evidence showing that people with **Alzheimer's disease** have low levels of certain 'building blocks' (nutrients) and because of their disease, they experience an increased need for such 'building blocks'. Souvenaid® provides the nutritional 'building blocks' that are required for **synapse formation** and memory performance.

How does Souvenaid support memory function? Souvenaid® provides the nutrients required, in addition to a person's normal daily dietary intake, to **support synapse formation which in turn is associated with memory function**. Therefore, Souvenaid® nutritionally supports memory function in people during the **early stages of Alzheimer's disease**.

How should Souvenaid be taken? Souvenaid® is a single serve drink making it easy and convenient for people to take. It can be drunk straight from the bottle, through a straw or popped into a glass. It comes in three flavours; vanilla, strawberry and cappuccino. It tastes best served chilled, so we recommend keeping a few bottles in the fridge. Alternatively if you want to turn your daily Souvenaid® into a delicious creation, check out our great [range of recipes](#).

Can Souvenaid be taken at the same time as medications for Alzheimer's disease? Souvenaid® is food for special medical purposes for the dietary management of patients diagnosed with **mild/early Alzheimer's disease**. It must be used under medical supervision. Clinical studies have demonstrated that Souvenaid® can be used safely alongside commonly prescribed **Alzheimer's disease** medication.

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How does Souvenaid taste? Souvenaid® comes in three flavours; vanilla, cappuccino and strawberry. It tastes best served chilled, so we recommend keeping a few bottles in the fridge. To taste all 3 flavour, request your [free sample pack](#) today.

How long do I need to take Souvenaid? In order to benefit from taking Souvenaid®, it is recommended that one 125mL bottle of Souvenaid® should be consumed once a day for a minimum of 6 months. The length of use of Souvenaid® by an individual should be determined by their **recommending healthcare professional**.

I have a family history of Alzheimer's disease. Should I take Souvenaid to prevent it developing in the future? Should I take it 'just in case'? Souvenaid® is indicated for the **dietary management of patients with early Alzheimer's disease**. Souvenaid® has not been tested in people who do not have **Alzheimer's disease**. You should consult your health care professional about whether it is appropriate to take Souvenaid®.

Will Souvenaid protect me from getting Alzheimer's disease or stop the progression of the disease? Souvenaid® is an Food for Special Medical Purpose for the dietary **management of early Alzheimer's disease**. It is not intended to prevent the disease nor is it a treatment and it should only be used by people who have already been **diagnosed with early Alzheimer's disease**. It must be used under medical supervision.

I am already taking coconut oil or food supplements for memory loss, will Souvenaid provide additional benefits? Souvenaid® should only be used under medical supervision and this should be discussed with your healthcare professional. Souvenaid® is a nutritional drink clinically proven to be beneficial in the **dietary management of patients with early Alzheimer's disease**. Clinical trials of Souvenaid® in combination with coconut oil or food supplements have not been carried out.

Why can't I just take fish oil and other vitamin supplements to get the same benefits for a fraction of the cost? This question is best answered by your healthcare professional. Clinical trials directly comparing Souvenaid® with fish oil and vitamin supplements have not been carried out.

Can't people living with Alzheimer's disease get the same benefits from consuming foods containing the ingredients present in Souvenaid? Souvenaid® contains a unique combination of nutrients at levels difficult to achieve from diet alone. In **early Alzheimer's disease**, dietary intake of nutrients may be affected by **worsening of appetite, taste and smell, which lead to reduced food consumption, food neglect and changes in food preferences**.

In addition, research suggests that people with **early Alzheimer's disease** have higher requirements than people without the disease for certain nutrients **supporting brain function**. It would be extremely difficult to modify your diet to achieve the right combination of specific nutrients and unreasonable to expect people to eat enough of the right foods.

(b) Likely to be taken to be for therapeutic use because of the way in which it is presented?

Yes, as above- multiple references to *dietary* management of Alzheimer's disease and supporting memory function, increasing the replacement of synapses. Despite a disclaimer on their website " It is not intended to prevent the disease nor is it a treatment and it should only be used by people who have already been diagnosed with early Alzheimer's disease ", it is likely to be taken for therapeutic use as defined in the TG Act.

(c) Likely to be taken to be for therapeutic use for any other reason?

NA

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Q6(2) – determine whether that use of the product is “therapeutic use” ie:

(a) Is any disease, ailment, defect, or injury identified? (If yes, describe.)

