A new treatment for Ulcerative Colitis

www.treatwithtrud.com
A NEW TOPICAL TREATMENT FOR ULCERATIVE COLITIS:

Non-pharmacological therapies

- 5-ASAs
- Steroids
- Immunomodulators
- Monoclonal antibodies

Topical administration

- Reduction of symptoms
- Unique formulation
- Designed for Ulcerative Colitis

Combination of oral and rectal treatments improves the therapeutical efficacy

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The latest treatment available for mild to moderate Ulcerative Colitis (UC) patients.

TRUD™
UNIQUE PROPERTIES

- Innovative formulation with High Molecular Weight (HMW) and Low Molecular Weight (LMW) sodium hyaluronates (HA)
- Muco-adhesiveness
- Rectal administration with good tolerability
- Dual Mode of action
**MODE OF ACTION**

**TRUD™:**
- Facilitates mucosa healing: LMW HA
- Provides protective barrier: HMW HA

**MUCOSA HEALING & PROTECTION**

1. **Inflamed colon (with ulcer)**
   - Affected region
   - LMW HA penetration - epithelial restitution of healthy cells
     - LMW HA

2. **HMW HA coating - protection**
   - HMW HA

3. **Healthy colon restored**
   - Healthy Mucus Lining

- Mucus Lining
- Epithelial cells
- Healthy Mucus Lining
**LMW HA – DIFFUSES INTO INTERSTITIAL SPACE TO PROMOTE EPITHELIAL RESTITUTION**[^3]

- Reorganise of the cytoskeleton to facilitate movement: **FLATTENING & SPREADING**

- Adjacent epithelial cells **MIGRATION** into the wound to cover the denuded area

- Facilitates epithelial cells **PROLIFERATION** to replenish the decreased cell pool

- Promotes **DIFFERENTIATION** to maintain the numerous functional activities of the mucosal epithelium

**HMW HA – FORMS PROTECTIVE COAT ON MUCOSA BY:**

- Provides hydration[^4], ensuring viscosity of the mucus

- Protects the colon from toxins and bacteria by acting as a barrier

- Moderates the migration of leucocytes to limit excessive inflammation[^5]
Safety and Efficacy of sodium hyaluronate in the induction of clinical and endoscopic remission in subjects with distal ulcerative colitis.


**Average Endoscopic Score**

- **Baseline**: 1.57
- **Day 28**: 1.10

Statistically significant reduction in Average Endoscopic score

**Average UCDAI Score**

- **Baseline**: 6.10
- **Day 28**: 3.81

Statistically significant reduction in Average UCDAI Score

**Remission rate (%)**

- **Clinical**: 38.1%
- **Endoscopic**: 47.6%

Clinical and Endoscopic Remissions at completion

**Response rate (%)**

- **Clinical**: 42.9%
- **Endoscopic**: 47.6%

Clinical and Endoscopic Responses at completion
BENEFITS OF TRUD™

- Symptoms relief
- Clinical and endoscopic remission in 50% of patients
- Complete mucosa healing in 25% of patients
- Optimal safety

A NEW OPTION IN TREATING UC

References:
The Medical Device for UC treatment

What is TRUD™?
TRUD™ is a white enema bottle containing a thick suspension that includes sodium hyaluronate and is used to relieve the symptoms of mild to moderate ulcerative colitis. Ulcerative colitis is a disease of the colon and rectum in which the mucosal lining becomes inflamed. Symptoms include rectal bleeding, frequent diarrhoea and abdominal pain. TRUD™ is applied via the rectum and forms a protective coat over the lining of the distal colon and rectum. This allows the mucosal tissue to heal naturally which reduces the symptoms of ulcerative colitis.

Warnings about the use of TRUD™
TRUD™ is for rectal administration only. Do not use for children. Do not use TRUD™ if you are allergic to parabens preservatives or sodium hyaluronate. Do not use if you are pregnant or breast feeding. Use each enema bottle of TRUD™ once only. Throw the bottle away after you have used it even if you have not emptied the bottle. If you use a TRUD™ bottle for a second time it may become contaminated with micro-organisms which would cause you harm.

How to use TRUD™
1. Use one TRUD™ enema every day at bedtime for 28 days.
2. It is recommended to empty your bowel and bladder before administration.
3. Wash your hands thoroughly with soap and water.
4. Take one enema bottle out of the box and shake it well for approximately 30 seconds. (fig 1).
5. Break the seal on the bottle by pressing the cap down, as shown. (fig 2).
6. Remove the protective cap from the bottle. (fig 3).
7. Lie down on your left side with the left leg outstretched and the right leg bent forward for balance (fig 4).
8. Carefully insert the applicator tip deep into the rectum and gently squeeze the enema out of the bottle. (fig 5).
9. When the bottle is empty withdraw the tip with the bottle still compressed.
10. The enema suspension should be retained in the bowel. Remain in the administration position for 5 to 10 minutes or until the urge to pass the enema has disappeared.
11. Replace the protective cap on the bottle and dispose of it safely according to local regulations. (fig 6).
12. Wash your hands thoroughly and try to resist the urge to empty your bowels until the next day.
13. You may experience a little discomfort and a feeling of urgency to empty your bowels immediately after applying TRUD™ for the first time. This is normal and very likely.
14. If you have forgotten to use TRUD™ at bedtime use one the next morning if it is convenient. Otherwise use the next one at night.

Adverse effects
Rarely an allergic reaction can occur. Tell your doctor if you get a rash after using TRUD™, any shortness of breath, palpitations or chest pains. These effects should disappear when you stop using TRUD™. Common side effects are bloating, flatulence, nausea and pain. If you have a serious side effect or you notice side effects not listed in this leaflet please tell your doctor.

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How to store TRUD™
Keep out of reach of children. Store TRUD™ between 2°C and 30°C. Protect the TRUD™ enema bottle from direct sunlight. Do not pierce or burn the TRUD™ bottle even if it is empty. Do not use TRUD™ after the expiry date printed on the bottle and box. Do not dispose of TRUD™ via wastewater or household waste. Dispose of TRUD™ according to local regulations. Ask your pharmacist how to dispose of used bottles.

Further Information
TRUD™ is intended to be used to supplement the intestinal mucosa of patients suffering from mild to moderate distal ulcerative colitis. TRUD™ provides a soft barrier to minimise the effects of continuous immune stimulation by triggers from the contents of the colon on the colonic mucosa and thereby provide the ideal environment for the regeneration of the intestinal mucosa. TRUD™ is composed of high molecular weight sodium hyaluronate 1.8 x 10^6 Daltons and low molecular weight sodium hyaluronate 0.35 x 10^6 Daltons together with other ingredients, which ensure that the enema solution adheres to the mucosa of the distal left side colon when administered via the rectum.

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