

Lubrizol Life Science Health's (LLS Health's) Carbopol® polymers, Pemulen™ polymers, and Noveon® AA-1 polycarbophil are best-in-class excipients, providing formulation performance and stability through simple and flexible processing. These excipients are used in a wide range of topical pain relief products, including innovator and generic drugs in the form of gels, emulsions, and liquids.

- Carbopol® polymers' and Noveon® polycarbophil's primary functions include rheology modification as well as mucoadhesion.
- Pemulen™ polymers provide exceptional emulsion stability without the need for additional surfactants, and can be combined with Carbopol® polymers.

#### **Properties Of LLS Health Polymers Suitable For Use In Topical Applications**

Pharmacopeia Monograph Compendial Name						Application Type			Viscosity Specification Ranges	
Product Trade Name	Polymerization Solvent	United States (USP/NF)	Europe (Ph.Eur.)/ India (I.P.)	Japan (JPE) <sup>1</sup>	China (Ch.P.)	Creams	Gels	Bio- adhesives	Min (Cp)	Max (Cp)
Carbopol*	polymers									
971P NF	Ethyl Acetate	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	-	•	4,000	11,000
974P NF	Ethyl Acetate	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	•	29,400	39,400
980 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type C	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	•	40,000	60,000
981 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type A	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	-	•	4,000	10,000
5984 EP	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type B	Carbomers	Carboxyvinyl Polymer	Carbomer Homopolymer	•	•	•	30,500	39,400
ETD 2020 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type B				•	•	•	47,000	77,000
Ultrez 10 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type A				•	•	•	45,000	65,000
Pemulen™	polymers									
TR-1 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type B				•	•	•	14,000	26,500
TR-2 NF	Cosolvent <sup>2</sup>	Carbomer Homopolymer Type A				•	•	•	4,500	13,500
Noveon® p	olycarbophil USP									
AA-1 USP	Ethyl Acetate	Polycarbophil				•	•	•	2,000	12,000



# LLS Health excipients offer a wide range of benefits for topical formulators, manufacturers, and end-product users:

### Formulation and manufacturing benefits

- Carbopol® polymers are <u>highly efficient</u> thickening agents, and therefore are only needed in small amounts for use in a formulation (0.2-3.0 wt%).
- Ingredient flexibility enables formulation for a wide range of applications, including creams, lotions, gels, and liquids.
- In topical formulations, LLS Health excipients enable shear thinning rheology, meaning that under applied force the viscosity of a formulation will decrease, but will immediately return to the initial value upon removal of the force.
  - This property has benefits in manufacturing processes, allowing for easier mixing, pumping, and packaging.
- Carbopol® Ultrez 10NF and ETD 2020NF polymers are self-wetting polymers that allow for easy dispersion, which facilitate simpler processing.

Typical LLS Health Topical Polymer Usage Levels

Application	Usage level (wt. %)				
Topical aqueous gel	0.5 - 3.0				
Topical hydroalcoholic gel	0.5 - 3.0				
Topical emulsions	0.2 - 0.4				



### Improving the patient experience

Users of topical pain relief products, particularly those with chronic pain, are seeking products that have optimal aesthetics and skin feel, fit in easily with daily activities, and provide fast, targeted relief.

- Upon application of emulsions formulated using Pemulen<sup>™</sup> polymers, ions present in skin make the polymer collapse, allowing the oil droplets to coalesce and form a continuous lipophilic film on the skin surface.
  - This promotes fast absorption and long-lasting drug delivery.

- Various Carbopol® polymer grades have differing rheology-modification properties, which gives developers the flexibility to achieve the desired sensory properties.
- The shear-thinning properties of LLS Health polymers facilitate simpler dosing, pouring, spreading, and spraying, making the end product easier to use.



# **Unique NSAID considerations & applicable APIs**

Among active pharmaceutical ingredients (APIs), non-steroidal anti-inflammatory drugs (NSAIDs) are commonly used in topical products to treat pain. These drugs typically exhibit poor water solubility or instability at specific pH values, necessitating the use of hydroalcoholic, anhydrous, or oil-in-water systems.

- LLS Health excipients bring value across all these formulation approaches and systems due to their versatile functionality.
- Carbopol® polymers are compatible with a wide range of pharmaceutical solvents, facilitating their use in aqueous, hydroalcoholic, anhydrous, and oil-in-water systems.

Below is an example list of active ingredients, including NSAIDs, used in pain relief topical products that can be successfully formulated with Carbopol®, Pemulen™, and Noveon® polymers\*:

- Aceclofenac
- Camphor
- Benzocaine
- Capsaicin
- Cannabidiol (CBD)
- Diclofenac
- Etofenamate
- Flurbiprofen
- Ibuprofen
- Indomethacin
- Ketoprofen
- Ketorolac
- Lidocaine
- Meloxicam
- Menthol
- Methocarbamol
- Methyl salicylate
- Naproxen
- Nepafenac
- Nimesulide
- Piroxicam
- Prilocaine

### Looking for inspiration? See our example formulations.

- <u>Ketoprofen Clear Hydroalcoholic Gel</u> contains Ketoprofen 2.5% w/w.
- Methyl Salicylate and Menthol Hydroalcoholic <u>Clear Gel</u> - contains Methyl Salicylate 15% and Menthol 7% w/w.
- Methyl Salicylate, Menthol, Thymol, Eucalyptus Oil Compound Emulgel - contains Methyl Salicylate 12.5%, Menthol 2.5%, Thymol 0.12% and Eucalyptus oil 0.2% w/w. This formulation also features both Pemulen™ polymer as an emulsifying agent and Carbopol® polymer as a rheology modifier.
- Nimesulide, Methyl Salicylate and Menthol Cream

   contains Nimesulide 1%, Methyl Salicylate 10%
   and Menthol 5% w/w.

LLS Health has developed a comprehensive selection of example base formulations for multiple dosage forms including gels, emulgels and creams, and also covering multiple system types such as aqueous, hydroalcoholic and oil-in-water.

All our formulations have undergone rigorous stability testing, and proved stable for a mimimum of 3 months under accelerated long-term ICH conditions.

Contact us, or request a sample to learn more.





<sup>\*</sup> This list is not exhaustive for every type of topical pain relief drug that can be formulated with LLS Health excipients

## Partner with LLS Health and formulate with confidence

- Worldwide technical and application support services
- Dedicated regulatory staff and quality assurance
- Sustainable, secure global supply chain
- Full excipient compendial compliance
- Decades of precedence of use in marketed topical pain products



To find out more about using Lubrizol excipients in your topical pain relief formulations, contact us here.



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