Yes. From above text from website: Alzheimer’s disease, synapse loss, mild cognitive impairment, dementia, memory loss.

(b) Is the product represented, presented or otherwise likely to be taken to prevent, cure or alleviate that disease, ailment, defect or injury? (If yes, describe.)

Yes. To alleviate/manage Alzheimer’s disease, to support synapse formation (statement immediately prior to reference of synapse formation “with Alzheimer’s... loss of synapses occurs at a faster rate than they can be replaced”).

(c) Is any physiological process in a person identified? (If yes, describe.)

Yes. Aid the naturally occurring processes in the brain that are involved in maintaining the brain’s integrity, nutrients absorbed, memory function, process of making new synapses/synapse formation.

d) Is the product represented, presented or otherwise likely to be taken to influence, inhibit or modify that process? (If yes, describe.)

Yes. To influence: the processes in the brain that are involved in maintaining the brain’s integrity, memory function, the process of making new synapses, synapse formation

Q7 - Is the product in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use?

Is the product in a class of goods?

Yes

☐ → Go to Q7(b)

No

☒ → Go to Q8

NOTE:

The ‘class’ of the goods refers to the category of products which the product belongs. Eg- The class of goods for loose plant leaves to be mixed in boiling water is ‘tea’ or ‘herbal tea’, the class of goods of a powder which contains amino acids is an ‘amino acid supplement’ etc.

The Act defines a *class of goods* as:

(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

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Which are:

- (i) for therapeutic use; or
- (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
- (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or

(b) What is the class of goods?

Describe how the goods fit the class you have selected (i), (ii) or (iii) as above.

(c) Does that class of goods have a therapeutic use under the definition of the Act subparagraphs (a) and (b)? ie. To prevent,

cure or alleviate a disease, ailment, defect or injury, or influence, inhibit or modify a physiological process?

Yes ☐ → Go to Q7(d)
No ☐ → Go to Q8

(d) Is that use the principal or ordinary use of the product?

Yes ☐ → Product is likely a therapeutic good – continue with assessment
No ☐ → Go to Q8

Q8 – biological or medical device as defined by the Act?

Biological

Medical device

Neither biological or medical device

A medical device is:

(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(iii) investigation, replacement or modification of the anatomy or of a physiological process;

A biological is a thing that:

(a) either:

(i) comprises, contains or is derived from human cells or human tissues; or

(ii) is specified under subsection (2); and

(b) is represented in any way to be, or is, whether because of the way in which it is presented or for any other reason, likely to be taken to be:

(i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or

☐ → Yes. Product is likely a therapeutic good
☐ → Yes. Product is likely a therapeutic good
☒ → No. Continue with assessment

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(ii) for use in making a medical diagnosis of
the condition of a person; or

Related assessments

Are there any previous food-therapeutic goods interface assessments that are relevant to this assessment?

STOP- Check TRIM.

Try searching 'FMI' in addition to the product name or its ingredients or its dosage form (eg. 'FMI Gummies')

Yes ☒ → Provide details below

No ☐ → Go to Other advice/information section below

Details and outcome:

[R13/683054](#) Completed in August 2013 on same product- determined to be a likely food under 2.9.5.

Summaries of other relevant advice/information

State/Territory agencies

Food Safety Victoria in the Health Protection Branch of the Victorian Department of Health and Human Services have confirmed to the TGA that a different product, Neurofolin—considered under Food Standard 2.9.5—is a therapeutic good. Food Standard 2.9.5 was considered for Neurofolin but was assessed by the TGA as being a therapeutic good for similar reasons as those detailed above for Souvenaid, though Neurofolin does not have any nutritional value in the form of macronutrients- unlike Souvenaid, which does.

TGA Food Medicine Internal Working group

Refer to file note [D19-5592248](#): Verbal clarification from [s22](#) from internal working group regarding question 5(c) and whether the goods would have a tradition of use as food. She agreed with my assessment- that the answer is "no".

Others

NA

Outcome

Likely to be therapeutic goods?

It is common to not have a clear outcome of an assessment. Please state your reasons below as to why you believe this assessment to be contentious.

Yes ☒

No ☐

Summary of reasons for outcome

It does not appear to meet the definition of a food for special medical purpose as the product is not for exclusive or partial feeding; there is no additional nutrient requirement for patients with early stage Alzheimer's compared to the normal population.

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There is not a use of the product as food for humans, though it does contain macronutrients, vitamins, and minerals.

