

## Copaxone® for multiple sclerosis (RRMS)

### Review Question:

What is the effect of Copaxone® in people with RRMS and SPMS/PPMS?

### The short answer:

The research suggests that for people with RRMS and SPMS/PPMS, Copaxone® does not prevent disability getting worse. However, it may slightly reduce the chance of having a relapse for people with RRMS. Common side effects include flushing, chest tightness, sweating, palpitations, anxiety and local injection-site reactions. Copaxone® does not appear to cause any major side effects.

This is the printable version of an online resource providing plain language summaries of high quality research about MS treatments. Visit the **Making Sense of MS Research** web site (or the back page of this document) to learn more [www.makingsenseofMSresearch.org.au](http://www.makingsenseofMSresearch.org.au)

### THE SHORT ANSWER

This is a summary of the research about the effect of Glatiramer Acetate (Copaxone®) in people with relapsing and progressive forms of MS, written in plain language for people with MS and their family members. It is based on a report (known as a systematic review) that was produced by The Cochrane Collaboration.

In August 2009, the authors of the report searched for all the randomised controlled trials (RCTs) on this topic and combined the results. They aimed to provide an overall picture of whether Copaxone® is effective in treating MS. They found six trials, including 540 people with relapsing-remitting multiple sclerosis (RRMS) and 1049 people with secondary progressive MS (SPMS) primary progressive multiple sclerosis (PPMS). As at August 2012, there are no new RCTs conducted in this area.



Up to date as at August 2012

## THE DETAILED ANSWER

### For people with RRMS: Relapses

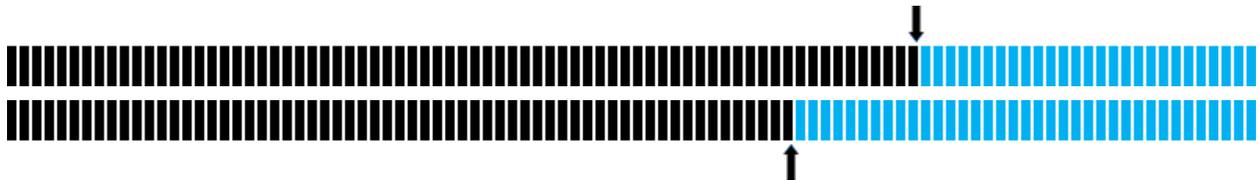
For people with RRMS, taking Copaxone® **may slightly decrease** the chance of having a relapse over two years.

*In words*

- **Without** Copaxone®, **73 per 100** people would have one or more relapses over two years and 27 would not
- **With** Copaxone®, **63 per 100** people would have one or more relapses over two years and 37 would not
- Therefore with Copaxone®, **10 fewer people** per 100 would have one or more relapses over two years compared to without Copaxone®

*In pictures*

**Without** Copaxone®, **73 per 100** people with MS are estimated to one or more relapses



**With** Copaxone®, **63 per 100** people with MS are estimated to one or more relapses

In technical terms, the result was just statistically significant, the confidence intervals touched 1 and the upper boundary was high. This means the effect of Copaxone® was unlikely to be due to chance alone.

### Do these results look different from what you've read elsewhere?

See the back page of this treatment summary for an explanation. You can also discuss the results with your local MS Australia office.

## For people with RRMS: Disability

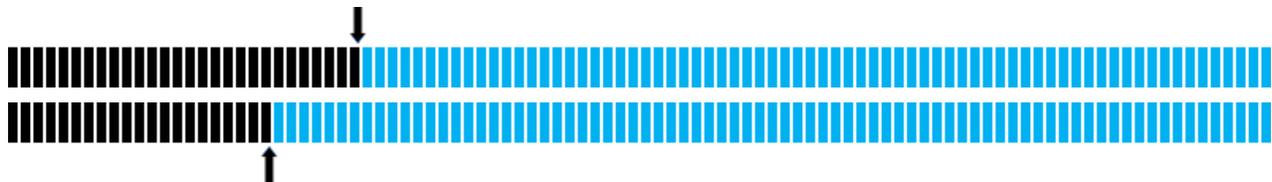
For people with relapsing-remitting multiple sclerosis (RRMS), we are uncertain about the effect of taking Copaxone® for **two years** on the chance of disability getting worse.

