Health Technology Briefing
July 2025

VER-01 for managing chronic low back pain

Company/Developer	Vertanical GmbH
☒ New Active Substance	☐ Significant Licence Extension (SLE)

NIHRIO ID: 33532	NICE ID: Not available	UKPS ID: 675162

Licensing and Market Availability Plans

Currently in phase III/II clinical trials.

Summary

VER-01 is in clinical development for management of chronic low back pain. Chronic low back pain typically lasts three months or more. It is a multifactorial condition influenced by physical, psychological and social risk factors including obesity, physical inactivity, heavy lifting, sleep disturbance, and stress or depression. Current treatments for low back pain mainly include non-steroidal anti-inflammatories (NSAIDs) and opioids. However, NSAIDs are not suitable for long-term use due to severe side effects, including gastrointestinal ulcers, bleeding, as well as an increased risk for cardiovascular events. For patients who require long-term analgesic (painkiller) treatment, opioids are frequently used but are associated with serious side effects, including constipation, physical dependence, addiction, and potentially fatal overdoses.

VER-01 is an extract from cannabis sativa flowers. It contains a mix of natural chemicals which all work together to manage pain, inflammation, mood, and other functions. VER-01 is administered orally (by mouth). If licensed, VER-01 will provide an additional treatment option in patients with chronic low back pain who require drug treatment and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications (circumstances that mean a drug should not be used) or intolerance.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.
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Proposed Indication

Management of chronic low back pain in adult patients whom drug treatment is indicated and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance.[1]

Technology

Description

VER-01 (Exilby) is an oral solution derived from the flowers of the cannabis sativa strain DKJ127 L.[2] containing Δ^9-tetrahydrocannabinol (THC) as the main active component and a complex mixture of cannabinoids, terpenes and other bioactive compounds, such as cannabigerol, β-caryophyllene and α-bisabolol, that contribute to its overall pharmacological effects. Cannabigerol has been shown to exert anti-nociceptive effects, particularly in models of neuropathic pain.[3,4] β-Caryophyllene and α-Bisabolol possess anti-inflammatory effects by downregulating key pro-inflammatory mediators such as TNF-α, IL-1β, IL-6, and NF-κB.[5,6]

VER-01 is currently in clinical development for management of chronic low back pain. In phase III clinical trials (NCT04940741, NCT05610813) participants received VER-01 orally twice a day. The maximum daily dose should not exceed 13 dose units (32.5 mg THC).[17]

Key Innovation

Currently, in patients with chronic low back pain who have had an inadequate response to non-drug treatment, non-steroidal anti-inflammatories (NSAIDs) are considered as first-line therapy which have potential differences in gastrointestinal, liver and cardio-renal toxicities, and the patient's risk factors, including age. Opioids are the last treatment option considered only in patients for whom other therapies have failed or are contraindicated, and only if the potential benefits outweigh the risks for individual patients.[13,14] If used over longer periods, opioids can lead to dependence and cause physical and mental health issues such as constipation, nausea, vomiting and sleep disturbance, or even death from accidental overdoses or heart conditions resulting from side effects.[15-17]
The Endocannabinoid System (ECS) is a widespread neuromodulatory system made up of cannabinoid receptors, endocannabinoids, and enzymes for their synthesis and degradation.[8] The ECS modulates neurotransmitter systems, including opioid pathways, and impacts pain and other physiological and psychological functions.[9] THC has psychoactive properties, acting as an agonist at CB1 receptors in the brain and CB2 receptors in the periphery.[10] CB1 is a key therapeutic target for pain and CNS disorders.[11] Activation of cannabinoid receptors produces analgesia by inhibiting nociceptive transmission, activating inhibitory pathways, and modifying the emotional component of pain.[12] Therefore, the ECS has emerged as a potential novel pathway for developing therapies to address chronic pain that is not adequately controlled by existing treatments.

If licensed, VER-01 will provide an additional treatment option in patients with chronic low back pain for whom drug treatment is indicated and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance.

