Compounded Medications in Pain Management

Options, Safety, and Answers

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Disclaimer

This presentation is for educational purposes and is not intended as an endorsement of any compounded preparation, pharmacy, or entity. The information is not all-inclusive and may include chemicals that are not FDA-approved. Also, all compounds are not FDA approved; however, API (Active Pharmaceutical Ingredients) come from FDA-registered manufacturers.

The information is based on current professional literature, clinical experience, and expert opinion. It does not establish a fixed set of rules or define the legal standard of care. Physician judgement must consider variation in resources, patient needs, and preferences.

Our Objectives for Today

1

Introduce compounding and its key aspects

What it is, why it is used, and how it is kept safe

2

Explore pain management options using compounded medications

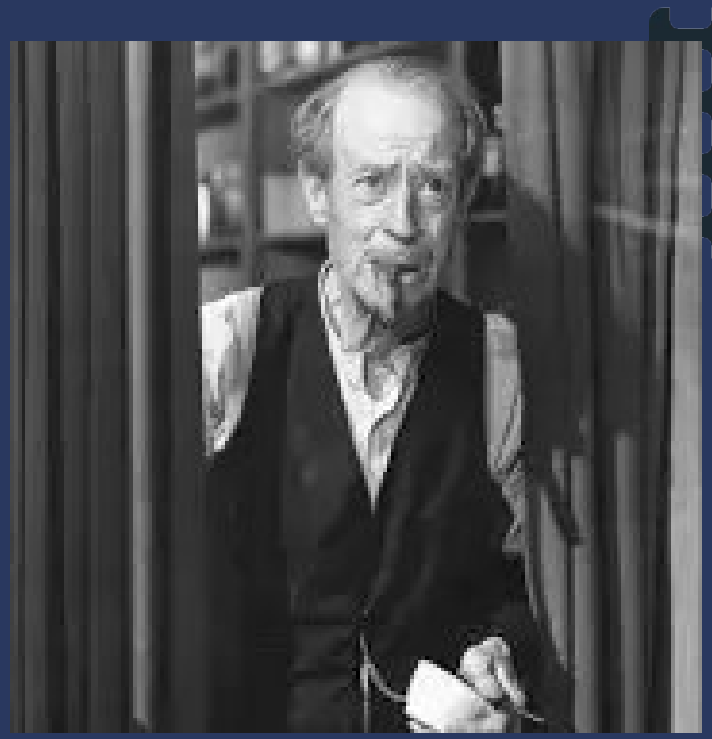
Topicals, Ketamine, and Low Dose Naltrexone (LDN)

3

Answer your questions and address your concerns

Ask any time; we will keep a parking lot for later

One Question Saved a Life



THEN

A tragic mistake caught because someone paused to ask one question.

NOW

Standards, regulations, laws, double-checks, and traceability built into modern compounding.

Organizations and governing boards such as the USP (U.S. Pharmacopeia), FDA (Food and Drug Administration), BOP (state Boards of Pharmacy), DEA (Drug Enforcement Administration), PCAB (Pharmacy Compounding Accreditation Board), NABP (National Association of Boards of Pharmacy)

Poll: Your Compounding Knowledge

How would you describe your knowledge of compounding?

A

I know very little about it

B

I know the basics but have never referred a patient

C

I've worked with patients on compounded medications

D

I'm very familiar and have specific questions

Poll: Your Compounding Knowledge "Passion for Pain Management"

What Is Compounding?

Customized

Medication tailored for patient's specific needs

Prescriber-directed

A prescription is required. Compounded under supervision of a licensed pharmacist

Regulated

Compounding Pharmacy is overseen by BOP, DEA, FDA and complies with USP standards, FDA oversight, NABP, PCAB



According to the USP, Compounding pharmacy is the practice of creating customized medications by combining , mixing, or altering, packaging, assembling, and labeling of a drug and, or ingredients with a licensed practitioner’s prescription to meet specific patient’s needs.