The overall presentation of the goods suggests therapeutic purposes rather than dietary management.

Assessor

S22

Date

14 June 2019

Comments/action items

Refer to ECT

Attachment 1 - Relevant definitions

Term	Source ³	Definition
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<add as required>

Attachment 2 - Examples of presentations/representations

Use this page to include copies of labels, advertising and any other relevant examples of presentation. **Please ensure you include the web-address, date and time in all of your captures.**

Website and factsheet for the goods updated between initiation of assessment and finalisation of assessment

Updated Souvenaid Fact Sheet from Souvenaid Website, accessed 13/06/2019. TRIM link: [D19-5633464](#)



D19-5633464 FMI - Souvenaid Factsheet - Souvenaid - Accessed 13 June 2019.pdf

Souvenaid Fact Sheet from Nutricia Store Website, accessed 08/05/2019. TRIM link: [D19-5459303](#)



Souvenaid-Factsheet
.pdf

Website captures from Nutricia Store Website: <https://www.nutriciastore.com.au/souvenaid-product.html> Accessed 08/05/2019 11:32. TRIM link: [D19-5474916](#)

³ Common sources of definitions are likely to include legislation, legislative instruments and dictionaries



FMI - Website
Capture - Nutricia Stc

Updated website captures from Souvenaid Australia Website: <https://www.souvenaid.com.au/>
Accessed 13/06/2019. TRIM link: [D19-5633512](#)

Older version of Souvenaid website

Website captures from Souvenaid Australia Website: <https://www.souvenaid.com.au/> Accessed 08/05/2019 11:35. TRIM link: [D19-5473983](#)

Text from Souvenaid website accessed 08/05/2019

Features

- Souvenaid is a food for special medical purposes that nutritionally supports memory function during the early stages of Alzheimer's disease
- Souvenaid contains a unique combination of nutrients, called Fortasyn™ Connect, designed to meet the specific nutritional needs of people in the early stages of Alzheimer's disease. These include: Omega 3 Fatty Acids (DHA* EPA*), UMP#, choline, B vitamins, selenium, phospholipids

Indications

- For the dietary management of early Alzheimer's disease
- To be used as a supplement to the normal dietary intake (not suitable as sole source of nutrition).

Contraindications

- Not for intravenous use
- Not suitable for patients with allergies to fish oil, milk or soy
- Not suitable for patients with Galactosaemia

Precautions

- Souvenaid does contain carbohydrate and as with other foods containing carbohydrate, it is advisable for people with diabetes to monitor their blood glucose levels as per normal.

Directions for use

- Souvenaid is designed to be taken as one bottle (125ml) once a day, in addition to the normal dietary intake
- The length of use of Souvenaid by an individual should be determined by their healthcare professional
- Shake well before use
- Ready to drink and best served chilled

Intake

Souvenaid® is designed to be taken once daily. It should be taken under the direction of your healthcare professional.

If the person taking Souvenaid® does forget to take it at the usual time, there is no need to wait until the same time the next day to consume it. They should just drink it when they remember or are reminded.

What is Souvenaid?

Souvenaid is food for special medical purposes for the dietary management of patients diagnosed with mild/early Alzheimer's Disease (AD). It must be used under medical supervision. It is a once daily 125mL drink which contains a unique, patented combination of nutrients designed to support synapse formation. Souvenaid taken daily has benefits in the dietary management of mild Alzheimer's Disease and Mild Cognitive Impairment.

Who is Souvenaid for?

Souvenaid is for people who are in the early stages of Alzheimer's Disease. The clinical benefit of Souvenaid has so far only been demonstrated in people during the early stages of Alzheimer's disease. Souvenaid must be used under medical supervision.

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What does Souvenaid contain?

Souvenaid contains a unique combination of nutrients, called Fortasyn™ Connect, at levels difficult to achieve from normal dietary intake alone. This combination of nutrients in Souvenaid supports brain health and includes fish oil, phospholipids, choline, uridine monophosphate, vitamin E, vitamin C, vitamin B12, vitamin B6 and folic acid. The unique combination of nutrients is designed to support synapse formation in people living with Alzheimer's Disease.

How does Souvenaid work?

There is a growing body of evidence showing that people with Alzheimer's Disease have low levels of certain 'building blocks' (nutrients) and because of their disease, they experience an increased need for such 'building blocks'. Souvenaid provides the nutritional 'building blocks' that are required for synapse formation and memory function.

How does Souvenaid support memory function?