Regulatory & Development Status

VER-01 does not currently have marketing authorisation in the EU/UK for any indication.

VER-01 is not in phase II/III clinical development for any other indication.

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Patient Group

Disease Area and Clinical Need

Low back pain often refers to pain in the lumbosacral area, from the 12th ribs to the iliac crest, and sometimes the buttocks and gluteal folds. Chronic low back pain typically lasts three months or more. Risk factors include obesity, physical inactivity, heavy lifting, and stress or depression.[18] Chronic low back patients often suffer from substantial comorbidities, including sleep disorder, depression and limitations in physical function. Increased pain can worsen these conditions, creating a vicious cycle where deteriorating sleep, depression, and mobility further intensify the pain. These comorbidities significantly impair patients' overall quality of life.[19-21]

Back pain is the largest single cause of disability in the UK, with lower back pain alone accounting for 11% of the total disability of the UK population. [22] Low back pain is ranked highest out of 291 conditions studied by the Global Burden of Disease study, ranking number one for years lost to disability worldwide. [23] About 3–4% of adults below 45 years of age have chronic low back pain and 5–7% of adults over 45 years of age have chronic low back pain. [24] Back pain accounts for 40% of sickness absence in the NHS and overall it costs £10 billion for the UK economy (2018).[25] In England (2023-24), there were 25,266 finished consultant episodes (FCE) and 21,909 admissions for unspecified back pain (ICD-10: M54-9) resulting in 7893 FCE day cases and 28,064 bed days.[26]

Recommended Treatment Options

The National institute for health and care excellence (NICE) currently recommends the following pharmacological management options for low back pain:[14]

- oral NSAIDs
- weak opioids (with or without paracetamol) for acute low back pain if NSAIDs are contraindicated

Clinical Trial Information

Trial	NCT04940741, 2020-000107-36; Proof of Efficacy, Maintenance of Efficacy, Long-term Safety and Investigation of the Potential for Dependence and Abuse and the Effect of Abrupt Drug Withdrawal of VER-01 in the Treatment of Patients With Chronic Non-specific Low Back Pain **Phase III** - completed **Locations:** Germany and Austria **Primary completion date:** March 2024
Trial Design	Randomised, parallel assignment, quadruple blind
Population	N=820 (actual) patients, aged 18 years and older, with chronic non-specific low back pain for whom drug treatment is indicated and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance
Intervention(s)	VER-01 is administered orally, twice a day
Comparator(s)	Matched placebo
Outcome(s)	Primary outcome measures:

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	• Phase A: efficacy based on pain reduction. [time frame: baseline up to 15 weeks] • Phase B: safety based on occurrence of treatment-related adverse events/significant adverse events (AEs/SAEs). [time frame: up to 29 weeks] • Phase C: safety based on occurrence of treatment-related AEs/SAEs. [time frame: up to 28 weeks] • Phase D: maintenance of efficacy [time frame: up to 4 weeks (from date of randomisation R2 until the first day of treatment failure)] See the trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**ELEVATE,** NCT05610813, 2022-001358-41; Multicentre, Randomised, Open-label Study to Prove an Additional Benefit of the Full-spectrum Cannabis Extract VER-01 Over Opioids in the Treatment of Patients With Chronic Non-specific Low Back Pain **Phase III** - Completed **Location:** Germany **Primary completion date:** October 2024
Trial Design	Randomised, parallel assignment, open label
Population	N=384 (actual), patients, aged 18 years and older, with chronic non-specific low back pain for whom drug treatment is indicated and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance
Intervention(s)	VER-01 is administered orally, twice a day.
Comparator(s)	Opioid therapy (with an authorised and marketed opioid, ATC code N02A)
Outcome(s)	Primary outcome measures: • Risk of developing constipation [Time frame: 190 days] See the trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