Why Compound? Common Reasons

Allergies and excipients

Dye-free and filler-free options

Doses off the shelf

Strengths not commercially available

Shortages and discontinuations

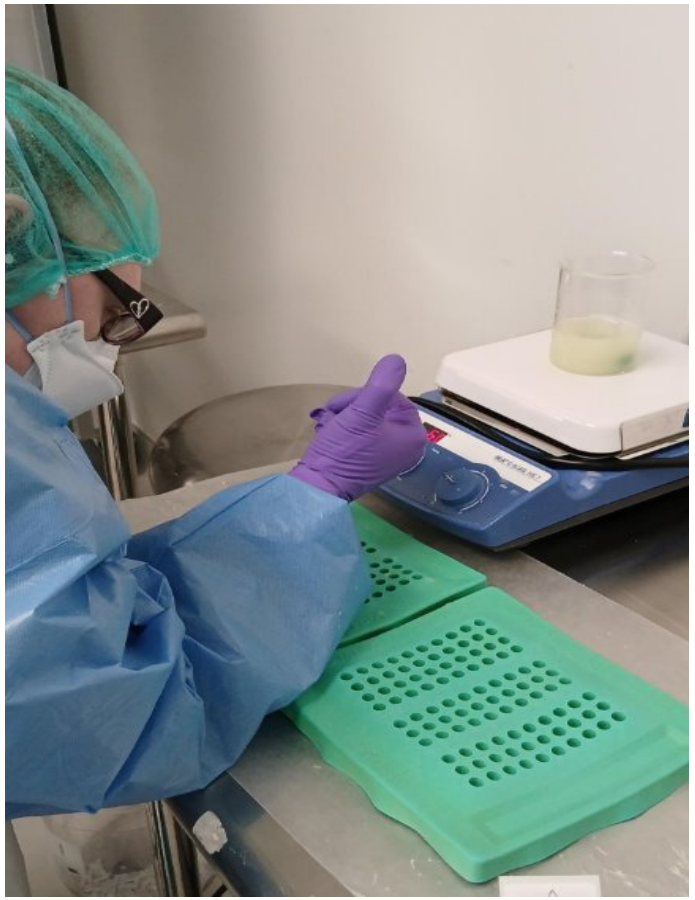
Keeping a needed therapy available

Fewer pills

Combine therapies to reduce pill burden

Different forms for children and pets

Topical, liquid, troche, sublingual



Safety and Regulation

503A vs. 503B
Patient-specific pharmacies vs. outsourcing facilities

USP <795>, <797>, <800>
Nonsterile, sterile, and hazardous drug standards

State boards and accreditation
Board inspections, plus voluntary accreditation (e.g., PCAB, NABP)

Back to Mr. Gower

- **Checks – pharmacy management system (PMS) barcode scans, certified equipment**
- **Standards – DP, standard operating procedures (SOP), continuous quality improvement (CQI), prescription monitoring program (PMP)**
- **Traceability – certificate of analysis (COA), master formulation record (MFR), compounding record (CR), Track Trace**

Sections 503A and 503B are in the FD&C Act. Section 503B was created by the Drug Quality and Security Act (DQSA) of 2013, after the 2012 New England Compounding Center fungal meningitis outbreak.

Working With a Compounding Pharmacy

What to ask any compounding pharmacy

- Licensure and accreditation (NABP, PCAB,)
- Where do ingredients come from, and how are they tested?
- How are beyond-use dates (BUD) and storage determined?
- What records allow traceability of each preparation?
- How does the pharmacy communicate with prescribers?
- What practices are upheld for Continuous Quality Improvements?

Collaborate with your compounding pharmacist



Let's Talk: What Gives You Pause?

What would make you hesitant to recommend a custom compounded medication?

Concerns we often hear:

Quality and consistency?

Insurance and cost?

Evidence and safety?

Jot yours on a sticky note. We will return to these in Q&A.

Three Options, One Finale

SAVING THE BEST FOR LAST

01



Topical Pain Creams

Targeted delivery with fewer systemic effects

02



Ketamine

Powerful, with real safety caveats

03



Low Dose Naltrexone LDN

My favorite and case studies

Interactive questions in each section. We'll pause for a stretch and a laugh before the finale.

Topical Pain Creams

Common Ingredients

- NSAIDs
- Local anesthetics (e.g., lidocaine)
- Neuropathic agents (e.g., gabapentin)
- Muscle relaxants and others per prescriber

Why topical: targeted delivery, fewer systemic effects

Common Indications – Practices – PAIN

- Orthopedic surgeries (Pre/Post)
- Diabetic Neuropathy
- Rectal hemorrhoids, anal fissures
- Arthritis
- Accident injuries
- Foot pain
- Dental procedures
- Dermatological procedures



TRUE OR FALSE?

Topicals are completely free of systemic effects.

