

# Painweek

## The 411 on Nonprescription Analgesics: When to Hold 'Em, When to Fold 'Em

Alexandra L. McPherson, PharmD, MPH

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## Disclosure

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## Learning Objectives

- 1) Describe the mechanism of action of common nonprescription analgesics
- 2) List and explain contraindications to self-treatment for tension headache and musculoskeletal pain
- 3) Given a simulated patient with a complaint of pain, select a nonprescription analgesic and provide dosing and use instruction



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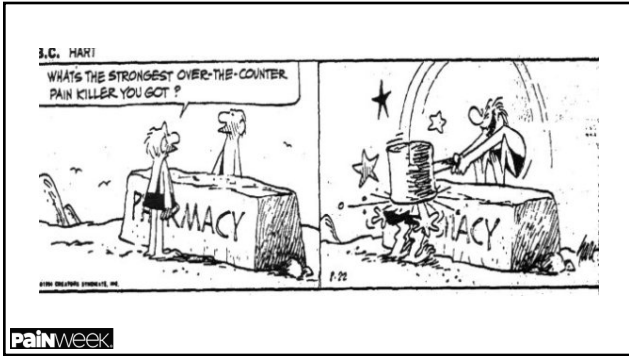
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### This should only hurt a little!



- Pain encountered in community pharmacies are typically mild-to-moderate and self-limiting
- Typical conditions include toothaches, headaches, dysmenorrhea, arthritis, and musculoskeletal injuries

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### OTC Analgesics

Oral	Topical	Other
<ul style="list-style-type: none"> <li>• Acetaminophen</li> <li>• NSAIDs</li> </ul>	<ul style="list-style-type: none"> <li>• Counterirritants</li> <li>• CBD oil</li> <li>• Blue emu</li> </ul>	<ul style="list-style-type: none"> <li>• Heat/thermal wraps</li> <li>• TENS</li> </ul>

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### OTC Analgesic Facts

- Analgesics = most frequently used of all OTC products
- 20% of the population uses OTC analgesics weekly
- 87% of women and 80% men used OTC analgesics in past year
- Most commonly used OTC products in children were analgesics/antipyretics



Terrie YC. Pharmacy Times, 2013. <http://www.pharmacytimes.com/print.php?url=/publications/otc/2013/otcguide-2013/pain-control-using-nonprescription-analgesics>

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### Half of all patients don't read the label!




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### So what?

#### Drug-Disease Interactions

- 58% do not consider their pre-existing medical conditions when selecting an OTC analgesic
- >80% did not know about the potential for adverse effects when aspirin is used in asthmatics
- >60% did not know the precautions for these drugs in those with hepatic or renal disease

#### Drug-Drug Interactions

- 65% do not consider other OTC medicines they're taking when selecting an OTC analgesic
- 88% are not aware that ibuprofen may interfere with the cardioprotective benefits of aspirin

#### Dosing

- 33% admit that they have taken more than the recommended amount of an OTC medication




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**Jerome**

- Jerome is a 26-year-old man who presents to his local pharmacy asking for advice to treat the “relentless” headache he’s had for the past several days
- Jerome recently graduated from law school, and has been studying furiously for the bar exam
- He denies having chronic headaches, but notices a pattern of headache when he is stressed and anxious (like now)

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**Jerome (cont’d)**

- He describes the pain as bilateral, extending over the top of his head and the base of his skull
- Jerome describes the pain as constricting, feels like his hat is too tight
- He states the pain evolved gradually over 4-6 hours, and has been present for 2 days
- He denies any throbbing sensation, pressure behind his eyes or face, and the pain is not worsened by light or sound

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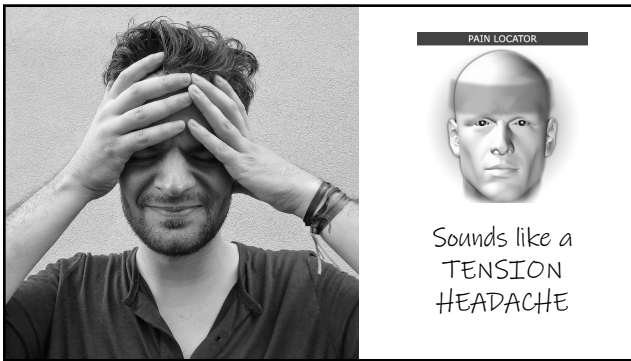
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**OTC Analgesics**

