

INFORMATION FOR THE CONSUMER

 ENTOCORT[®] ENEMA

budesonide enema

0.02mg/ml, when reconstituted

Before using ENTOCORT retention enema, please read this instruction leaflet. It has been prepared by the makers of ENTOCORT Enema to help you get the most benefit from this medicine. It contains general points about ENTOCORT Enema and should add to more specific advice from your doctor or pharmacist.

Why is ENTOCORT Enema Used?

ENTOCORT Enema is used to treat ulcerative colitis localised in the rectum and the lower large bowel. Ulcerative colitis is caused by inflammation in the bowel wall.

How Does ENTOCORT Enema Work?

ENTOCORT belongs to a group of medicines called glucocorticosteroids (a type of cortisone), that are used to reduce inflammation.

ENTOCORT Enema reduces inflammation in the large bowel and the rectum. After preparation ENTOCORT Enema is placed directly into the rectum.

What Should I Tell My Doctor Before/During Use of ENTOCORT Enema?

Inform your doctor:

- If you have any unusual reaction to budesonide or any other ingredients in ENTOCORT Enema (tablet and liquid) like lactose and the propyl- and methylparahydroxybenzoates, or to any other medicines.
- If you have any ongoing infections (including active tuberculosis) or if you get an infection.
- About any health problems you have such as liver disease, bowel problems (obstructions, perforations, fistulas), diabetes, stomach ulcers, osteoporosis and glaucoma.
- About all medicines you take (including steroids) and the ones you have bought without a prescription.
- If you are pregnant, plan to become pregnant or are breastfeeding. If your symptoms become worse. Do not stop using ENTOCORT Enema until your doctor tells you to.

ENTOCORT Enema has been specifically prescribed for your current condition. Do not use it for other problems unless your doctor tells you to do so.

Never give your medicine to someone else.

Dosage

The dosage is individual. Follow your doctor's directions carefully. They may differ from the information in this leaflet.

Before using this, or any other enema with rigid tubing, colostomy and ileostomy patients should consult with their doctor.

The budesonide enema should be administered in the evening before going to bed.

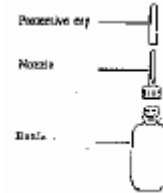
The budesonide enema (0.02 mg/mL) consists of a dispersible tablet (I) and solution (II).

- I. 1 dispersible tablet contains: Budesonide 2.3 mg, lactose, colour (riboflavin-5-phosphate sodium), and constituents.
- II. 1 mL solution contains: Sodium chloride, preservatives (methylparaben and propylparaben) and up to 1 mL purified water.

There is limited information available about the use of ENTOCORT Enema in children.

How To Prepare The Enema

1. Remove the nozzle, with the protective cap on, from the bottle.
2. Take a tablet from the aluminum foil pack and put it into the bottle. **DO NOT SWALLOW THE TABLET.**



- Put the nozzle back on the bottle and make sure that the protective cap is firmly on. Shake the bottle vigorously for at least 10 seconds or until the tablet has dissolved and a slightly yellowish liquid has been formed. The final volume is about 115 mL.



A plastic bag has been enclosed which you may use to protect your hand when you administer the enema.

- Lie down on your left side. Shake the bottle again before removing the protective cap. Empty the contents into the rectum.
- Roll over on your stomach. Stay in this position for 5 minutes.
- Choose a suitable position to sleep in. Try to retain the enema as long as possible, preferably for the whole night.

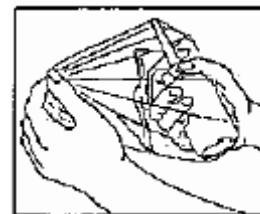
NB: After preparation, the budesonide enema is intended for immediate use.



- Put your hand inside the plastic bag and grip the bottle.



- Empty the contents into the rectum.



- After use, remove the plastic bag from your hand by pulling it over the bottle.

Overdose

Do not use ENTOCORT Enema more often or over a longer period than your doctor has prescribed. If by accident you take more ENTOCORT than prescribed on a single occasion no harmful effects should occur. If too much ENTOCORT is used over a longer period (months or more) it is possible that side effects may arise, see “What Are the Undesirable Effects?”. If you think that this may have happened to you, please discuss it with your doctor.

What To Do In Case You Forget To Take A Dose

If you forget to take an occasional dose of ENTOCORT Enema it is not necessary to make up the missed dose. Just continue with the next dose as prescribed.

What Are The Undesirable Effects?

Side effects that you may get while you are using ENTOCORT Enema are usually mild. However, be sure to tell your doctor if any of the following side effects bother you:

Common side effects that may occur are indigestion (e.g. gas in stomach or bowels), nausea, diarrhea, skin rash and/or itching.

Uncommon side effects that may occur are agitation, sleeplessness and in very rare cases, severe allergic reactions with symptoms such as rash, swelling of tissues, and/or difficulties in breathing.

Contact your doctor if you get any other unusual effects while using ENTOCORT Enema.

How Should ENTOCORT Enema Be Stored?

Store the tablets and the liquid at room temperature (below 30°C).

Always keep ENTOCORT Enema, including the plastic bags, in a safe place out of sight and reach of children.

Note:

This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using ENTOCORT Enema.

This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. Please refer to the Consumer Information Leaflet located at www.astrazeneca.ca, to see if more up-to-date information has been posted.

Customer Inquiries: 1 800 668-6000

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