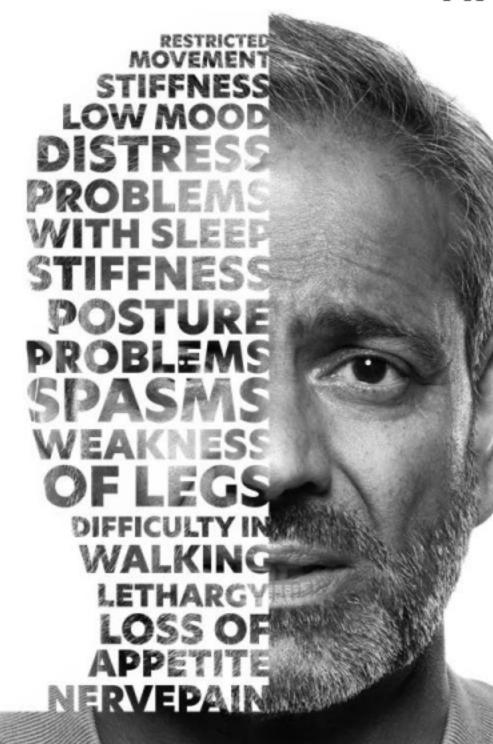
**HALEON** 



Non-specific Low Back Pain Protocol

#ListenToPain

Directed to Healthcare Professionals. Item Code: PM-SA-PAN-24-00038 Preparation date: Dec. 2024 For full product information please refer

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## NON-SPECIFIC LOW BACK PAIN PROTOCOL HALEON IN PRIMARY CARE SETTINGS



#### STEP 1: ASSESS LOW BACK PAIN

#### ASK PATIENT ABOUT LOW BACK PAIN SYMPTOMS1-5

Duration of pain

Increase in pain with lifting and bendina

Stiffness in the morning when awakening

Pain that radiates away from the back into the buttocks, leg, or hip

Pain that restricts the movement

#### IDENTIFY SYMPTOMS OR CIRCUMSTANCES REQUIRING REFERRAL<sup>2,3,6</sup>



- Duration of pain > 6 weeks
- Fever, chills, night sweats
- Pain worsened by coughing or sitting
- Pain radiating below knee
- Prolonged use of corticosteroids

- Unexpected weight loss
- History of malignancy (Cancer)
- Major trauma or minor trauma in elderly
- Major muscle weakness

#### → STEP 2: IDENTIFY TREATMENT CONSIDERATIONS

#### IDENTIFY ANY CONDITIONS OR MEDICATIONS LIMITING TREATMENT OPTIONS7-11

#### Medications limiting treatment

- NSAIDs\* risk of bleeding, decreased antihypertensive efficacy, increased drug levels of medicines like methotrexate
- Paracetamol: Increased risk of paracetamol toxicity
- Opioids- risk of drug abuse

#### Medical conditions limiting treatment

- Chronic kidney disease
- Liver disease
- Peptic Ulcer disease
- Cardiovascular Disease

NSAIDs, non-steroidal anti-inflammatory drugs; \* With oral NSAIDs only

#### IDENTIFY WHAT THE PATIENT HAS USED IN THE PAST TO TREAT LOW BACK PAIN

#### → STEP 3: RECOMMEND TREATMENT FOR ACUTE LOW BACK PAIN¹-4,6,12

#### DOES THE PATIENT HAVE ANY PREFERENCE FOR TREATMENT BASED ON WHAT WAS USED IN THE PAST?

#### IF YES

Recommend non-pharmacological treatment

- Patient Education
- Remain active
- Continue/return to work
- Patient Reassurance
- Physical therapy to help strengthen the muscles that support the back (after consultation with a physician)
- · Life-style changes

#### AND

Recommend the patient's preference if possible, taking into consideration step 2

#### IF NO

Recommend non-pharmacological treatment

- Patient Education
- Remain active
- Continue/return to work
- Patient Reassurance
- Physical therapy to help strengthen the muscles that support the back (after consultation with a physician)
- Life-style changes

