

COLIFOAM®

Hydrocortisone Acetate 10% w/w

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about COLIFOAM. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using COLIFOAM against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What COLIFOAM is used for

COLIFOAM is a type of cortisone and belongs to the group of medicines called corticosteroids.

COLIFOAM is used to treat inflammation of the lower bowel. These diseases can produce severe diarrhoea and pain.

Your doctor may have prescribed COLIFOAM for another purpose.

Ask your doctor or pharmacist if you have any questions about why COLIFOAM has been prescribed for you.

There is no evidence that COLIFOAM is addictive.

This medicine is available only with a doctor's prescription.

Before you use COLIFOAM

When you must not use it

Do not use COLIFOAM if you have:

1. An allergy to:
 - Hydrocortisone Acetate and/or
 - to any of the ingredients at the end of this leaflet
2. Viral skin infection (such as cold sores, shingles, chicken pox or anal warts).
3. Fungal skin infection (such as thrush, tinea or ringworm).
4. Peritonitis, bowel obstruction, abscess, perforation, fresh intestinal anastomoses, or extensive fistulae

Ask your doctor to be sure you do not have any of these conditions.

Do not breastfeed while you are using COLIFOAM unless your doctor says it is safe.

Do not use COLIFOAM just before having a bath, shower or going swimming.

If you do, you may reduce the effectiveness of COLIFOAM.

Do not use COLIFOAM if the expiry date (EXP) printed on the pack has passed.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use COLIFOAM if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else.

If you are not sure whether you should start using COLIFOAM, contact your doctor.

Before you start to use it

See your doctor for a check-up before you start to use COLIFOAM.

You must tell your doctor if:

1. You have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

2. You are pregnant or intend to become pregnant.

Your doctor can discuss with you the risks and benefits of using this medicine during pregnancy.

3. You are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using COLIFOAM when breastfeeding.

4. You have or have had any other medical conditions including:

- Liver problems
- Infections, fever or inflammation
- Stress
- Severe affective disorders including depression, manic depressive, anxiety disorders or steroid psychosis
- Diabetes
- Tuberculosis
- Eye problems such as cataracts or glaucoma
- Severe ulcerative disease
- Myasthenia gravis

- High blood pressure
- Heart disease
- Renal failure.

If you have not told your doctor about any of the above, tell them before you start using COLIFOAM.

Using other medicines

Tell your doctor or pharmacist if you are using other creams, ointments or lotions or taking any other medicine. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interfere with COLIFOAM. These include:

- Aspirin
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Cardiac glycosides (e.g. Digoxin)
- Anticoagulants (blood thinners)
- Diuretics (fluid pills)
- Anticonvulsants
- Macrolide antibiotics
- Ketoconazole

- Antiretroviral medicines
- Antidiabetic medicines.
- Vaccination with live vaccines or other vaccination procedures

These medicines may be affected by COLIFOAM or may affect how well it works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using COLIFOAM.

How to use COLIFOAM

How much to use

Your doctor will prescribe the amount to be used each day. It is normally one to two Applicators full, one in the morning and one at night. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it is not, or you are not sure, ask your doctor or pharmacist.

Follow all directions given to you by your doctor and pharmacist carefully.

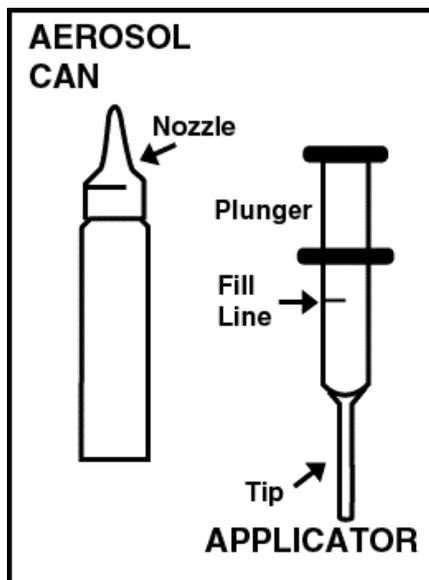
They may differ from the information contained in this leaflet.

If you do not understand the instructions in the leaflet, ask your doctor or pharmacist for help.