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Trial	**RESPONSE,** NCT06475001, 2023-507358-34; Multicentre, Double-blind, Randomized, Placebo-controlled, Dose Response Trial With the Full-spectrum Cannabis Extract VER-01 in Patients With Chronic Non-specific Low Back Pain **Phase II** - Active, not recruiting **Locations:** UK, Germany, Spain, Poland and Czech Republic[a] **Primary completion date:** August 2025
Trial Design	Randomised, parallel assignment, quadruple blind
Population	N=652 (actual), patients, aged 18 years and older with chronic non-specific low back pain for whom drug treatment is indicated and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance
Intervention(s)	VER-01, administered orally. One unit corresponds to 2.5 mg THC
Comparator(s)	Placebo
Outcome(s)	Primary outcome measures: • Efficacy based on pain reduction [time frame: end of the treatment phase (week 7) compared to baseline (week -1)] See the trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	**EXPAND,** NCT06956014; Multicenter, Double-blind, Randomized, Placebo-controlled Trial to Evaluate the Efficacy and Safety of the Full-spectrum Cannabis Extract VER-01 in Patients With Chronic Low Back Pain **Phase III** - Not yet recruiting **Location:** United States of America **Primary completion date (estimated)**: May 2027
Trial Design	Randomised, parallel assignment, quadruple blind
Population	N=700 (estimated) patients, aged 18 years and older, with chronic low back pain, for whom drug treatment is indicated and previous optimised treatments with non-opioid analgesics have not led to sufficient pain relief or were unsuitable due to contraindications or intolerance
Intervention(s)	• VER-01 corresponding to 22.5 mg THC • VER-01 corresponding to 32.5 mg THC
Comparator(s)	Placebo
Outcome(s)	Primary outcome measures: Efficacy based on pain reduction [time frame: from baseline to treatment week 12] See the trial record for full list of other outcomes.

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Results (efficacy)	-
Results (safety)	-

Estimated Cost

The cost range of VER-01 was confidential at the time of producing this briefing.

Relevant Guidance

NICE Guidance

- NICE clinical guideline, Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain (NG193). April 2021.
- NICE clinical guideline, Low back pain and sciatica in over 16s: assessment and management (NG59). December 2020.
- NICE quality standard, Low back pain and sciatica in over 16s (QS 155). July 2017.
- NICE Interventional procedures guidance. Neurostimulation of lumbar muscles for refractory non-specific chronic low back pain (IPG739). September 2022.
- NICE Interventional procedures guidance. Transaxial interbody lumbosacral fusion for severe chronic low back pain (IPG620). July 2018
- NICE Interventional procedures guidance. Lateral interbody fusion in the lumbar spine for low back pain (IPG574). February 2017.
- NICE Interventional procedures guidance. Percutaneous coblation of the intervertebral disc for low back pain and sciatica (IPG543). January 2016.
- NICE Interventional procedures guidance. Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. IPG544. January 2016
- NICE Interventional procedures guidance. Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain(IPG545). January 2016.
- NICE Interventional procedures guidance. Peripheral nerve-field stimulation for chronic low back pain (IPG451). March 2013.
- NICE Interventional procedures guidance. Non-rigid stabilisation techniques for the treatment of low back pain (IPG366). November 2010.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013 NHS Standard Contract for Specialised Pain. D08/S/a

Other Guidance

- WHO guideline for non-surgical management of chronic primary low back pain in adults in primary and community care settings. December 2023.[27]
- NHS Derbyshire joint area prescribing committee. Management of Low back pain and Sciatica in primary care. 2021.[28]
- The Royal College of Emergency Medicine Best Practice Guideline. Management of Pain in Adults. 2021.[29]
- George SZ, Fritz JM, Silfies SP, Schneider MJ, Beneciuk JM, Lentz TA, Gilliam JR, Hendren S, Norman KS, Beattie PF, Bishop MD. Interventions for the management of acute and chronic low back pain: revision 2021.[30]

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References

1 Clinical Trials.gov. *NCT04940741*. *Trial ID: NCT04940741*. 2021. Status: Completed Available from: https://clinicaltrials.gov/study/NCT04940741 [Accessed 23 May 2025].