#### AND

Recommend appropriate treatment for acute and chronic back pain

- Naproxen 250-500 mg
- Paracetamol 650 ma
- Cyclobenzaprine: 5 mg to 10 mg
- Ibuprofen 400-800 mg
   Tizanidine: 4 mg to 8
  - Tramadol 25-50mg
  - Duloxetine 30 mg

## NON-SPECIFIC LOW BACK PAIN PROTOCOL HALEON IN PRIMARY CARE SETTINGS



#### STEP 1

#### ASSESS SYMPTOMS

- · Questions to ask (Table 1)
- · Assess type of low back pain (Table 2)
  - Low back pain is frequently classified and treated on the basis of symptom duration, potential cause, presence or absence of radicular symptoms, and corresponding anatomical or radiographic abnormalities.
- · Symptoms or circumstances requiring referral (Table 3)

#### → STEP 2

#### IDENTIFY TREATMENT CONSIDERATIONS

- Questions to ask to customize treatment (Table 4)
- · Conditions and medications (Tables 5 and 6)
- · Assess previous treatment (Table 7)
- · Questions to ask about previous treatment (Table 7)

#### STEP 3

#### RECOMMEND TREATMENT

- · Non-pharmacological recommendations (Table 8)
- · Pharmacological recommendation (Table 9)



## STEP 1: ASSESS SYMPTOMS

#### TABLE 1

#### QUESTIONS TO ASK1,2,4

#### Can you tell me about your backache symptoms?

- · Can you describe your pain? (e.g. sharp, aching, burning)
- · Where is the exact location of your back pain?
- · When did the pain start and how long have you had the pain?
- · What were you doing when you first noticed the pain?
- · How severe or bad is the pain?
- · What makes the pain worse or better?

#### DO you have any other symptoms?2

- · Look for symptoms that require referral to a doctor (red flag symptoms)
- · Does chronic pain run in your family (such as arthritis or back pain)?

Is it a first episode or a recurrent episode? Recurrent episodes usually are more painful with increased symptoms

#### → TABLE 2

### DIFFERENTIATING BETWEEN TYPES OF LOW BACK PAIN (LBP)1,2,5,13

Acute	Sub-acute	Chronic
Happens suddenly and usually lasts less than 4 weeks	Can come on suddenly or over time and lasts 4 to 12 weeks.	May come on quickly or slowly and lasts longer than 12 weeks and occurs daily.

- Low back pain is usually nonspecific or mechanical.
- Mechanical low back pain arises intrinsically from the spine, intervertebral disks, or surrounding soft tissues.
- Acute low back pain is often nonspecific and therefore cannot be attributed to a definite cause.
- Non-radicular LBP is back pain that typically does not radiate past the knee.
- Radicular low back pain results in lower extremity pain (radiates from the back and hip into the legs), paresthesia (tingling, numbness), and/or weakness and is a result of nerve root impingement (compression).

STEP 1: CONT.



## **STEP 1: ASSESS SYMPTOMS**

→ TABLE 3

# SYMPTOMS OR CIRCUMSTANCES REQUIRING REFERRAL TO SPECIALISTS (RED FLAGS)1-4,6,12

Red Flags	Possible cause/concern	
Pain that lasts longer than 6 weeks	80% to 90% of all episodes of low back pain resolve within 6 weeks. (hence a red flag)	
Pain that radiates below the knee	Herniated disc or nerve root compression below the L3 nerve root.	
Radicular pain that radiates into the legs in the distribution of a lumbar or sacral nerve root and is often accompanied by sensory and motor deficits	Sciatica	
Major trauma or minor trauma in elderly	Possibility of fracture	
Fever, chills, night sweats, malaise, or undesired weight loss	Infection or malignancy	
Prolonged use of corticosteroids	Fracture	
Pain that occurs at night, awakens the patient from sleep, or is unrelenting despite appropriate analgesia and rest	Tumor or infection	
Pain that is worsened by coughing, sitting and is relieved by lying supine.	Herniated disc	
Patient who reports sudden or progressive onset of new urinary retention, fecal incontinence with low back pain.	Cauda equina syndrome (occurs when the nerve roots in the lumbar spine are compressed, cutting off sensation and movement.)- EMERGENCY referral to ER	

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# STEP 2: IDENTIFY TREATMENT CONSIDERATIONS

#### TABLE 4

#### QUESTIONS TO ASK TO CUSTOMIZE LOW BACK PAIN TREATMENT

- Are you taking any medication, both prescribed and over the counter? If yes, what are those and what is the dose?
- · Do you have any medical conditions?
- · What have you used before for your low back pain?
- · What are the aggravating or relieving factors?