How to fill the Applicator and administer COLIFOAM

COLIFOAM is a foam enema supplied in an Aerosol Can, filled with white, odourless and expanding foam. Aerosol Can is fitted with white Nozzle. Plastic Applicator with Plunger is also included in the carton and is used to administer foam into the rectum.

Do not attempt to use COLIFOAM until you have examined the illustrations and have read and understood these instructions.

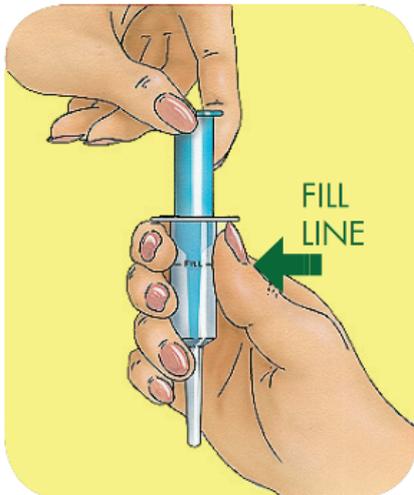


Follow these simple steps:

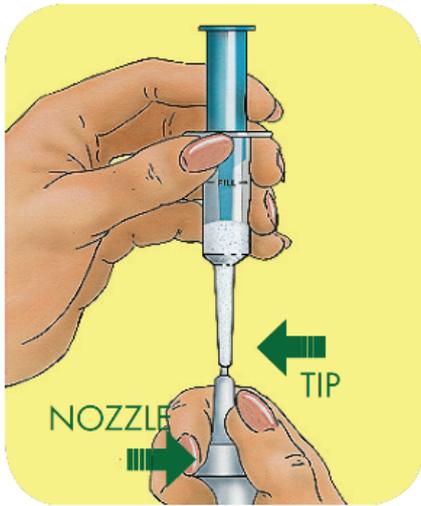
1. Closely examine the Applicator, Aerosol Can and Nozzle.
2. **IMPORTANT: Shake the Aerosol Can vigorously up and down for sixty seconds before each use. DO NOT REMOVE NOZZLE.**



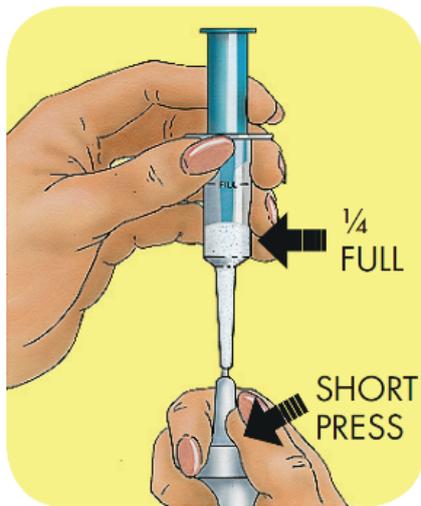
3. Place the Aerosol Can upright on a table or a level surface. **KEEP THE AEROSOL CAN UPRIGHT DURING THE ENTIRE FILLING PROCEDURE.**
4. Withdraw the Plunger until it stops at the fill line.



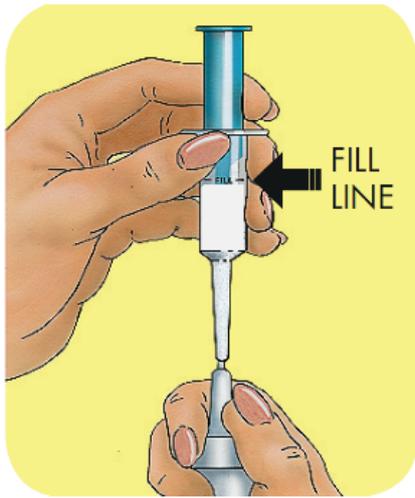
5. Hold the Plunger upright and insert the Aerosol Can Nozzle into the Applicator Tip. Make sure you hold the Plunger and Applicator **FIRMLY** with your fingers as shown.



