

SOUVENAID

A DIETARY TREATMENT FOR MILD ALZHEIMER'S DISEASE

Souvenaid® is a nutritional supplement for people with mild Alzheimer's disease. It contains a combination of nutrients that are thought to support brain functions affected in early Alzheimer's. Souvenaid is intended to be used under medical supervision. This Help Sheet describes what Souvenaid is, how it works, how it should be used, and who may benefit from its use.

What is Souvenaid?

Souvenaid is a medical food¹ designed to help people with Alzheimer's disease by providing nutrients important for the formation of synapses in the brain (the connections between brain cells that are vital for learning and memory). Souvenaid is taken as a once-daily 125ml drink containing a combination of nutrients. Clinical research trials with Souvenaid have demonstrated some improved scores on memory tests in people with early or mild Alzheimer's disease. However, in other clinical trials Souvenaid failed to slow cognitive decline in people with mild to moderate Alzheimer's disease.

Souvenaid is designed to support memory function. It is not a cure for Alzheimer's disease and it will not stop the disease from progressing over time.

Who makes Souvenaid?

Souvenaid is produced by Nutricia Advanced Medical Nutrition, a healthcare division of the multi-national French food company, Danone. Souvenaid is manufactured in The Netherlands.

What does Souvenaid contain?

Souvenaid contains a patented combination of nutrients. The levels of individual nutrients in Souvenaid would be difficult to obtain from a normal diet alone. The nutrients in Souvenaid include uridine monophosphate, choline, fish oil (EPA and DHA omega-3 fatty acids), phospholipids, vitamin C, vitamin E, selenium, vitamin B6, vitamin B12 and folic acid². Research suggests each of these is important for brain health, in building healthy cell membranes and connections between cells, and in maintaining brain functions including memory.

How is Souvenaid taken?

Souvenaid comes as a drink in a 125ml bottle and is available in two flavours; vanilla and strawberry. The recommended dose is one bottle of Souvenaid once a day. It is recommended Souvenaid is consumed chilled (only for taste). It does not matter what time of day Souvenaid is taken, or whether you take it with or without food. Souvenaid is not suitable as a sole source of nutrition and should only be used in addition to the normal diet, not as a meal replacement. Souvenaid should be taken in conjunction with a balanced healthy diet and exercise program as recommended for people with mild Alzheimer's disease.

Who is Souvenaid suitable for?

Souvenaid is for people who have been medically diagnosed as being in the early stages of Alzheimer's disease. People wanting to know if Souvenaid is suitable for them should always discuss this with their doctor.

Any clinical benefit of Souvenaid has so far only been demonstrated in people with early or mild Alzheimer's disease. A clinical trial involving people with moderate stage Alzheimer's disease failed to demonstrate any benefits of Souvenaid at this later stage of the illness. There is no data available regarding the use of Souvenaid in people who do not have Alzheimer's disease, such as those with other forms of dementia, those with mild cognitive impairment, those with concerns about their memory, or those wanting to prevent dementia. Souvenaid is therefore not recommended for use by anyone other than people with mild Alzheimer's disease.

FIGHTDEMENTIA.ORG.AU NATIONAL DEMENTIA HELPLINE 1800 100 500

Who is Souvenaid NOT suitable for?

Souvenaid is not suitable for people with galactosaemia (a rare genetic disorder of galactose metabolism). Souvenaid contains ingredients obtained from milk, fish/seafood and soy, and should not be used by people with allergies to any of these. Souvenaid is gluten and lactose free.

What benefits should I expect to see?

As with any medical intervention, the benefits of Souvenaid will vary from person to person. The clinical trials of Souvenaid to date have only reported scores on standard cognitive tests. They have not investigated the effects of Souvenaid on everyday memory abilities, activities of daily living, mood, behaviour, or quality of life. It is not possible to say whether individuals or their families will notice any difference from taking Souvenaid. Some may notice improvement, while others will not see any change.

Alzheimer's is a progressive disease in which we expect to see brain function (including memory abilities) gradually deteriorate. As with the four currently approved medications for Alzheimer's disease, Souvenaid is designed to support brain function, and may temporarily alleviate or slow down the progression of symptoms. However, neither Souvenaid nor the approved medications can stop the underlying disease progression. So an individual person taking Souvenaid may not notice any improvements and their symptoms will inevitably get worse over time.

How long should Souvenaid be used?

To derive benefits from Souvenaid, Nutricia recommends it should be taken for a minimum of 3 months. There has not as yet been any research to determine the optimum length of time Souvenaid should be used by a person with Alzheimer's disease. The length of use of Souvenaid by any individual should be determined by their healthcare professional, taking into account any effects it is having and any changes in the person's condition and needs over time.

Are there any side-effects?

No side-effects of Souvenaid have been reported. The findings of the clinical trials conducted to date suggest Souvenaid is safe and well-tolerated. There are also no reported interactions with any medications.

Can Souvenaid be used in combination with other Alzheimer's treatments?

Souvenaid can be taken at the same time as the currently approved medications for Alzheimer's disease (donepezil, rivastigmine, galantamine and

memantine). This was tested in a clinical trial which found Souvenaid was well tolerated in combination with medications for Alzheimer's, however, the trial found no evidence of benefit from taking Souvenaid in combination with medication.