Oral	Topical	Other
<ul style="list-style-type: none"> <li>• Acetaminophen</li> <li>• NSAIDs</li> </ul>	<ul style="list-style-type: none"> <li>• Counterirritants</li> <li>• CBD oil</li> <li>• Blue emu</li> </ul>	<ul style="list-style-type: none"> <li>• Heat/thermal wraps</li> <li>• TENS</li> </ul>

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### Acetaminophen – Mechanism of Action

- Mechanism is poorly understood
- Weak COX-2 inhibitor
- Reduces PG in the CNS, inhibiting endogenous pyrogens
- Interacts with the endocannabinoid system
- Reduces nitric oxide pathway
- Activates descending serotonergic pain pathways

*Analgesic  
Antipyretic*

**A**nti  
**P**ain  
**A**nti  
**P**yreitic

**PainWeek** Mallick-Searle T. J for Nurse Prac 2016;12(3)174-180.

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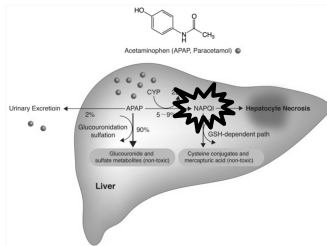
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### Acetaminophen – Adverse Effects

- Hepatotoxicity
  - Early symptoms:
    - Abdominal pain
    - Nausea/vomiting
    - Diarrhea
    - Fatigue
  - ↑ LFTs
  - Jaundice
  - Encephalopathy
  - Coma



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### Acetaminophen

- Preferred in the following patient populations:
  - Elderly
  - History of peptic ulcer disease, GI bleed
  - Patients taking warfarin
    - Recommend limiting acetaminophen dose to ≤ 2 g weekly
- Labeled acetaminophen dosing varies by formulation
  - Do not exceed 4 grams daily; consider all drugs
- Use caution/avoid with liver disease, chronic alcohol use

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### NSAIDs – Mechanism of Action

- Ibuprofen, naproxen, aspirin
  - Nonselective inhibition of COX-1 and 2, reducing prostaglandin and thromboxane synthesis
  - Interact with endocannabinoid system
- Aspirin
  - Binds **irreversibly** to COX-1
  - Anti-inflammatory effect is seen at higher doses

*Analgesic  
Antipyretic  
Anti-inflammatory  
Antiplatelet*

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### NSAIDs – Adverse Effects

- **Gastrointestinal**
  - Epigastric pain, dyspepsia, nausea/vomiting (most common)
  - Gastric ulceration with/without bleeding, peptic ulcer disease, or GI perforation
- **Cardiovascular**
  - Myocardial infarction, stroke
  - Increase systolic blood pressure by ~ 4 mmHg
- **Renal**
  - Decreased synthesis of PGs involved in maintaining renal blood flow can result in sodium and water retention
- **Respiratory**
  - Bronchospasm, deterioration of symptoms in asthmatics

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### NSAIDs

- Use at the **lowest possible dose** for the **shortest possible duration**
- Labeled NSAID dosing varies by formulation
- Use caution/avoid in the following patient populations:
  - GI disorders/bleeding
  - Cardiovascular disease, heart failure, or a history of stroke
  - Renal impairment
  - Asthma

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### OTC Analgesics for Adults and Children > 12

Agent	Dosage Forms	Usual Adult Dose (maximum daily dose)
Acetaminophen	Immediate-release tablets Extended-release tablets Effervescent tablets Disintegrating tablets Rapid-release tablets Chewable tablets	Capsules Liquid drops Elixirs Suspension Suppositories
Ibuprofen	Immediate release tablets Chewable tablets Suspension, Liquid drops	325-1000 mg every 4-6 hours (FDA recommended max 4 g daily)
Naproxen sodium	Tablets	200-400 mg every 4-6 hours (1200 mg)
Aspirin	Immediate-release, buffered, enteric-coated, film-coated, effervescent and chewable tablets Suppositories	220 mg every 8-12 hours (660 mg) Over age 65: 220 mg every 12 hours (440 mg)
Magnesium salicylate	Tablets	650-1000 mg every 4-6 hours (4000 mg)



Kirnskey D, et al. Handbook of Nonprescription Drugs, 19th ed. APNA, 2014.