#### → TABLE 5

Concern	Potential drug interaction
Increased risk of bleeding with oral NSAIDs	<ul> <li>Some Selective-Serotonin Reuptake Inhibitors (SSRI)</li> <li>Some tricyclic antidepressants</li> <li>Acetylsalicylic acid (ASA)</li> <li>Corticosteroids</li> <li>Warfarin</li> <li>Ginkgo biloba</li> </ul>
Decreased antihypertensive efficacy with oral NSAIDs	Angiotensin converting enzyme (ACE) inhibitors     Angiotensin II receptor blockers (ARB)     Diuretics     Beta-blockers
Increased drug levels with oral NSAIDs	Lithium     Methotrexate
Increased risk of paracetamol toxicity	Epilepsy medications (e.g. carbamazepine)     Other P450 enzyme inducers (e.g. isoniazid, rifampin)     Alcohol

STEP 2: CONT.



# STEP 2: IDENTIFY TREATMENT CONSIDERATIONS

#### → TABLE 6

# CONSIDERATIONS WHEN SELECTING ANALGESICS IN PATIENTS WITH COMORBIDITIES7-11

Comorbidity	Notes		
Chronic kidney disease	<ul> <li>NSAIDs have proven nephrotoxic class effects and should be avoided where possible in patients with symptoms of renal impairment</li> <li>Paracetamol is the preferred first-line analgesic for episodic treatment of mild pain in patients with renal dysfunction, CKD, and/or requiring dialysis. However, dose minimization may sometimes be warranted (maximum of 3 g/day has been recommended for patients with advanced kidney failure)</li> </ul>		
Liver disease	NSAIDs- NSAIDs can cause acute liver injury with variable severity.     Paracetamol: Not contraindicated in liver disease. Can cause liver toxicity if taken in large amounts.		
Peptic-ulcer disease	Chronic NSAID drug use is associated with potentially serious upper gastrointestinal adverse drug reactions including peptic ulcer disease and gastrointestinal bleeding.     Paracetamol – Lesser risk of adverse effects compared to NSAIDs		
Cardiovascular disease	<ul> <li>All non-aspirin NSAIDs may be associated with a potential increase in CV thrombotic risk.</li> <li>NSAIDs are contraindicated in patients who have undergone coronary artery bypass graft surgery</li> <li>Use of paracetamol at recommended doses is not associated with any additional risk of major CV events.</li> </ul>		

#### → TABLE 7

#### QUESTIONS TO ASK TO ABOUT PREVIOUS TREATMENT

- · What have you used before to treat your low back pain?
  - o What dose did you use?
  - o Was it effective?
  - o Did you have any side effects from it?
- · Do you have any preference for any specific treatment?



# **STEP 3: RECOMMEND TREATMENT**

#### **TABLE 8**

Patient Education and Self-care	<ul> <li>Empowering patients with evidence-based information on low back pain (using handouts or counseling) vital for its management.</li> <li>Advise the patient to stay active, avoiding bed rest as much as possible, and to return to normal activities as soon as possible.</li> <li>Advise the patient to avoid twisting and bending.</li> </ul>
Exercise and physical therapy (Is important for the patient to check with the physician/ physical therapist before starting any exercise routine.)	<ul> <li>Physical therapy to help strengthen the muscles that support the back, which can improve mobility, posture, and positioning.</li> <li>Strengthening exercises can also help decrease pain.</li> </ul>
Life-style changes	<ul> <li>Move the body properly when performing daily activities, especially those involving heavy lifting, pushing, or pulling.</li> <li>Avoid any activities that cause or increase pain.</li> <li>Practice healthy habits such as exercise, relaxation, regular sleep, healthy diet, and quitting smoking.</li> </ul>
Heat	Moderate evidence indicates that heat wrap may reduce pain and disability in patients with pain.
Massage	Small to moderate effect on pain and function
Acupuncture	Reasonable option for patients who have an access
Spinal manipulation (form of manual therapy done by physical therapists that involves the movement of a joint near the end of the clinical range of motion)	Modest improvement in pain and function

STEP 3: CONT.

