

The pharmacological management of back pain and sciatica in adults: a pragmatic, randomised controlled, adaptive platform trial of analgesic ladders. The MEDAL trial.

Treatment information for Ladder E

Version 2.0, 17-Sep-2024

Thank you for taking part in the MEDAL trial. Please do help us by filling in the questionnaires through the app when you receive them. This will greatly help us with the quality of the data and identify the best way to treat disabling back pain for everyone.

Your medications

You have been randomised to **Ladder E**

Your GP will have prescribed the first step medication of Ladder E (Co-codamol 30/500 2 tablets four times daily). Please take this for at least 3 days. If you feel the medication isn't controlling your pain, then you can contact your GP practice and they can issue you the next step of medication. You **do not** need an appointment for this unless you would like to see your GP.

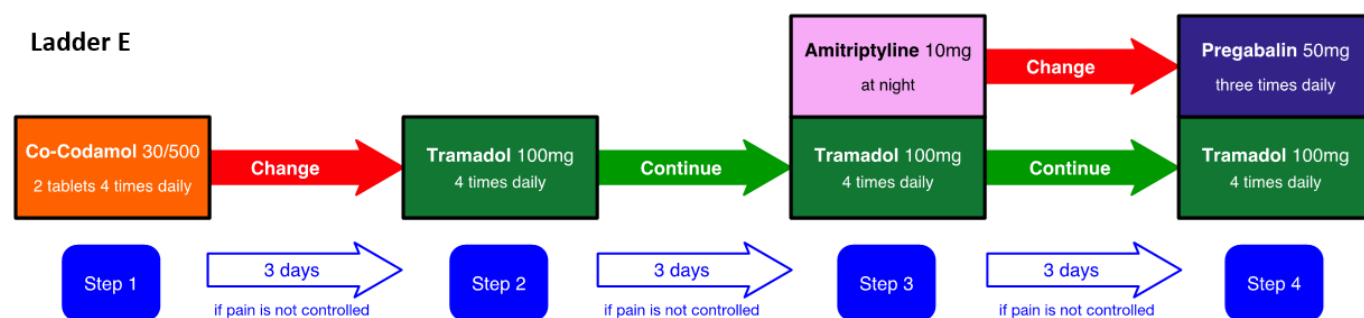
The instructions for your medications are as follows:

Step 1: Co-codamol 30/500 2 tablets four times daily

Step 2: Stop Co-codamol 30/500 and add Tramadol 100mg four times daily.

Step 3: Add Amitriptyline 10mg at night.

Step 4: Stop Amitriptyline 10mg and start Pregabalin 50mg three times daily.



At any step of the medication ladder, **if your pain is controlled for 5 days in a row**, you will not need to go up any more steps of the ladder.

Ladder E

Once you have started on the medication ladder, **PLEASE DO NOT** take any over the counter medications. This could impact on the effectiveness of the trial ladder medications but more importantly may interact with some of the medications on the ladder or result in over-dose (for example some of the medications being trialled contain paracetamol).

You can seek other therapies should you want to, whether physical (e.g. physiotherapy), complementary (e.g. acupuncture) or herbal (e.g. Turmeric, with the approval of your GP) but please do record these in the app.

All medications have the potential for side-effects, but fortunately these are unusual. Sometimes your GP may prescribe a medication to reduce the risk of side-effects especially if you are at risk of developing them because of other illnesses or medications you might be taking.

The side-effects most commonly seen for the medications you have been prescribed in Ladder E are:

Co-Codamol: Constipation, feeling sick, feeling dizzy, feeling sleepy, headaches.

Tramadol: Feeling sick, feeling dizzy, headaches, feeling sleepy or tired, constipation, dry mouth sweating, low energy

Amitriptyline: Constipation, feeling dizzy, dry mouth, feeling sleepy or tired, headache difficulty passing urine.

Pregabalin: Feeling sleepy tired or dizzy, feeling sick, diarrhoea, mood changes, blurred vision, dry mouth, memory disturbance, headaches, difficulty getting an erection, getting more infections, arm or leg swelling, weight gain.

Pregabalin should never be taken during pregnancy.

As pregabalin is part of this ladder, there is an absolute requirement for a monthly pregnancy test during the trial even if you are using an effective method of contraception. This is really important for your safety. We will provide the pregnancy test kit when required.

A full description of your medications can be found by scanning the QR code using your smartphone camera at the end of this sheet.

You do not need to report these side-effects to your GP if you experience them but recording them in the MEDAL App diary will help us with developing the best approach to back pain treatment. If you are suffering other side-effects or you feel the side-effects are too severe for you, please contact your GP for a review.