Souvenaid provides the nutrients required, in addition to a person's normal daily dietary intake, to support synapse formation which in turn is associated with memory function. Therefore, Souvenaid nutritionally supports memory function in people during the early stages of Alzheimer's disease.

How should Souvenaid be taken?

Souvenaid must be used under medical supervision. Souvenaid is a single serve drink making it easy and convenient for people to take. It can be drunk straight from the bottle, through a straw or popped into a glass. It comes in three flavours; vanilla, strawberry and cappuccino and tastes best when consumed straight from the fridge.

Can Souvenaid be taken at the same time as medications for AD?

Souvenaid is food for special medical purposes for the dietary management of patients diagnosed with mild/early Alzheimer's Disease. It must be used under medical supervision. Clinical studies have demonstrated that Souvenaid can be used safely alongside commonly prescribed AD medication.

How does Souvenaid taste?

Souvenaid comes in three flavours; vanilla, cappuccino and strawberry. It tastes best when consumed from the fridge.

How long do I need to take Souvenaid?

In order to benefit from taking Souvenaid, it is recommended that one 125mL bottle of Souvenaid should be consumed once a day for a minimum of 6 months. The length of use of Souvenaid by an individual should be determined by their recommending healthcare professional.

I have a family history of AD. Should I take it to prevent it developing in the future? Should I take it 'just in case'?

Souvenaid is indicated for the dietary management of patients with early AD. Souvenaid has not been tested in people who do not have Alzheimer's Disease. You should consult your Doctor about whether it is appropriate to take Souvenaid.

Will Souvenaid protect people from getting AD or stop the progression of the disease?

Souvenaid® is an FSMP (Food for Special Medical Purpose) for the dietary management of early Alzheimer's Disease. It is not intended to prevent the disease nor is it a treatment and it should only be used by people who have already been diagnosed with early AD. It must be used under medical supervision.

I am already taking coconut oil or food supplements for memory loss, will Souvenaid provide additional benefits?

Souvenaid should only be used under medical supervision and this should be discussed with your healthcare professional. Souvenaid is a nutritional drink clinically proven to be beneficial in the dietary management of patients with early AD. Souvenaid must be used under medical supervision. Clinical trials of Souvenaid in combination with coconut oil or food supplements have not been carried out.

Can't I just take fish oil and vitamin supplements to get the same benefits for a fraction of the cost?

This question is best answered by your healthcare professional. Clinical trials directly comparing Souvenaid with fish oil and vitamin supplements have not been carried out.

Can't people living with AD get the same benefits from consuming foods containing the ingredients present in Souvenaid?

Souvenaid contains a unique combination of nutrients at levels difficult to achieve from diet alone.

In early Alzheimer's Disease, dietary intake of nutrients may be affected by worsening of appetite, taste, and smell, which lead to reduced food consumption, food neglect, and changes in food preferences. In addition, research suggests that people with early AD have higher requirements than people without AD for certain nutrients supporting brain function. It would be extremely difficult to modify diet to achieve the right combination of specific nutrients and unreasonable to expect people to eat enough of the right foods.

Are there any contraindications when taking Souvenaid?

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Souvenaid is not suitable for patients with galactosaemia. Galactosaemia is a genetic disease where a person cannot metabolise galactose.

Are there any precautions when taking Souvenaid?

Souvenaid should only be used under medical supervision and this should be discussed with your healthcare professional.

Souvenaid is not suitable as a sole source of nutrition and should only be used in addition to the normal diet.

Souvenaid contains ingredients obtained from milk, fish and soy. People who have an allergy to milk protein, fish or soy may not be able to consume Souvenaid.

Souvenaid is low in gluten (<0.02g/100g).

Souvenaid is low in lactose (<0.02g/100g).

People with diabetes can consume Souvenaid. However, Souvenaid does contain carbohydrate and as with other foods containing carbohydrate, it is advisable for people with diabetes to monitor their blood glucose levels as per normal. Nutricia therefore advise consultation with your diabetes medical team.

Where can I get Souvenaid?

Souvenaid is designed to be used under medical supervision after diagnosis of early Alzheimer's Disease so speak to your healthcare professional. Upon recommendation by your healthcare professional, Souvenaid can be purchased directly from Nutricia via the 'buy Souvenaid' link on the website. It can also be purchased from selected pharmacies.

Attachment 3 – Flow chart

GUIDANCE TOOL DIAGRAM – IS THE PRODUCT A “THERAPEUTIC GOOD”?