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# **STEP 3: RECOMMEND TREATMENT**

## → TABLE 9

Medication and single dose	Adverse effects	Drug interactions	Comments	
ACUTE AND SUBACUTE LOW BACK PAIN				
NSAIDs  Ibuprofen 400-800 mg every 8 hours as needed  Naproxen 250-500 mg orally every 12 hours, as needed.  Diclofenac 50 - 75 mg twice a day.	Increased risk for GI bleeding (higher in elderly) Risk of renal dysfunction in elderly.	Can worsen blood pressure among patients with hypertension.	Helps reduce or relieve symptoms, including pain, and to improve physical function.  Consider gastrointestinal, liver and cardio-renal toxicity, and the person's risk factors, including age.  It is recommended to take the lowest dose for the shortest time possible.	
Paracetamol 650 mg every 6 hours as needed. (maximum 3 grams per 24 hours)	Overdose may cause hepatic toxicity.  Lower dose in patients on multiple medications, and patients with other factors that predispose them to hepatotoxicity (e.g., alcohol abuse).	Chronic alcohol use increases the risk of hepatotoxicity.  Acetaminophen has been reported to increase INR in warfarin-treated patients.	Suitable alternative for patients who are unable to take NSAIDs (i.e., due to allergy or other intolerance, chronic kidney disease, hypertension, peptic ulcer disease, or cardiovascular disease)	



## **STEP 3: RECOMMEND TREATMENT**

# TABLE 9 CONT.

CHRONIC LOW BACK PAIN  NSAIDs - same as acute pain management			
Tramadol* – 25-50mg orally every 6 or 8 hours, as needed), then increase the dose if necessary (e.g., tramadol 50-100 mg orally every 6 hours, as needed).	Associated with the risk for prolonged use and abuse.  Can cause neurologic adverse events (Agitation, anxiety, blurred vision, confusion, dizziness, drowsiness, etc.)	Erythromycin increases and rifampicin decreases the effects of opioids.  Carbamazepine, phenytoin and the barbiturates can enhance the metabolism of opioids.	Lowest effective immediate release opioid dose for the shortest period possible is advised.  Duration of treatment is restricted to ≤ 7 days.
Duloxetine [Serotonin norepinephrine re-uptake inhibitor (SNRI)]  Started at 30 mg orally once daily, and after 1 week it is increased to 60 mg orally once daily, if tolerated.	Adverse effects- nausea and constipation	May increase the risk of bleeding with concomitant use of ibuprofen, aspirin, warfarin and other blood thinners.	Duloxetine is preferred over tramadol inpatients for whom there is a concern over the possibility of drug abuse or misuse.

<sup>\*</sup> Weak" opioid analgesics (Codeine, dihydrocodeine and tramadol) (with or without paracetamol) are recommended by NICE guidelines for managing acute low back pain only if an NSAID is contraindicated, not tolerated or has been ineffective.<sup>22</sup>