2 Clinical Trials.gov. *Efficacy and Safety of VER-01 in the Treatment of Patients With Chronic Low Back Pain (EXPAND)*. *Trial ID: NCT06956014*. 2025. Available from: https://clinicaltrials.gov/study/NCT06956014 [Accessed 02/07/2025].

3 Nachnani R, Sepulveda DE, Booth JL, Zhou S, Graziane NM, Raup-Konsavage WM, et al. Chronic Cannabigerol as an Effective Therapeutic for Cisplatin-Induced Neuropathic Pain. *Pharmaceuticals (Basel, Switzerland)*. 2023;16(10). Available from: https://doi.org/10.3390/ph16101442.

4 Sepulveda DE, Morris DP, Raup-Konsavage WM, Sun D, Vrana KE, Graziane NM. Cannabigerol (CBG) attenuates mechanical hypersensitivity elicited by chemotherapy-induced peripheral neuropathy. *European Journal of Pain*. 2022;26(9):1950-66. Available from: https://doi.org/10.1002/ejp.2016.

5 Ramazani E, Akaberi M, Emami SA, Tayarani-Najaran Z. Pharmacological and biological effects of alpha-bisabolol: An updated review of the molecular mechanisms. *Life Sciences*. 2022;304:120728. Available from: https://doi.org/10.1016/j.lfs.2022.120728.

6 Scandiffio R, Geddo F, Cottone E, Querio G, Antoniotti S, Gallo MP, et al. Protective Effects of (E)-beta-Caryophyllene (BCP) in Chronic Inflammation. *Nutrients*. 2020;12(11). Available from: https://doi.org/10.3390/nu12113273.

7 Clinical Trials.gov. *Comparison of VER-01 to Opioids in Patients With Chronic Non-specific Low Back Pain (ELEVATE)*. *Trial ID: NCT05610813*. 2024. Status: Completed Available from: https://clinicaltrials.gov/study/NCT05610813 [Accessed 02 Jul 2025].

8 Lu HC, Mackie K. An Introduction to the Endogenous Cannabinoid System. *Biological Psychiatry*. 2016;79(7):516-25. Available from: https://doi.org/10.1016/j.biopsych.2015.07.028.

9 Freeman-Striegel L, Hamilton J, Kannappan R, Bell T, Robison L, Thanos PK. Chronic Δ9-tetrahydrocannabinol treatment has dose-dependent effects on open field exploratory behavior and [3H] SR141716A receptor binding in the rat brain. *Life Sciences*. 2023;327:121825. Available from: https://doi.org/10.1016/j.lfs.2023.121825.

10 Finn DP, Haroutounian S, Hohmann AG, Krane E, Soliman N, Rice ASC. Cannabinoids, the endocannabinoid system, and pain: a review of preclinical studies. *Pain*. 2021;162. https://journals.lww.com/pain/fulltext/2021/07001/cannabinoids,_the_endocannabinoid_system,_and.3.aspx.

11 Dutta S, Selvam B, Das A, Shukla D. Mechanistic origin of partial agonism of tetrahydrocannabinol for cannabinoid receptors. *Journal of Biological Chemistry*. 2022;298(4). Available from: https://doi.org/10.1016/j.jbc.2022.101764.

12 Uberall MA. A Review of Scientific Evidence for THC:CBD Oromucosal Spray (Nabiximols) in the Management of Chronic Pain. *Journal of Pain Research*. 2020;13:399-410. Available from: https://doi.org/10.2147/JPR.S240011.

13 British National Formulary (BNF). *Low back pain and sciatica- Drug treatment* Available from: https://bnf.nice.org.uk/treatment-summaries/low-back-pain-and-sciatica/ [Accessed 26 May 2025].

14 National Institute for Health and Care Excellence (NICE). *Low back pain and sciatica in over 16s: assessment and management*. 2016. Available from: https://www.nice.org.uk/guidance/ng59/chapter/Recommendations [Accessed 23 May 2025].

