

Information for Users of TRUD™

Read this leaflet carefully before using TRUD™

Keep the leaflet you may need to read it again.

Ask your pharmacist or doctor if you have any questions before using TRUD™.

Use of TRUD™ might affect the efficacy of other treatments you are receiving. Discuss this with your doctor.

If you have any serious side effects or you have any side effects that are not in this leaflet please tell your doctor or pharmacist.

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.

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 1.8×10^6 Daltons and low molecular weight sodium hyaluronate 0.35×10^6 Daltons together with other ingredients, including xanthan gum, 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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Symbols used on the packaging

-  Lot number
-  Expiry Date
-  Use each enema bottle of TRUD™ once only
-  Store between 2°C and 30°C
-  Protect from light
-  Manufacturer
-  Read all of this leaflet carefully before using TRUD™