Topical Options: NSAIDs

Drug	Strength	Use / Function	Mechanism	Notes
Diclofenac	2-10%	NSAID, analgesic	Non-selective COX inhibitor	More pruritus than ketoprofen
Flurbiprofen	Max 10%	Joint pain; inflammatory pain	Propionic acid NSAID	
Ibuprofen	5-30%	Joint pain/inflammation; inflammatory pain	Propionic acid NSAID	
Ketoprofen	5-20%	NSAID, analgesic, neuropathic pain	Propionic acid NSAID	1st line for joint pain; has affinity for synovial fluid

Source: PCCA, Drugs Used Topically in Pain Management Using a Permeation-Enhancing Base (see PCCA Document #99047 for full references)

Topical Options: Local Anesthetics

Drug	Strength	Use / Function	Mechanism	Notes
Bupivacaine	0.25-10%	Local anesthetic; shingles pain, neuropathic pain, allodynia	Similar to benzocaine: blocks Na+ channels and nerve impulse conduction	
Lidocaine	2-10%	Local anesthetic; acute and chronic pain, shingles pain	Similar to benzocaine: blocks Na+ channels and nerve impulse conduction	2nd line for trigger point pain gels (add on, 2%) Rectal combos
Prilocaine	2-10%	Local anesthetic; acute and chronic pain, shingles pain	Similar to benzocaine: blocks Na+ channels and nerve impulse conduction	

Source: PCCA, Drugs Used Topically in Pain Management Using a Permeation-Enhancing Base (see PCCA Document #99047 for full references)

Topical Options: Neuropathic Agents

Drug	Strength	Use / Function	Mechanism	Notes
Amitriptyline	1-5%	Chronic/neuropathic pain, shingles, diabetic peripheral neuropathy, plantar fasciitis	Sympatholytic; NE reuptake inhibitor	Synergistic effect with ketamine
Imipramine	2-10%	Chronic/neuropathic pain incl. post-herpetic neuralgia, diabetic neuropathy, headache	NE reuptake inhibitor	Not more than 10%
Gabapentin	6-12%	Chronic/neuropathic pain; burning, stabbing, electric-shock pain	Na+ and Ca++ channel blockade; glutamate antagonist	Could use topical to wean off oral; great for trigger points
Clonidine	0.1-0.3%	Chronic/neuropathic pain	Alpha2 agonist (reduces sympathetic outflow)	Anti-hypertensive effects start above 0.4%
Topiramate	1%	Augments performance of multiple medications	Modulates Na+ and Ca++ channels; increases GABA inhibition; blocks glutamate (NMDA)	

Source: PCCA, Drugs Used Topically in Pain Management Using a Permeation-Enhancing Base (see PCCA Document #99047 for full references)

Topical Options: Ketamine and More

Drug	Strength	Use / Function	Mechanism	Notes
Ketamine	5-15%	Neuropathic pain of various origins (post-herpetic neuralgia, CRPS, cancer, orofacial, phantom limb); painful neuropathy when other methods failed; post-op and post-traumatic pain	NMDA-Ca++ channel blocker; blocks a cascade that inhibits hyperexcitability of spinal cord neurons	Highest affinity for NMDA receptors
Baclofen	2%	Muscle relaxant/anti-spastic; decreases pain, improves motor function	Direct GABA-B agonist; precise mechanism not fully known	Works well as an add-on in fibromyalgia
Cyclobenzaprine	1-4%	Skeletal muscle relaxant/anti-spastic	Like other tricyclics, potentiates norepinephrine	2nd-line therapy; may cause drowsiness
Acyclovir	4-5%	Antiviral; shingles: reduces pain, shortens healing time, limits spread of virus	Inhibits viral DNA synthesis (competitive inhibition of viral DNA polymerase)	

Source: PCCA, Drugs Used Topically in Pain Management Using a Permeation-Enhancing Base (see PCCA Document #99047 for full references)

Topical Pain Creams

Common Formulas

- Diclofenac/Lidocaine/Pentoxifylline 4%/5%/3%
- Diclofenac/Baclofen/Gabapentin/Lidocaine 1.5%/2%/3%/5%
- Meloxicam/Lamotrigine/Lidocaine/Prilocaine 0.2%/2.5%/2%/2%
- Lidocaine/Tetracaine/Phenylephrine 20%/4%/2%
- Benzocaine/Lidocaine/Tetracaine 20%/8%/4%

Counseling Points

- Wash hands before and after application or wear gloves
- Apply to clean, dry, intact skin and rub in well 1-2 min
- Allow skin to dry before putting clothing over
- Avoid large areas and occlusive dressings or heat
- May take a few days for full benefits
- Rare occurrence but if any rash occurs, wash off, discontinue, and call us
- Store at room temperature; away from direct sun and moisture



What are some benefits of topical formulations?