#### REFERENCES

- Casazza BA. Diagnosis and treatment of acute low back pain. Am Fam Physician. 2012 Feb 15;85(4):343-50.
- Della-Giustina D. Acute low back pain: recognizing the "red flags" in the workup.
   Volume 53 Issue 6 June 2013
- Verhagen AP, et al. Red flags presented in current low back pain guidelines: a review.
   Eur Spine J. 2016 Sep;25(9):2788-802. doi: 10.1007/s00586-016-4684-0.
- National Institute of Arthritis and Musculoskeletal and Skin Diseases. Back Pain. Available at https://www.niams.nih.gov/health-topics/back-pain. Accessed on 16th Jan 2024.
- 5. World Health Organization. Low Back Pain. 19th June 2023. Available at Doi https://www.who.int/news-room/fact-sheets/detail/low-back-pain #:~:text=Low%20back%20pain%20(LBP)%20has,LBP%2C%20including%20children %20and%20adolescents. Accessed 16th Jan 2024.
- Oliveira CB, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. Eur Spine J. 2018 Nov;27(11):2791-2803. doi: 10.1007/s00586-018-5673-2.
- Moore N, Pollack C, Butkerait P. Adverse drug reactions and drug-drug interactions with over-the-counter NSAIDs. Ther Clin Risk Manag. 2015 Jul 15; 11:1061-75
- John Alchin, Arti Dhar, Kamran Siddiqui & Paul J. Christo (2022) Why paracetamol (acetaminophen) is a suitable first choice for treating mild to moderate acute pain in adults with liver, kidney or cardiovascular disease, gastrointestinal disorders, asthma, or who are older, Current Medical Research and Opinion, 38:5, 811-825, DOI: 10.1080/03007995.2022.2049551
- Meunier L, Larrey D. Recent Advances in Hepatotoxicity of Non-Steroidal Anti-Inflammatory Drugs. Ann Hepatol. 2018 Mar 1;17(2):187-191.
- McEvoy L, Carr DF, Pirmohamed M. Pharmacogenomics of NSAID-Induced Upper Gastrointestinal Toxicity. Front Pharmacol. 2021 Jun 21; 12:684162.
- Ghlichloo I, Gerriets V. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) [Updated 2023 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK547742/. Accessed December 2023
- Derek Gyllenhammer et al. The Community Pharmacist's Role in Managing Lower Back Pain. US Pharm. 2017;42(8):35-38.
- Quaseem et al. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians. Ann Intern Med. 2017 Apr 4;166(7):514-530. doi: 10.7326/M16-2367

REFERENCES CONT.



#### REFERENCES CONT.

- Vostinaru O. Adverse Effects and Drug Interactions of the Non-Steroidal Anti-Inflammatory Drugs [Internet]. Nonsteroidal Anti-Inflammatory Drugs. InTech; 2017. Available from: http://dx.doi.org/10.5772/intechopen.68198. Accessed December 2023.
- Agrawal S, Khazaeni B. Acetaminophen Toxicity. [Updated 2023 Jun 9]. In: StatPearls
  [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from:
  https://www.ncbi.nlm.nih.gov/books/NBK441917/.
- Corp N, et al. Evidence-based treatment recommendations for neck and low back pain across Europe: A systematic review of guidelines. Eur J Pain. 2021 Feb;25(2):275-295. doi: 10.1002/ejp.1679.
- Mena Alrais Dellarocca. Evidence-Based Management of Nonspecific Low Back Pain in Adults. March 2021. Continuing Education for Pharmacists & Pharmacy Technician. Available at https://journalce.powerpak.com/ce/evidence-based-management-of-nonspecific. Accessed 17th Jan 2024.
- Baroncini A, et al. Nonopioid pharmacological management of acute low back pain: A level I of evidence systematic review. J Orthop Res. 2023 Aug;41(8):1781-1791. doi: 10.1002/jor.25508.
- Koes B, Schreijenberg M, Tkachev A. Paracetamol for low back pain: the state of the research field. Expert Rev Clin Pharmacol. 2020 Sep;13(9):1059-1066. doi: 10.1080/17512433.2020.1817738.
- Cyclobenzaprine HCL- Interactions. Available at https://www.webmd.com/drugs/2/drug-8888-8087/cyclobenzaprineoral/cyclobenzaprine-oral/details. Accessed on 16th Jan 2024.
- Tizanidine HCL- Interactions. Available at https://www.webmd.com/drugs/2/drug-1024/tizanidine-oral/details. Accessed on 16th Jan 2024.
- 22. Low back pain and sciatica in over 16s: assessment and management NICE guideline [NG59]Published: 30 November 2016 Last updated: 11 December 2020