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### FDA Approved Doses for OTC Analgesics in Children < 12 years

Age (years)	Weight (lb)	Ibuprofen (mg) Dose by body weight (mg/kg): 5-10 mg/kg	Acetaminophen (mg) 10-15 mg/kg	Aspirin (mg) 10-15 mg/kg
< 2	< 24	Ask prescriber	Ask prescriber	Ask prescriber
2-3	24-35	100	160	160
4-5	36-47	150	240	240
6-8	48-59	200	320	320
9-10	60-71	250	400	400
11	72-95	300	480	480



Kirnskey D, et al. Handbook of Nonprescription Drugs, 19th ed. APNA, 2014.

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### Clinically Important Drug-Drug Interactions

Analgesic/Antipyretic	Drug	Potential Interaction	Management/Preventive Measure
Acetaminophen	Alcohol	Increased risk of hepatotoxicity	Avoid concurrent use if possible; minimize alcohol intake when using acetaminophen
Acetaminophen	Warfarin	Increased risk of bleeding (↑ INR)	Limit acetaminophen to occasional use; monitor INR for several weeks when acetaminophen 2-4 grams daily is added or discontinued in patients on warfarin
Aspirin	Valproic acid	Displacement from protein-binding sites and inhibition of valproic acid metabolism	Avoid concurrent use; use naproxen instead of aspirin (no interaction)
Aspirin	NSAIDs, including COX-2 inhibitors	Increased risk of gastroduodenal ulcers and bleeding	Avoid concurrent use if possible; consider use of gastroprotective agents (eg, PPIs)



Kirnskey D, et al. Handbook of Nonprescription Drugs, 19th ed. APNA, 2014.

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### Clinically Important Drug-Drug Interactions

Analgesic/Antipyretic	Drug	Potential Interaction	Management/Preventive Measure
Ibuprofen	Aspirin	Decreased antiplatelet effect of aspirin	Aspirin should be taken at least 30 minutes before or 8 hours after ibuprofen. Use acetaminophen (or other analgesic) instead of ibuprofen
Ibuprofen	Phenytoin	Displacement from protein-binding sites	Monitor free phenytoin levels; adjust dose as indicated
NSAIDs (several)	Bisphosphonates	Increased risk of GI or esophageal ulceration	Use caution with concomitant use
NSAIDs (several)	Digoxin	Renal clearance of digoxin inhibited	Monitor digoxin levels; adjust dose as indicated
Salicylates and NSAIDs (several)	Antihypertensive agents; beta-blockers, ACE inhibitors, vasodilators, diuretics	Antihypertensive effect inhibited; possible hyperkalemia with potassium-sparing diuretics and ACE inhibitors	Monitor BP, cardiac function, and potassium levels



Kinsley D, et al. Handbook of Nonprescription Drugs, 18th ed. APNA, 2014.

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### Clinically Important Drug-Drug Interactions

Analgesic/Antipyretic	Drug	Potential Interaction	Management/Preventive Measure
Salicylates and NSAIDs	Anticoagulants	Increased risk of GI bleeding	Avoid concurrent use, if possible; risk is lowest with salicylate and choline magnesium trisilicylate
Salicylates and NSAIDs	Alcohol	Increased risk of GI bleeding	Avoid concurrent use, if possible; minimize alcohol intake when using salicylates and NSAIDs
Salicylates and NSAIDs (several)	Methotrexate	Decreased methotrexate clearance	Avoid salicylates and NSAIDs with high-dose methotrexate therapy; monitor levels with concurrent treatment
Salicylates (moderate-high doses)	Sulfonylureas	Increased risk of hypoglycemia	Avoid concurrent use, if possible; monitor blood glucose levels when changing salicylate dose



Kinsley D, et al. Handbook of Nonprescription Drugs, 18th ed. APNA, 2014.

