



SUGGESTED FORMULA

Urea/Docusate Sodium/LEP Gel

Version number: 1.0

Volume: 30gm

| | |
|---------------------------------------|-----------|
| Docusate Sodium, USP 85% | 10gm |
| Urea, USP (UR107) | 10gm |
| Citric Acid Hydrous, USP | 2.5gm |
| Polysorbate 80 (PO138) | 10gm |
| Purified Water (W1014) | 45mL |
| Lecithin/Isopropyl Palmitate Solution | 20gm |
| Isopropyl Palmitate, NF (IS160) | q.s 100gm |

SUGGESTED COMPOUNDING PROCEDURES

1. Triturate Docusate Sodium, Urea and Citric Acid together
2. Add enough Polysorbate 80 to form a paste
3. Add remaining Polysorbate 80 and LIP Solution and mix well
4. Add Purified Water and Q.S. with Isopropyl Palmitate
5. Mill all ingredients well, if needed final product can be milled or levigated on ointment slab
6. Suggested quality assessments:
 - a. Uniform gel with no lumps
 - b. Color
 - c. Label (s)- auxiliary labels (external use), storage, BUD

Store Room Temperature

No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Beyond-Use Dates of preparations are conservative estimates by the formulator using reference books, peer-reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic observations and current USP guidelines. Compounders may have stability studies performed by a reputable laboratory if they wish to extend the Beyond-Use Date.

It is recommended that you follow USP <795> recommendations for potency testing.

Beyond-Use Date should be assigned base on the current USP 795 Guidelines – 30 days for topical use.

Precautions should be taken to prevent cross-contamination and exposure of ingredients to the compounder and contamination of the preparation by the compounder. Wear appropriate protective equipment. Use safety enclosures (hoods) when weighing and mixing.

JD 5/18