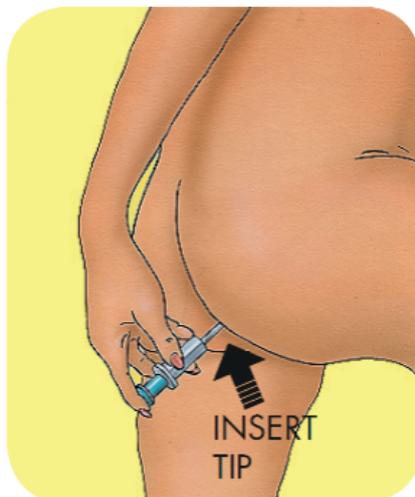
6. Press down gently on top of Aerosol Can with your fingers, until the foam has filled up approximately one quarter of the Applicators body. Only a short press is needed to do this. **KEEP PLUNGER WITHDRAWN DURING THIS PROCEDURE.**



7. Wait for a few seconds until the foam stops expanding. **DO NOT** fill the Applicator in one go. Always release the Nozzle after a short press.
8. Repeat steps 6 and 7 above until the foam expands to just reach the fill line. Remove Applicator from Aerosol Can. Allow some foam to remain on the Applicator Tip.



9. Hold Applicator by barrel as shown on the picture below and gently insert Tip sufficiently into the anus to ensure the foam is fully deposited into the rectum. With Applicator in place, depress the Plunger in order to expel foam, and then withdraw Applicator. Some patients find it easier when standing with one leg raised on a chair, or lying down on their side.



REMEMBER:

Shake the Aerosol Can vigorously up and down for 60 seconds prior to each use. Wash the Applicator thoroughly after use. Store the container below 25°C. Do not refrigerate.

How to use COLIFOAM

Follow cleaning instructions carefully.

Make sure that the Applicator is washed thoroughly in warm soapy water and allowed to dry before the next application.

Do not leave the Applicator with the previous dose in it, clean it up immediately.

The product must never be used for any other purpose than rectal insertion via the Applicator.

It is important to use COLIFOAM exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and your problem may not improve. Using it more often than you should may not improve your problem any faster and may cause or increase side effects.

Use COLIFOAM at the same time every day.

It is best to have a routine of waking up in the morning and going to the toilet to move the bowels then using this medication. Remember if you have moved your bowels just after applying the medication you have lost all the benefit. Apply the evening dose before you go to bed.

How long to use it

Your doctor or pharmacist will tell you how long to use COLIFOAM.

This medicine is usually used for 2-3 weeks but your doctor may want you to use it for a longer period of time. Please discuss this with your doctor to make sure that you are using it for the correct amount of time.

If you need to stop using COLIFOAM for any reason, seek advice from your doctor first.

If you have been using COLIFOAM for a long time, COLIFOAM needs to be discontinued gradually with your doctor's advice. Stopping COLIFOAM treatment suddenly could cause severe illness.

Do not use COLIFOAM for longer than your doctor tells you.

If you use COLIFOAM for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are not sure how long to use COLIFOAM, talk to your doctor or pharmacist.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase your chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you swallow it

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 (Australia) or the National Poisons Centre on 0800 764 766 (New Zealand), or go to casualty at your nearest hospital, if you think that you or anyone else may have swallowed COLIFOAM. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

While you are using COLIFOAM

Things you must do

Keep all of your doctors' appointments so that your progress can be checked.

Tell all doctors and pharmacists who are treating you that you are using COLIFOAM.

If you feel that COLIFOAM is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used COLIFOAM exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using COLIFOAM, tell your doctor.

Things you must not do

Do not give COLIFOAM to anyone else, even if they have the same symptoms as yours.

Do not use COLIFOAM to treat other complaints unless your doctor tells you to.

Things to be careful of

Do not use large amounts of COLIFOAM for a long time.

If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increases.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using COLIFOAM.

Side effects

Check with your doctor or pharmacist as soon as possible if you have any problems while using COLIFOAM, even if

you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, COLIFOAM can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Water retention
- Nervousness
- Sleeplessness
- Mood swings
- Feeling depressed
- Wounds that don't heal well
- Swollen face
- Pimples
- Rash
- Skin more easily damaged

- Skin irritation, burning
- Irregular periods
- Increase in infections.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- Changes in eyesight
- Irregular heartbeats
- Fits.

These are serious side effects. You may need urgent medical attention.

If any of the following happen, stop taking COLIFOAM and tell your doctor immediately or go to casualty at your nearest hospital:

- Sudden signs of allergy, such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or difficulty breathing or wheezing
- Severe chest pains
- Broken bones.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

More information concerning your condition

Is there anything I can do to avoid an attack?

