

Goat serum (Aimspiro)

Fact Sheet

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We hope you find the information in this factsheet helpful. If you would like to speak with someone about any aspect of MS, contact the MS Trust information team and they will help find answers to your questions.

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MS Trust information service

Helping you find the information you need

The MS Trust offers a wide range of publications, including a newsletter *Open Door*, which provides an ongoing update on research and developments in MS management. In addition it contains articles from people with MS and health professionals.

For a full list of MS Trust publications, to sign up for Open Door and much more visit our website at www.mstrust.org.uk

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1.Introduction

Aimspro is the brand name of an experimental product derived from the serum of goats that have been inoculated with a number of vaccines so as to develop antibodies to a range of diseases. Serum is the liquid component of blood, in which the blood cells, clotting agents and other cells are suspended.

Aimspro was initially put forward as a treatment for HIV/AIDS. Little success was shown in that area but researchers thought the strong anti-inflammatory properties of the goat serum could be beneficial in MS.

Aimspro is developed and manufactured by Daval International.

2. Research

There is currently no peer reviewed published evidence of efficacy or long-term safety for this treatment.

Aimspro was initially given, by weekly injection, to people with MS by a GP in Kent as an experimental treatment. Data gained from these patients suggested a significant clinical improvement and this information was used to help obtain approval for two double-blind, randomised, placebo-controlled trials in the UK.

3. Trials involving goat serum and MS

There have been two small trials of Aimspro in the UK. The first, at St George's Hospital in London, involved 40 people with secondary progressive MS who were able to walk, but who had seen a significant decline over the past year. This trial was halted at the manufacturer's request in March 2005.

The second trial was carried out at the John Radcliffe Hospital in Oxford¹. The trial recruited 12 people who had some continuing loss of vision following earlier optic neuritis. Participants were on active treatment for two weeks. Researchers found that the two main outcome measures of the trial, looking at the effect on vision, were negative. A third outcome measure, the effect on visual field size, showed transient improvement in people on Aimspro not seen in the placebo group who had received an inactive dummy drug. However, this effect was not significantly different from placebo. The drug was well tolerated and no serious side effects were observed during the short course of the trial.

A phase II study at the Royal Free Hospital in London is looking at Aimspro as a possible treatment for bladder problems in secondary progressive MS². The manufacturer's website announced in June 2011 that this trial is complete³. As yet no results have been published.

4. Being prescribed goat serum

Aimspro is not licensed in the UK and its availability is based on a special licence.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the body that licenses drugs in the UK. Part of the MHRA's role is to ensure that products are manufactured and supplied lawfully. For unlicensed products such as Aimspro, there are exemptions for people who have clinical needs that cannot be met by licensed medicines. In order to meet these particular needs the law allows for the manufacture and supply of unlicensed medicines - known as 'specials' - subject to certain conditions. Specials may not be advertised or promoted.

Prescription is on a named patient basis. Named patient prescribing is a scheme that allows a doctor to prescribe an unlicensed drug to a particular named patient. Supply has to be arranged by the doctor and the manufacturer on an individual basis. Drugs prescribed on a named patient basis are on the direct responsibility of the prescribing doctor. Funding for named patient prescriptions may or may not be accepted by the local primary care trust. Aimspro is expected to cost about £180 per vial, with users needing to inject once or twice a week.

Doctors willing to undertake prescription can contact the manufacturer, Daval International, through their website – www.davalinternational.com

5. References

1. Burke G, Cavey A, Matthews P, Palace J. The evaluation of a novel 'goat serum' (Aimspro) in multiple sclerosis. Proceedings of the Association of British Neurologists; 2005 Mar 30-Apr 1; Queens University of Belfast, Ireland. *Journal of Neurology Neurosurgery and Psychiatry* 2005;76:1326.
2. Clinicaltrials.gov website. Aimspro in the treatment of bladder dysfunction in secondary progressive multiple sclerosis. [Cited 05 Apr 2012] Available from URL: www.clinicaltrials.gov/ct2/show/NCT01228396
3. Daval International announces completion of phase II trial in multiple sclerosis. Daval International news item - 6 June 2011. [Cited 05 Apr 2012] Available from URL: www.davalinternational.com/news/news_4.html

Please contact the MS Trust Information Team if you would like any further information about reference sources used in the production of this publication.