*In words*

- **Without** Copaxone® **28 per 100** people would experience worsening disability over two years and 72 would not
- **With** Copaxone® **21 per 100** people would experience worsening disability over two years and 79 would not
- Therefore with Copaxone® **7 fewer** people per 100 would experience worsening disability over two years compared to without Copaxone®

*In pictures*

**Without** Copaxone®, **28 per 100** people with MS are estimated to have worsening disability



**With** Copaxone®, **21 per 100** people with MS are estimated to have worsening disability

In technical terms, the result was not statistically significant, the confidence intervals crossed 1 and the boundaries were wide. This means the effect of Copaxone® could easily have occurred by chance alone and the effect in the broader MS population could be variable.

### Do these results look different from what you've read elsewhere?

See the back page of this treatment summary for an explanation. You can also discuss the results with your local MS Australia office.

## THE DETAILED ANSWER

### For people with SPMS/PPMS: Disability

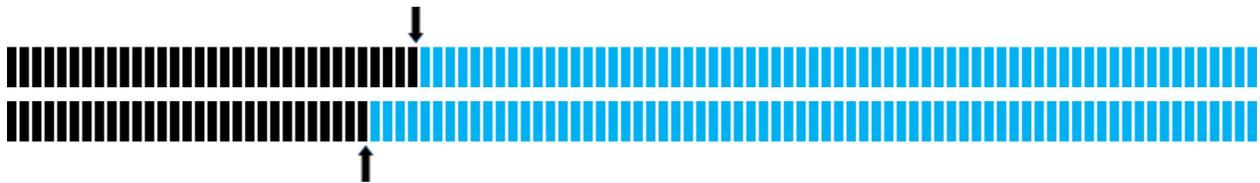
For people with secondary progressive MS (SPMS) and primary progressive MS (PPMS) we are uncertain about the effect of taking Copaxone® on the chance of disability getting worse over two years.

*In words*

- **Without** Copaxone® **33 per 100** people would experience worsening disability over two years and 67 would not
- **With** Copaxone® **29 per 100** people would experience worsening disability over two years and 71 would not
- Therefore with Copaxone® **4 fewer** people per 100 would experience worsening disability over two years compared to without Copaxone®

*In pictures*

**Without** Copaxone®, **33 per 100** people with MS are estimated to experience worsening disability



**With** Copaxone®, **29 per 100** people with MS are estimated to experience worsening disability

In technical terms, the result was not statistically significant, the confidence intervals crossed 1 and the boundaries were moderately wide. This means the effect of Copaxone® could easily have occurred by chance alone and the effect in the broader MS population could be variable.

#### Do these results look different from what you've read elsewhere?

See the back page of this treatment summary for an explanation. You can also discuss the results with your local MS Australia office.

## Side effects

Copaxone® was not associated with any serious side effects.

People who took Copaxone® were more likely to experience the following side effects

- Immediately after injecting, people with Copaxone® reported feeling a combination of feeling flushed, chest tightness, sweating, heart palpitations and anxiety. This went away within 30 minutes.

Other side effects that people who took Copaxone® were more likely to experience

- heart palpitations
- shortness of breath
- injection site reactions (including itching, swelling, redness, and pain)

Taking Copaxone® was not associated with an increased risk of

- headache
- anxiety
- feeling lightheaded
- drowsiness
- cramps
- joint pain
- appetite loss
- constipation
- abdominal discomfort
- nausea and vomiting

## WHAT IS THIS TREATMENT?

Glatiramer acetate (Copaxone®) is a synthetic protein made up of a combination of four amino acids, which are the natural building blocks of protein in the body. It is thought to work by connecting cells to stop them attacking the myelin. It is administered by a daily injection given under the skin.

Taken from: *Understanding MS : An introduction for people living with MS*, MS Australia 2012

## What we don't know from the results of this review

The research is unclear about the effect of Copaxone® on the chance of disability getting worse. Because the studies in this review only went for up to three years we don't know the effect of Copaxone® on MS in the longer term.

## What about the quality of the included studies?

Overall, the quality of these results is low. The studies were randomised controlled trials (RCTs), which are considered the most rigorous study design that minimises the risk of misleading results. However, the RCTs had a number of flaws in them. As such, the effects of Copaxone® on the chance of disability getting worse are uncertain.

## The really detailed answer

For more information, or to read about the individual studies included in this review, you can access the Cochrane review on which this treatment summary is based:

- LaMantia L, Munari LM, Lovati R. Glatiramer acetate for multiple sclerosis. Cochrane Database of Systematic Reviews 2010, Issue 5.

## DOES THIS APPLY TO ME?

When deciding if this information applies to you it's helpful to think about how similar you are to the people that were included in the studies.