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#### OTC pain relievers dosage chart for adults and children 12 years and older

Drug	AMOUNT	DOSE & FREQUENCY	DAILY LIMIT
<b>Acetaminophen</b>			
Acetaminophen regular strength <i>Tylenol</i> Regular Strength	325 mg (per pill)	2 pills every 4 to 6 hours while symptoms last	Do not take more than 10 pills in 24 hours.
Acetaminophen extra strength <i>Tylenol</i> Extra Strength	500 mg (per pill)	2 pills every 6 hours while symptoms last	Do not take more than 6 pills in 24 hours.
Acetaminophen extended release <i>Tylenol</i> XR, Arthritis Pain	650 mg (per pill)	2 pills every 8 hours	Do not take more than 6 pills in 24 hours.
<b>NSAIDs</b> (nonsteroidal anti-inflammatory drugs)			
Ibuprofen <i>Motrin</i> IB and <i>Advil</i>	200 mg (per pill)	1 pill every 4 to 6 hours while symptoms last (1 pill or fewer does not require a pill)	Do not take more than 6 pills in 24 hours.
Naproxen sodium <i>Alleve</i>	220 mg (per pill)	1 pill every 8 to 12 hours while symptoms last (1 pill or fewer does not require a pill)	Do not take more than 2 pills in any 8 to 12-hour period. Do not take more than 3 pills in 24 hours.
Aspirin regular strength <i> Bayer</i> Regular Strength	325 mg (per pill)	1 or 2 pills every 4 hours, or 3 pills every 6 hours	Do not take more than 12 pills in 24 hours.
Aspirin extra strength <i> Bayer</i> Extra Strength	500 mg (per pill)	1 or 2 pills every 4 to 6 hours	Do not take more than 9 pills in 24 hours.

**Acetaminophen dosage daily limit is 4,000 mg.**  
For your safety, do not take more than this amount in 24 hours.

**Ibuprofen dosage daily limit is 1,200 mg.**  
For your safety, do not take more than this amount in 24 hours.

**Naproxen sodium dosage daily limit is 660 mg.**  
For your safety, do not take more than this amount in 24 hours.

**Aspirin dosage daily limit is 4,000 mg.**  
For your safety, do not take more than this amount in 24 hours.

**Check the box if you:**

- drink 3 or more alcoholic beverages every day
- have liver disease
- take prescription medicines, such as NSAIDs, diuretics, or blood thinning drugs (anticoagulants)
- take other OTC medicines containing NSAIDs, including cough and cold or allergy products, sleep aids, and pain relievers
- have a history of stomach bleeding or stomach ulcers
- have a history of stomach problems, such as heartburn
- have kidney disease
- have heart disease
- have high blood pressure
- have asthma

**NSAIDs**  
**Naproxen sodium** for example, *Alleve*

**6** levels of risk, professional if you have questions.

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**Sally**

- Sally is a 68-year-old woman who presents to the pharmacy with complaints of an aching back. She wants to know what she can take to “make the pain go away!”
- *“Since the weather was so gorgeous yesterday, I spent all day outside gardening and playing with my toddler grandson. I was constantly chasing him around and picking him up.”*
- She denies other signs/symptoms, including weakness.
- Her past medical history includes hypertension (uncontrolled), dyslipidemia & osteoarthritis

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**Sally (cont'd)**

- She describes her pain as “achy” and “sore,” and states it’s mostly located in her mid-to-lower back
- She rates her pain as a 5/10
- She tried the ThermaCare® HeatWrap but has not experienced any significant relief

What are our options?

