

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 B

Version 1.0, 21-May-2024

Thank you for taking part in the MEDAL trial. Please help us by filling in the questionnaires through the MEDAL App whenever 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 B**

Your GP will have prescribed the first step medication of Ladder B (Naproxen 500mg twice daily with food). 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.

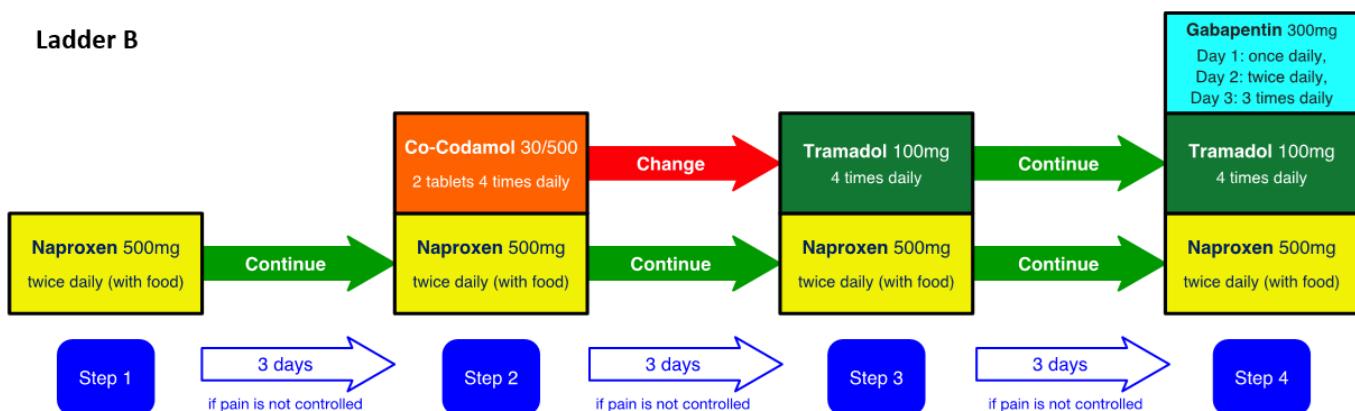
The instructions for your medications are as follows:

Step 1: Naproxen 500mg twice daily (with food)

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

Step 3: Stop Co-codamol 30/500 and add Tramadol 100mg four times daily.

Step 4: Add Gabapentin 300mg Day 1 once daily, Day 2 twice daily, Day 3 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 B

Once you have started on the treatment 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 MEDAL 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 B are.

Naproxen: Confusion, headache, ringing in ears, vision changes, feeling sleepy or tired, feeling dizzy, rashes.

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

Gabapentin: Headaches, feeling sleepy, tired or dizzy, diarrhoea, mood changes, feeling sick swollen hands, arms, legs and feet, blurred vision, difficulties with getting an erection, memory problems and weight gain (because Gabapentin can make you feel hungry).

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.

Ladder B

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.

Ladder B

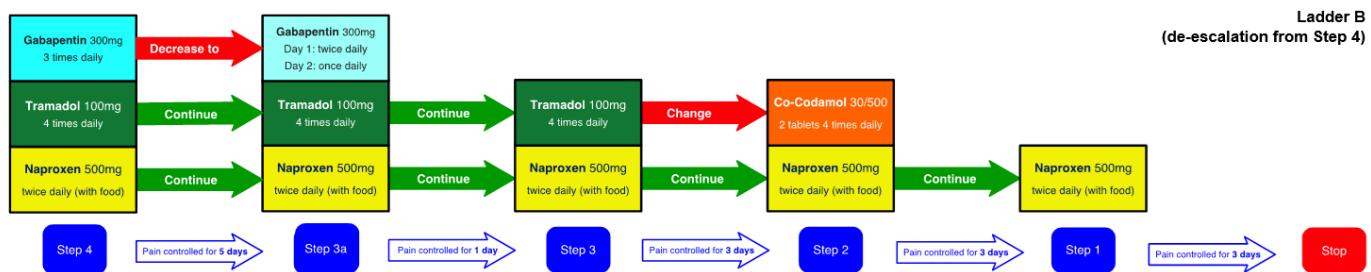
How to reduce your ladder medications

If the prescribed 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.