Ketamine: Forms and Safety



Compounded forms

- Topical
- Oral or sublingual
- Nasal spray
- Injectable



Safety essentials

- Schedule III controlled substance
- FDA has raised concerns about compounded ketamine used outside supervised settings

Uses

- General analgesia
- Neuropathic pain
- Migraines
- Palliative/Hospice
- KAP Sessions



What monitoring would you want in place?

Ketamine: Mechanism of Action

KETAMINE – Blocks NMDA

- Ketamine is a non-competitive NMDA receptor antagonist that has a different mechanism of action than conventional nociceptive drugs.

SHOW OF HANDS

Who has used ketamine for treatment of pain for your patients?

Schedule III Controlled Substance – commonly used for anesthesia

Pain, migraines, refractory depression, PTSD

How Ketamine Helps: The Pain Cascade

KETAMINE BLOCKS HERE



Repeated pain signals

Intense or prolonged input reaches the spinal cord



NMDA receptors switch on

Calcium floods in and neurons become excitable



Central sensitization

The pain system's volume gets stuck on high



What the patient feels

Allodynia, hyperalgesia, burning or shooting pain



Opioids work less

Reduced opioid relief and faster tolerance



Think of it as a volume knob stuck on high. Blocking NMDA helps turn it back down and may help opioids work better.

Ketamine: Dosage Forms and Dosing

Common Compounded Dosage Forms

- Ketamine 100mg up to 250mg Troche
- Ketamine 100 to 150mg/ml nasal sprays
- Ketamine oral capsules
- Ketamine as an added ingredient in topical pain creams 5%, 10%

Controlled

- Habit or abuse potential
- Can be phoned in
- Max 5 refills – rx expires in 6 months from written date
- DEA, pt address, on prescription

Dosing and titration

Breakthrough pain: 50 mg intranasal (100 mg/mL nasal spray)

Migraines: 25 mg intranasal; reduces aura severity, not duration

Fibromyalgia: 6 mg/kg/day

Oral: start low (about 0.5 mg/kg per dose) and titrate; range varies with treatment goal

Side effects and cautions

Confusion

Dizziness

Euphoria

Perceptual disturbances - dissociation

Increased blood pressure

The treatment goal changes the dose. Always titrate: start low and go slow.

Stand Up! Quick Energy Break



Stand if you worked a 12-hour shift this week



Stay standing if you worked more than three



Everyone: stretch, shake it out, deep breath

JOKE TIME

Why did the pharmacist get promoted?

(Take a guess…)

She had great compound interest!

Thank you, I'll be here all session.



Now, saving the best for last...

Let's talk about LDN.

LDN: Low-Dose Naltrexone



Thinking outside the box

Naltrexone at a fraction of its usual dose (LDN)

SHOW OF HANDS

Has a patient ever asked you about LDN?



Off-label use

Used off-label for chronic pain, neuropathic pain, cancer, fibromyalgia, auto-immune disorders;

always prescriber-directed



Low doses only available through Compounding

What the evidence shows

Dr. B. Bihari, renowned neurologist and psychiatrist pioneered in 1980s

Dr. I. Zagon researched endorphins and LDN for over 29 years publishing nearly 300 papers of his work

Toljan and Vrooman (2018) – narrative review of 85 papers

Mostly small, open-label studies; review calls for better trials

2026 review (105 studies, 15 RCTs): early positive findings were rarely replicated in placebo-controlled trials

LDN

Mechanism of Action

Opioid Receptor Antagonist

Up-regulation of endorphin production

Immuno-modulator

Blocks Toll-like receptor 4 (TLR4) on microglial cells; reduces inflammatory cytokines

Conditions studied

Off-Label Use in auto-immune conditions, MS, chronic fatigue, fibromyalgia, chronic pain, and much more

Dosing and titration

1 to 1.5mg q hs and increase weekly by 0.5mg to target dose (usually 4.5mg but dose is patient dependent)

Fast titration 1.5mg q hs for 2 weeks, 3mg q hs for 2 weeks, then 4.5mg thereafter

Side effects and cautions

(Minimized when titrated)

Nausea (5-10%)

Sleep disturbances – vivid dreams (20-30%)

Mild headache (10-15%)

Initial fatigue (5-10%)

Caution: LDN blocks opioids and can precipitate withdrawal. Opioid taper and LDN start are managed by the prescriber.

Case Study

Patient A, 49 y.o. female with a history of chronic low back pain and fibromyalgia.