For information on the approved drug treatments for Alzheimer's disease, see Dementia Q&A Sheet 1 *Drug treatments for Alzheimer's disease – Cholinesterase inhibitors*, and Dementia Q&A Sheet 3 *Drug treatments for Alzheimer's disease – Memantine*.

Where can I get Souvenaid?

Souvenaid can be purchased at Australian pharmacies. Souvenaid does not require a prescription from a doctor, however, it is recommended that its use is supervised by a healthcare professional. Souvenaid can also be purchased directly from Nutricia, online at souvenaid.com.au, or call Nutricia Customer Service on 1800 884 367.

How much does Souvenaid cost?

The recommended retail price (RRP) for Souvenaid is \$4.16 per bottle, and this is the price charged by Nutricia if buying directly from them. The price may vary between pharmacies, but the cost of taking Souvenaid daily as recommended will be around \$130 per month. There is no government subsidy available for Souvenaid, so the full cost must be borne by the consumer.

However, for veterans, the RPRC (Repatriation Pharmaceutical Reference Committee) will assess Department of Veterans Affairs (DVA) funding applications for Souvenaid on a case-by-case basis. RPRC applications must be submitted by a clinician and certain criteria must be fulfilled for funding to be approved. This funding is applicable to all DVA Gold card holders.

How does Souvenaid work?

Alzheimer's disease causes damage to synapses, the connections between brain cells through which signals are transmitted in order for the brain to perform its many functions. As synapses are damaged and lost, brain function becomes impaired. Typically in early Alzheimer's, synaptic loss occurs in brain regions important for memory function.

A working synapse relies on healthy brain cell membranes (the outer layer of the cell). The nutrients in Souvenaid have been shown to be important for building cell membranes and synapses. People with Alzheimer's disease may have low levels of these nutrients, when because of their disease they have an increased need for them.

Souvenaid is designed to provide nutrients that can

2 SOUVENAIID

support synapse formation and function, and hence memory function, in people with mild Alzheimer's disease. It cannot stop Alzheimer's disease from progressing, only provide support for one of the problems that the disease causes.

What is the evidence that Souvenaid helps people with Alzheimer's?

Three clinical trials to date have been conducted on Souvenaid. The results point to modest improvements in memory performance, only in people with mild Alzheimer's disease. Further studies are underway to determine the effects of Souvenaid over longer timeframes and in people with mild cognitive impairment.

The Souvenir I study³ involved 225 people with mild Alzheimer's disease (Mini-Mental State Examination (MMSE) scores 20-26). Half the participants took Souvenaid for 12 weeks and half took a placebo (a similar drink but without the nutrients in Souvenaid). Souvenaid was well tolerated and improved memory performance on a delayed verbal recall test. However, there was no change in the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog), a test widely used to assess the effects of Alzheimer's treatments.

The S-Connect study⁴ involved 527 people with mild-to-moderate Alzheimer's disease (MMSE scores 14-24). All participants were on stable use of an Alzheimer's medication (a cholinesterase inhibitor and/or memantine). Half the participants took Souvenaid for 24 weeks and half took a placebo. There was no difference in ADAS-Cog score changes between the Souvenaid and placebo groups. Souvenaid was well tolerated in combination with standard medication for Alzheimer's disease.

The Souvenir II study² involved 259 people with mild Alzheimer's disease (MMSE scores ≥ 20). Half the participants took Souvenaid for 24 weeks and half took a placebo. Souvenaid modestly improved the memory score of the Neuropsychological Test Battery. Souvenaid also improved measures of brain electrical activity suggesting increased synaptic activity in the brain.

Based on these findings, Souvenaid is only recommended for people with early or mild Alzheimer's disease. There is no evidence available that it helps at moderate or later stages of the disease, or for people with other forms of dementia, or to prevent dementia, but future research may change this.

Further information

People with mild Alzheimer's disease and their families or carers wanting to know more about Souvenaid and whether it may be suitable for them should speak to their doctor. Information about Souvenaid is also available from souvenaid.com.au or the Souvenaid Helpline on 1800 038 314.

For healthcare professionals, further information on Souvenaid is available from hcp.souvenaid.com.au or from the Nutricia Clinical Care Line on 1800 060 051.

Notes and References

1. A 'medical food' is defined by the US Food and Drug Administration as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognisable scientific principles, are established by medical evaluation". In Australia, Souvenaid is classified as a 'Food for Special Medical Purposes' under Standard 2.9.5 of the Food Standards Code of Food Standards Australia New Zealand.
2. Scheltens P, et al. Efficacy of Souvenaid in mild Alzheimer's disease – results from a randomised, controlled trial. *J Alzheimers Dis.* 2012;31:225-236.
3. Scheltens P, et al. Efficacy of a medical food in mild Alzheimer's disease: a randomized controlled trial. *Alzheimer's & Dementia.* 2010;6:1-10.
4. Shah R, et al. The S-Connect study: results from a randomized, controlled trial of Souvenaid in mild-to-moderate Alzheimer's disease. *Alzheimer's Research & Therapy.* 2013;5:59.

FURTHER INFORMATION

Alzheimer's Australia offers support, information, education and counselling. Contact the National Dementia Helpline on **1800 100 500**, or visit our website at fightdementia.org.au



For language assistance phone the Translating and Interpreting Service on **131 450**

SOUVENAID 3