## What we know about the people included in the Interferons studies:

- They had RRMS or SPMS/PPMS
- They were aged between 18 to 65 years
- They included people with a range of disability levels

## If I am similar to the people in the studies, can I expect the same results?

It is important to remember that studies deal with averages and statistics. Even if you are similar to the people in the studies, we can't know for sure that you will respond in the same way. What we can say, is that, on average, Copaxone® does not appear to offer significant benefits to people with SPMS/PPMS or RRMS.

Up to date as at August 2012

## QUESTIONS FOR MY HEALTH PROFESSIONAL

You might like to ask your health professional to help you answer the following questions:

- What other options do I have for managing my MS?
- If I get side effects from taking Copaxone®, what are my options to manage these?

## FIND OUT MORE

For more information about Copaxone® you can contact:

- Your health professional or MS Nurse
- Your local MS Australia office

Or, you can Google the following web-based resources:

- Copaxone (Glatiramer Acetate) (National Multiple Sclerosis Society)

## Would you like to talk to someone about this?

Information can be unsettling or overwhelming, particularly when it relates to making a decision that requires weighing up difficult choices. Finding out about possible side effects can be scary. Inconclusive or negative findings can be frustrating or confusing.

If you would like to talk to someone about the information that is presented here, please contact your local MS Australia office on the details below

### MS Australia – ACT/NSW/VIC

Free call: 1800 042 138 (from all three states)

E: [msconnect@msaustralia.org.au](mailto:msconnect@msaustralia.org.au)

### MS Australia – Queensland

P: (07) 3840 0888

Freecall: 1800 287 367

E: [info@msqld.org.au](mailto:info@msqld.org.au)

### MS Australia – SA & NT

P: (08) 7002 6500

E: [info@ms.asn.au](mailto:info@ms.asn.au)

### MS Australia – Tasmania

P: (03) 6220 1111

E: [aboutus@mstas.org.au](mailto:aboutus@mstas.org.au)

### Multiple Sclerosis Society of WA

P: (08) 9365 4888

Country callers: 1800 287 367

E: [enquiries@mswa.org.au](mailto:enquiries@mswa.org.au)



These summaries have been derived from Cochrane reviews published in the Cochrane Database of Systematic Reviews in The Cochrane Library. Their content has, as far as possible, been checked with the authors of the original reviews, but the summaries should not be regarded as an official product of the Cochrane Collaboration.

Up to date as at August 2012

## ABOUT THIS MS TREATMENT SUMMARY

The results presented here are only one piece of the information jigsaw you might need to make a decision

### Where does the treatment summary information come from?

We have based our treatment summaries on systematic reviews, produced by the Cochrane Collaboration. The Cochrane Collaboration is recognised as a world leader in the production of independent, high-quality research about health care.

A systematic review is a report that sums up the best available research on a particular topic. This allows the results from a number of studies to be pooled together. The authors follow careful procedures and look at the strength of the evidence to make informed conclusions about the overall findings. Systematic reviews help us to decide if treatments work and whether any more research needs to be done. Systematic reviews of multiple studies are generally considered more convincing than just looking at the results of single studies alone.

### This information is only one piece of the information jigsaw

We present how well this treatment works *on average* because that is the way the research is conducted. How an individual responds might be different. Each summary is only one piece of the information jigsaw. If you are making a decision, the complete jigsaw would include other pieces, such as your preferences, your health professional's clinical experience, and other pieces of information, such as how treatments work over a long time span. Please talk to your health professional or local MS Australia staff for more information.

### Why might these results look different from what I've seen elsewhere?

There can be a number of different reasons for this, including:

- Cochrane Collaboration researchers may analyse the results of the studies in different ways from the original study authors. They do this if they think this will provide a more accurate estimate of how well the treatment works. This may lead to more conservative findings.
- Usually, Cochrane reviews only include the highest quality research. High-quality research tends to provide more conservative estimates of how well a treatment works. Less rigorously designed studies can overestimate the effectiveness of treatments.
- There are ways of presenting statistics that look more or less convincing. We have tried to present the results in an understandable and accurate way that does not overstate their effect
- It is also important to note that health professionals and MS Australia rely on a range of research on which to base their advice about MS treatments. Cochrane reviews rely on information collected in clinical studies, often randomised controlled trials. This doesn't always give a complete picture about treatments. For example, long term follow up studies are needed to suggest how well MS treatments work over 10 or 20 years, or to learn about side-effects.

Up to date as at August 2012