Medical Hx: bowel disorders, fibromyalgia

Surgical Hx: hysterectomy, bowel resection, appendectomy, and cholecystectomy

Medications/treatments: has tried muscle relaxers; declined any opioid treatment; chiropractic care and lidocaine infusion

Baseline Pain: She reported 9/10 on pain scale; pain is constant

LDN titration: Started at 1mg and titrated up to 4.5mg over several weeks with changes every 14 days

Maintenance dose: 4.5mg daily

1. Pain: Went from 9/10 to 0-3
2. She now holds a regular job and participates in family activities
3. Overall, quality of life improved

Important to note

Gradual improvements

Important to have patient who is committed

Educating the patient of 3-6 month trial

Case Study

Patient B: 44 y.o. female reporting persistent, intense pain worsening with activity and occasionally radiating down her leg.

Medical Hx: T1DM, bone cell lympoma (surgically removed- most pain stems from), depression/anxiety
Surgical Hx: gastric bypass surgery in 2013, frozen shoulder surgery in 2016, a pancreas transplant in 2017, and lymphoma diagnosis in 2019
Medications: Prednisone 5 mg once a day, Humalog
Fluoxetine 60 mg qd, Gabapentin 600 mg BID
MS Contin 30 mg BID-TID
Norco 7.5 QID"
Baseline Pain: pain scale 7-10
LDN Titration/Maintenance: Ultra-LDN, LDN slow titration over 1 month; maintenance 4.5mg

1. Ultra Low Dose Naltrexone 1mcg daily started and titrated up over 2 months and opioids were decreased
2. Pain now 4 and off all narcotics, gabapentin, and pain meds
3. Improved quality of life; reduced medications

Important to note

Slowly reduced opioids as LDN was increased to therapeutic dose

Use of LDN Solution used at the start of therapy

Patient was eager to get off of all pain meds

Side by Side: The Three Options

Option	Best-suited conditions	Route	Key cautions	Monitoring
Topicals	Local pain, arthritis, orthopedics, dental, dermatology, cancer	Topical, transdermal	Local irritation rare; minimal systemic absorption	Relief of pain to help customize formula
Ketamine	Topical adjunct	Varies: topical, oral, sublingual, injectable	Schedule III; dissociation possible (dose related); blood pressure effects when used intranasally, SL, or injection	1st use supervised, relief of pain,
LDN	Chronic pain, inflammation	Oral (capsule or liquid); also available topically	Opioid interaction (blocks opioids); trial of 3-6 months, consultation is vital to pt adherence	Relief of pain, dosage, QOL

Key Takeaways

1

Compounding pharmacy delivers needed specialized therapy to patients.

2

Topicals, ketamine, and LDN each play a different, yet valuable role in pain management.

3

Provider-Nurse-Compounding Pharmacist Collaboration in education, monitoring, and communication is key to success in patient care.

Compounded medications require a prescription and are tailored to meet patient's specific needs that could not be met with commercially available medications. They are not FDA-approved, but the ingredients are from FDA regulated manufacturers.

Questions and Concerns

Let's revisit what gave you pause.

Parking lot for follow-up by email

Isabella@rvcrx.com



Human Drug Compounding Laws | FDA

Compounding Pharmacy Accreditation Explained (2026)

Pain Management Algorithm - PCCA

The Uses of Ketamine (PCCA)

2026_Prescriber_Guide.pdf

2026 Dosing Guide Fianal Checked

Therapeutic Uses and Efficacy of Low-Dose Naltrexone: A Scoping Review - PMC

Therapeutic Uses and Efficacy of Low-Dose Naltrexone: A Scoping Review - PubMed

WEBINAR: What is Low Dose Naltrexone (LDN) with Pharmacist Michelle Moser

WEBINAR: Low Dose Naltrexone (LDN) with Pharmacist Heather Rae Paschal

Pain Management Clinician’s Guide. PharmAcademy

Summary-Compounded Topical Pain Creams: Review of select ingredients for safety, effectiveness, and use. Jackson LM, Schwinn DA. National Acadamies Press. 2020 May 13

Understanding Your Options for Topical Pain Relief. Mayo Clinic Press. Healthy Aging. J Maloney, MD. S. Youngblood, Gregory. Nov 15, 2024

Pain Management Therapeutic Line Overview. McKettrick, Greg, Rph Revelation Pharma

Toljan K, Vrooman B. Low-Dose Naltrexone (LDN)—Review of Therapeutic Utilization. Med Sci (Basel). 2018;6(4):82. doi:10.3390/medsci6040082

Low-Dose Naltrexone: What Is the Evidence? A Narrative Review. Adv Ther. 2026. doi:10.1007/s12325-026-03612-5