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15 NHS England. *Reducing long-term opioid use*. 2023. Available from: https://www.england.nhs.uk/long-read/reducing-long-term-opioid-use/ [Accessed 23 May 2025].
16 NHS Health Research Authoritiy. *VER-CLBP-004 (RESPONSE)*. 2024. Available from: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/ver-clbp-004-response/ [Accessed 23 May 2025].
17 Benyamin R, Trescot AM, Datta S, Buenaventura R, Adlaka R, Sehgal N, et al. Opioid complications and side effects. *Pain Physician*. 2008;11(2 Suppl):S105-20. https://www.ncbi.nlm.nih.gov/pubmed/18443635.
18 National Institute for Health and Care Excellence (NICE). *Back pain - low (without radiculopathy)*. 2024. Available from: https://cks.nice.org.uk/topics/back-pain-low-without-radiculopathy/ [Accessed 22 May 2025].
19 Fullen B, Morlion B, Linton SJ, Roomes D, van Griensven J, Abraham L, et al. Management of chronic low back pain and the impact on patients' personal and professional lives: Results from an international patient survey. *Pain Pract*. 2022;22(4):463-77. Available from: https://doi.org/10.1111/papr.13103.
20 Hadi MA, McHugh GA, Closs SJ. Impact of Chronic Pain on Patients' Quality of Life: A Comparative Mixed-Methods Study. *J Patient Exp*. 2019;6(2):133-41. Available from: https://doi.org/10.1177/2374373518786013.
21 Fredheim OM, Kaasa S, Fayers P, Saltnes T, Jordhoy M, Borchgrevink PC. Chronic non-malignant pain patients report as poor health-related quality of life as palliative cancer patients. *Acta Anaesthesiologica Scandinavica*. 2008;52(1):143-8. Available from: https://doi.org/10.1111/j.1399-6576.2007.01524.x.
22 NHS England. *The National Back Pain Pathway* 2016. Available from: https://www.england.nhs.uk/blog/charles-greenough/ [Accessed 23 May 2025].
23 The British Pain Society. *UK Pain Messages*. 2024. Available from: https://www.britishpainsociety.org/british-pain-society-publications/uk_pain_messages/ [Accessed 23 May 2025].
24 National Institute for Health and Care Excellence (NICE). *How common is it?* 2024. Available from: https://cks.nice.org.uk/topics/back-pain-low-without-radiculopathy/background-information/prevalence/ [Accessed 22 May 2025].
25 The British Pain Society. *British Pain Society Press release: Chronic pain costs the UK £billions but research funding is inadequate*. 2018. Available from: https://www.britishpainsociety.org/mediacentre/news/british-pain-society-press-release-chronic-pain-costs-the-uk-billions-but-research-funding-is-inadequate/ [Accessed 23 May 2025].
26 NHS Digital. *Hospital Admitted Patient Care Activity 2023-24*. 2024. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2023-24 [Accessed 26 May 2025].
27 World Health Organisation (WHO). *WHO guideline for non-surgical management of chronic primary low back pain in adults in primary and community care settings*. 2023. Available from: https://www.who.int/publications/i/item/9789240081789 [Accessed 27 May 2025].
28 NHS DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE. *Management of Low back pain and Sciatica in primary care*. 2021. Available from: https://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_10/Low_back_pain_and_sciatica.pdf [Accessed 27 May 2025].
29 The Royal College of Emergency Medicine. *Management of Pain in Adults*. Available from: https://rcem.ac.uk/wp-content/uploads/2021/10/RCEM_BPC_Management_of_Pain_in_Adults_300621.pdf [Accessed 27 May 2025].

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30 George SZ, Fritz JM, Silfies SP, Schneider MJ, Beneciuk JM, Lentz TA, et al. Interventions for the Management of Acute and Chronic Low Back Pain: Revision 2021. *Journal of Orthopaedic and Sports Physical Therapy*. 2021;51(11):Cpg1-cpg60. Available from: https://doi.org/10.2519/jospt.2021.0304.

NB: This briefing presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

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