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### OTC Analgesics



Topical	Other
<ul style="list-style-type: none"> <li>• Counterirritants</li> <li>• CBD oil</li> <li>• Blue emu</li> </ul>	<ul style="list-style-type: none"> <li>• Heat/thermal wraps</li> <li>• TENS</li> </ul>

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### Counterirritants – Mechanism of Action



- Paradoxical pain relieving effect
  - Produce a less severe pain to counter a more intense one
  - Relieve pain indirectly by stimulating cutaneous receptors to induce sensations of cold, warmth, or itching and distracting from deep-seated pain in muscles, tendons, joints, etc
- Psychological component

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### Counterirritants

Group	Ingredients	Concentration	Mechanism of Action	Frequency and Duration of Use
A	Allyl isothiocyanate	0.5 – 5 %	Rubefaciants (increase blood flow)	Apply no more than 3-4 times daily for up to 7 days
	Ammonia water	1 – 2.5 %		
	Methyl salicylate	10 – 60 %		
	Turpentine oil	6 – 50 %		
B	Camphor	3 – 11 %	Produce cooling sensation	Same as group A
	Menthol	1.25 – 16 %		
C	Histamine dihydrochloride	0.025 – 0.1 %	Cause vasodilation	Same as group A
	Methyl nicotinate	0.25 – 1 %		
D	Capsicum	0.025 – 0.25 %	Incite irritation without rubefaction; are as potent as group A ingredients	Acute pain: Same as group A Chronic pain: Apply 3-4 times daily for duration of pain
	Capsicum oleoresin	0.025 – 0.25 %		
	Capsaicin	0.025 – 0.25 %		

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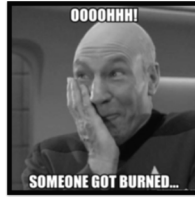
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### Counterirritants – Adverse Effects

- Skin irritation and/or rash
- Erythema
- Blistering
- Thermal hyperalgesia
- Systemic reactions
  - Salicylate toxicity



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### Counterirritants – Application

- If pain, swelling, or blistering of the skin occurs after application of a topical analgesic, patients should immediately discontinue use of the product and seek medical attention
- Do not bandage the area tightly where the product has been applied
- Do not use any heat where the product has been applied
- Do not apply to wounded, damaged, broken, or irritated skin
- Do not allow these medications to come in contact with the eyes, or inside the nose, mouth, or genitals

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### Counterirritants

- **Methyl salicylate**
  - Occurs naturally as wintergreen oil or sweet birch oil
  - Usually combined with other ingredients (eg, menthol and/or camphor)
  - Responsible for the “hot” action in many topical counterirritant products
  - **Mechanism of action:**
    - Vasodilation of cutaneous vasculature → reactive hyperemia + increase in localized skin temperature = counterirritant effect
    - Inhibition of central and peripheral prostaglandin synthesis
  - **Contraindications/precautions:**
    - Avoid heat exposure and exercise after application
    - Avoid use in children and patients with aspirin sensitivities, severe asthma or nasal polyps due to possible percutaneous absorption

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### Counterirritants (cont'd)

▪ **Camphor**

- Obtained naturally from camphor tree, but majority is synthetic
- **Mechanism of action** – dose-dependent effect
  - **Camphor 0.1-3%:** depresses cutaneous receptors and acts as a topical analgesic, anesthetic, and antipruritic
  - **Camphor > 3%:** stimulates nerve endings in the skin and induces relief of pain and discomfort by masking moderate-severe deeper visceral pain, with a milder pain arising from the skin at the level of innervation
- **Precautions:**
  - Camphor toxicity – tonic-clonic seizures, nausea, vomiting, colic, headache, dizziness, delirium, coma, and death




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### Counterirritants (cont'd)

▪ **Menthol**

- Extracted from peppermint oil or prepared synthetically
- Also used as a flavoring agent and permeability enhancer
- Responsible for the "cold" action in many topical counterirritant products
- **Mechanism of action** – dose-dependent effect
  - **Menthol <1%:** depresses cutaneous receptor response (anesthetic)
  - **Menthol >1.25%:** stimulates cutaneous receptor response (counterirritant)
  - Activates TRPM8 menthol receptor, triggering the sensation of cold.
- **Contraindications/precautions:**
  - C/I in patients with hypersensitivity or sensitization to the agent (eg, urticaria, erythema, and other cutaneous lesions)




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### Counterirritants – Product Examples