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Please call 999 immediately if you experience any of the following symptoms after taking your medications:

- Difficulty breathing
- Swollen lips or tongue
- Wheezy chest
- Severe worsening rash

Please contact your GP immediately, or attend your nearest accident and emergency department without delay, if you experience any of the following symptoms, which may indicate that your back problem has become more serious:

- Numbness around your bottom
- Sudden weakness in one or both legs
- Loss of control of your bladder or bowel or loss of sensation of your bladder

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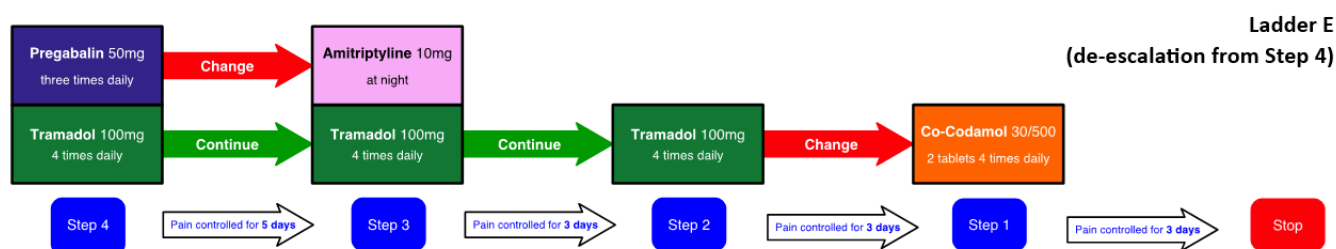
How to reduce your medications

If the prescribed ladder medication(s) have controlled your back pain well **for 5 days in a row**, then you can consider reducing and stopping your medication, but this can be guided by your own assessment of how your symptoms are.

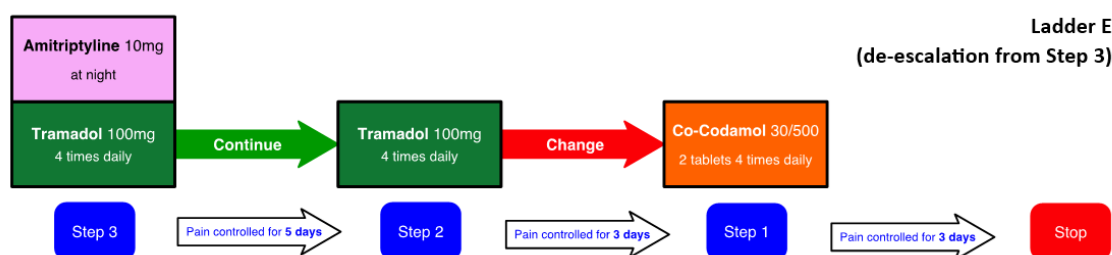
It is safe to simply stop all your medications at once. However, there is a risk that your pain may return and so we advocate a process of reducing the medications according to the step that you have reached on your medication ladder.

If after reducing your medications at any step you find your pain isn't controlled, continue taking that step medication until your pain has been controlled for 3 days, then continue to reduce your medications as described below.

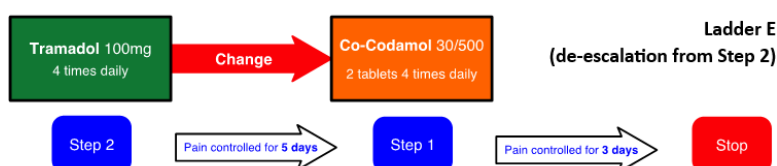
If you reached Step 4: If pain is adequately controlled, go to step 3 by stopping Pregabalin 50mg, re-starting Amitriptyline 10mg at night, while continuing Tramadol 100mg 4 times daily. If pain continues to be adequately controlled, you can continue going down one more step every 3 days.



If you reached Step 3: If pain is adequately controlled, go to step 2 by stopping Amitriptyline 10mg at night, while continuing Tramadol 100mg 4 times daily. If pain continues to be adequately controlled, you can continue going down one more step every 3 days.

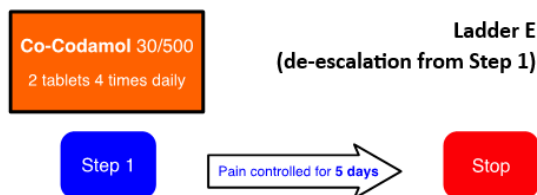


If you reached Step 2: If pain is adequately controlled, go to step 1 by stopping Tramadol 100mg and re-starting Co-codamol 30/500 2 tablets 4 times daily. If pain continues to be adequately controlled, you can continue going down a further step after 3 days.



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If you reached Step 1: If pain is adequately controlled for 5 days, you can stop Co-codamol 30/500, which will stop all medication from the Ladder.



If after reducing your medications at any step you find your pain isn't controlled, continue taking that step medication until your pain has been controlled for at least 3 days, then continue to reduce your medications as described above.

If your pain gets worse or you develop new or different symptoms while reducing your medication, please arrange a review with your GP.

Again, we very much thank you for taking part in the MEDAL trial and contributing to developing a more effective approach to treating back pain. Please do complete the questionnaires fully to ensure we get the best quality data we can.




Should you have any questions or problems please contact the MEDAL trial team:

Telephone: 0121 414 8528

Email: MEDAL@trials.bham.ac.uk

Ladder E

For more information on the medications in your ladder, scan the following QR codes using your smartphone camera.

<u>Tramadol</u>	
<u>Co-Codamol</u>	
<u>Amitriptyline</u>	
<u>Pregabalin</u>	