It is not possible to prevent attacks happening altogether. There are some things though that you can do that will reduce the chances of an attack occurring.

Some people with ulcerative colitis can work out what triggers an attack. The trigger in one person may not produce symptoms in another.

Is there anything I can do to reduce the severity of an attack?

The earlier an attack is treated the less severe it is likely to be. So if you have an attack, contact your doctor as soon as possible. Some people keep a can of steroid foam or steroid

liquid enema at home for use as soon as they get symptoms. You may wish to discuss this with your doctor.

Does alcohol affect ulcerative colitis?

Alcohol, particularly wine, may cause diarrhoea in some people with ulcerative colitis. It is best to avoid alcohol if it has this effect on you.

Do I need a special diet?

Most people with ulcerative colitis can eat a normal diet. However, some people find that milk causes diarrhoea and gives them wind. If you discover that particular foods give you diarrhoea you should avoid eating them.

Can I play sport?

Yes, if you feel well enough you can continue to play sport or even take up new sports.

What can I do if I need to use a toilet urgently when I am out?

Large shops, pubs and restaurants usually have public toilets. Even smaller shops will let you use staff toilets if you explain you have a problem. You do not need to explain in detail. A useful aid, in this situation is the "Can't Wait" card provided by the Australian Crohn's and Colitis Association for their members.

Most people worry about having an accident when they are away from home. An emergency kit of pants and moist wipes can be reassuring.

Can I travel abroad?

Check with your doctor if you are unsure whether you are fit to travel. It is probably best to avoid travelling abroad during an attack.

Can I pass the diarrhoea on to my family and friends?

The diarrhoea caused by ulcerative colitis is not infectious and so cannot be passed on to your family or friends.

Will ulcerative colitis affect my sex life?

As with any sort of recurring illness, sympathy and understanding from your partner and family will lessen the strains caused by ulcerative colitis. You and your partner may find it embarrassing to discuss your symptoms. However, talking about them will help your partner understand your problems and help you to understand your partner's concerns.

People with ulcerative colitis often worry about sex. They may find that treatments, such as liquid enemas used last thing at night disrupt a spontaneous sex life. Also they may not feel like having sex because they feel dirty or tired or worry about having an accident in bed. Partners of people with ulcerative

colitis often have similar worries and may worry in particular about causing pain.

Discussing these worries with each other and explaining, for example, that you need to lie on your side after an enema will help to prevent misunderstandings and help you enjoy a normal sex life.

What about pregnancy?

Women who have ulcerative colitis are less likely to become pregnant during an attack. However, the fact that a mother has ulcerative colitis does not put the health of her unborn child at risk. Some doctors prefer to avoid giving steroids during pregnancy.

Is it safe to take the pill?

Yes it is safe to take the contraceptive pill. However, you must remember that the diarrhoea associated with an attack of ulcerative colitis can reduce the pill's effectiveness. So, it is advisable to use an extra form of contraception, eg condoms, until the menstrual period after the diarrhoea has stopped.

After using COLIFOAM

Storage

Keep your medicine in the packaging until it is time to use it.

Keep COLIFOAM in a cool dry place where the temperature stays below 25°C. Do not refrigerate, incinerate or puncture Aerosol Can.

Do not store COLIFOAM or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep COLIFOAM where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using COLIFOAM or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

COLIFOAM is a foam enema supplied in an Aerosol Can, filled with white, odourless and expanding foam. Aerosol Can is fitted with white Nozzle. Plastic Applicator with Plunger is also included in the carton and is used to administer foam into the rectum.

Ingredients

Your COLIFOAM contains:

Active Ingredient:

Hydrocortisone acetate 10% w/w (Each gram of COLIFOAM contains 100 mg hydrocortisone acetate).

Inactive Ingredients:

- Propane
- Isobutane
- Trolamine
- Propylene Glycol
- Emulsifying Wax
- Cetyl Alcohol
- Steareth-10
- Methyl Hydroxybenzoate
- Propyl Hydroxybenzoate

COLIFOAM contains hydroxybenzoates.

Sponsor

Australia:

Mylan Health Pty Ltd

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AUSTRALIA

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Telephone: 1800 314 527

New Zealand:

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NEW ZEALAND

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The Australian Registration Number is AUST R 43026.

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