Product	Ingredients	Packaging
Bengay Ultra Strength Pain Relieving Cream	Methyl salicylate 30% Menthol 10% Camphor 4%	
Icy Hot Cream Extra Strength/Precise Pain Relieving Cream	Methyl salicylate 30% Menthol 10%	
Salonpas Pain Relief Patch	Methyl salicylate 10% Menthol 3%	




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### Counterirritants – Product Examples (cont'd)

Product	Ingredients	Packaging
Tiger Balm Arthritis Rub Cream	Camphor 11% Menthol 11%	
Aspercreme Heat Pain Relieving Gel	Menthol 10%	
Mineral Ice	Menthol 2%	

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### Counterirritants

▪ **Capsaicin**

- Major ingredient in hot chili peppers
- Available OTC in many different formulations
- Available Rx as Qutenza® (capsaicin 8% patch)
- Mechanism of action:
  - Depletion of substance P from sensory neurons
  - When substance P is released, burning pain occurs but diminishes with repeated application

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### Counterirritants (cont'd)

▪ **Capsaicin**

- Patient counseling points:
  - Instruct patients to wear gloves during application and wash hands following use; if the hands are the site of application, the patient should wait 30 minutes after application and then wash their hands
  - Do not allow capsaicin to come into contact with eyes or mucous membranes
  - Pain relief is usually noted within 14 days but can take up to 6 weeks
  - Adherence is important – once capsaicin has begun to relieve pain, its use must be continued regularly 3-4 times daily

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### Counterirritants – Product Examples

Product	Ingredients	Packaging
Capzasin Arthritis Pain Relief No-Mess Applicator	Capsaicin 0.15%	
Capzasin-HP Arthritis Pain Relief Cream	Capsaicin 0.1%	
Zostrix Arthritis Pain Relief Cream	Capsaicin 0.025%	




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### Cannabidiol (CBD) Oil



- Most comes from industrial hemp; extracted then added to a carrier oil
- Commonly used for arthritis pain
- Concentrations found to vary significantly from product labeling




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### Blue Emu

- Originates from Australian Aborigines
- Comes from emu fat
- Anti-inflammatory properties
- Shown to be effective in mice




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### Heat/Thermal Wraps

- May help reduce pain by increasing blood flow
- Has been studied in the treatment of acute low back pain (< 4 weeks duration) with favorable effects
- Osteoarthritis guidelines recommend heat as adjunct nonpharmacologic treatment for pain and stiffness
- Apply for 15-20 minutes 3-4 times daily (regular heat); ThermaCare® products can be worn for up to 8-12 hours
- Should not be applied to recently injured (< 48 hours) or inflamed areas; should not be used with other topical agents or over broken skin




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### Transcutaneous Electrical Nerve Stimulation (TENS)



- Class II Medical Device FDA-approved for the relief of pain associated with sore, aching muscles, joint pain, or chronic intractable pain
- Mechanism of action:
  - Alteration of pain transmission
  - Increase in production of natural endorphins
- Typically used for 15-30 minutes up to 3 times daily
- Should not be used in patients with internal or attached medical devices (eg, pacemakers, defibrillators), pregnant patients, or in the pediatric population




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### Does Sally have any exclusions for self-tx?

- Moderate-to-severe pain (pain score > 6)
- Pain that lasts > 10 days
- Pain that continues > 7 days after tx w/ a topical analgesic
- Increased intensity or change in character of pain
- Pelvic or abdominal pain (other than dysmenorrhea)
- Accompanying nausea, vomiting, fever, or other signs of systemic infection or disorder
- Visually deformed joint, abnormal movement, weakness in any limb, or suspected fracture
- Third trimester of pregnancy
- < 2 years of age




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**Sally**

- She does not have any exclusions to self-treatment
- But she has a history of uncontrolled hypertension
  - Avoid NSAIDs, can recommend acetaminophen instead
- Recommend a topical analgesic
  - Apply SalonPas original patch (methyl salicylate 6.3%, menthol 5.7%, and camphor 1.2%) to back 3-4 times a day
    - This is just one example. Any available OTC patch would work!
  - Can use for up to 7 days
  - Do not use heat when you are using this medication




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**The 411 on Nonprescription Analgesics:  
When to Hold 'Em, When to Fold 'Em**

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