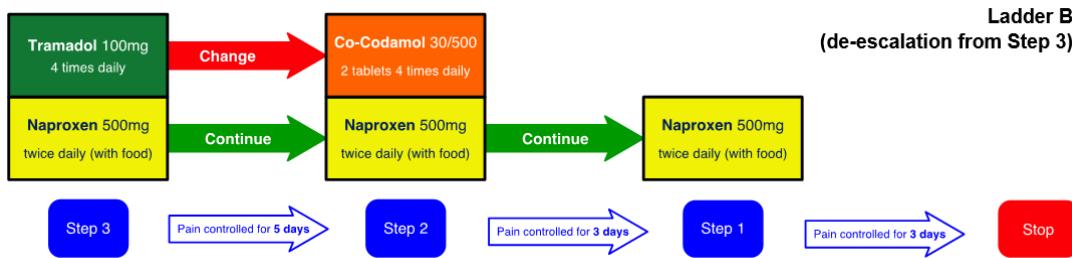
It is safe to simply stop all your medications at once. However, there is a risk that your pain may return and so we advocate a process of reducing the medications according to the step that you have reached on your medication ladder.

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 for 5 days, you can go to step 3 as follows. First, reduce Gabapentin 300mg to twice a day and continue Tramadol 100mg four times daily, and Naproxen 500mg twice daily (with food) for 1 day. Then, reduce Gabapentin 300mg to once a day, continue Tramadol 100mg 4 times daily, and Naproxen 500mg twice daily (with food) for 1 day. Then, stop Gabapentin 300mg, continue Tramadol 100mg 4 times daily, and Naproxen 500mg twice daily (with food). If pain continues to be adequately controlled, you can continue going down one more step every 3 days.

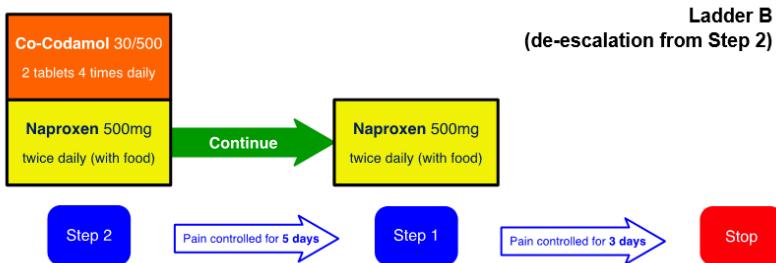


If you reached Step 3: If pain is adequately controlled for 5 days, you can go to step 2. Stop Tramadol 100mg, start Co-codamol 30/500 2 tablets 4 times daily, and continue Naproxen 500mg twice daily (with food) for 3 days. If pain continues to be adequately controlled, you can continue going down one more step every 3 days.

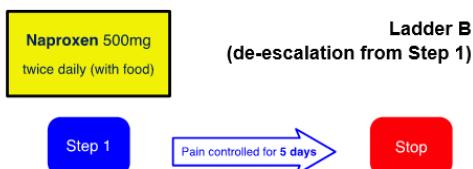


If you reached Step 2: If pain is adequately controlled for 5 days, you can go to step 1. Stop Co-codamol 30/500 and continue Naproxen 500mg twice daily (with food) for 3 days. If pain continues to be adequately controlled, you can continue going down one step every 3 days.

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If you reached Step 1: If pain is adequately controlled for 5 days, you can stop Naproxen 500mg, 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 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](mailto: MEDAL@trials.bham.ac.uk)

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

<u>Naproxen</u>	
<u>Co-Codamol</u>	
<u>Tramadol</u>	
<u>Gabapentin</u>	