

Souvenaid - a dietary treatment for mild Alzheimer's disease

Souvenaid[®] is a nutritional supplement that contains a combination of nutrients that are thought to support brain functions affected in early Alzheimer's. Medical advice should be sought before using Souvenaid. This sheet describes what Souvenaid is, how it might work, how it is recommended to be used, and the evidence for it providing benefit.

What is Souvenaid?

Souvenaid is a nutritional supplement¹ containing nutrients important for the formation of synapses in the brain (the connections between brain cells that are vital for learning and memory). The company that makes Souvenaid recommend that Souvenaid is taken as a once-daily 125ml drink. Limited research has been conducted on Souvenaid. Two studies in people with mild Alzheimer's disease suggest that people who drank Souvenaid were more likely to experience small improvements in test of memory function. A third randomized controlled trial in mild to moderate dementia due to Alzheimer's disease failed to show a significant effect of Souvenaid in decreasing the rate of cognitive decline or delaying Alzheimer's disease progression. A fourth trial, conducted independently of Nutricia, in mild cognitive impairment due to Alzheimer's disease demonstrated a reduced rate of cognitive decline and a reduced loss of hippocampal volume after three years of use. Souvenaid may support memory function but 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, including uridine monophosphate, choline, 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.

How does Souvenaid work?

The mechanism is not known. However, the nutrients in Souvenaid are important for building cell membranes and synapses. Alzheimer's disease causes damage to synapses, the connections between brain cells through which signals are transmitted. As synapses are damaged and lost, brain function becomes impaired. Supplementing the diet with the nutrients in Souvenaid is thought to support the building of synapses. Currently there is no evidence that this actually occurs.

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

Three clinical trials to date have been conducted on Souvenaid by Nutricia.

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 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.

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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.

A trial in 311 people with prodromal Alzheimer's disease (also known as Mild Cognitive Impairment due to Alzheimer's disease), funded by the European Union, showed a modest improvement in some memory measures and in the Clinical Dementia Rating scale in those on Souvenaid compared to those on placebo. Three-year data (unpublished) shows the primary endpoint, a selection of five measures from the Neuropsychological Test Battery, was significantly improved in those on Souvenaid compared to those on placebo, and there was significantly less loss of hippocampal volume in those on Souvenaid, suggesting a biological mechanism for the improvement on cognition and overall function.

There is currently insufficient evidence to recommend the routine use of Souvenaid in people with moderate to advanced Alzheimer's disease. Souvenaid should be considered as one option for people with mild cognitive impairment and mild dementia due to Alzheimer's disease.⁵

How is Souvenaid taken?

Souvenaid comes as a drink in a 125ml bottle and is available in three flavours; vanilla, cappuccino and strawberry. The dose recommended by Nutricia is one bottle of Souvenaid once a day. 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.

Who is Souvenaid suitable for?

Souvenaid is marketed to 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.

A clinical trial involving people with moderate stage Alzheimer's disease failed to demonstrate any benefits of Souvenaid³. 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 concerns about their memory, or those wanting to prevent dementia.

Who is Souvenaid NOT suitable for?

According to Nutricia, 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?

The clinical trials of Souvenaid which have been conducted by Nutricia 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.

Alzheimer's is a progressive disease in which we expect to see brain function (including memory abilities) gradually deteriorate.

How long should Souvenaid be used?

To derive benefits from Souvenaid, Nutricia recommends it should be taken for a minimum of 6 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 use of Souvenaid by any individual should be discussed with their healthcare professional.

Are there any side-effects?

One study conducted by Nutricia investigated once-daily use of Souvenaid in 201 people with mild Alzheimer's Disease³. This study indicated that Souvenaid was well-tolerated. Some subjects reported adverse events such as dizziness, diarrhoea and headache while taking Souvenaid. However the percentage of people reporting adverse events was similar to a control group who did not use Souvenaid.

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

A clinical trial conducted by Nutricia 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 sheets *Dementia Q&A 1 Drug treatments for Alzheimer's disease – Cholinesterase inhibitors*, and *Dementia Q&A 3 Drug treatments for Alzheimer's disease – Memantine*.

Where can I get Souvenaid?

Souvenaid can be purchased at Australian pharmacies or directly from Nutritica. Souvenaid does not require a prescription from a doctor, however, it is recommended that its use is supervised by a healthcare professional.

How much does Souvenaid cost?

The recommended retail price (RRP) for Souvenaid is approximately \$4 per bottle. 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.

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.

Notes and References

- 1 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.
- 5 Soininen et al. 24-month intervention with a specific multivitamin in people with prodromal Alzheimer's disease (LipiDiDiet): a randomized, double-blind, controlled trial. 2017:16