

New Zealand Consumer Medicine Information

Ultraproct®

Fluocortolone pivalate, Fluocortolone hexanoate, Cinchocaine hydrochloride
Ointment and Suppositories

The ointment contains 0.92 mg fluocortolone pivalate, 0.95 mg fluocortolone hexanoate and 5 mg cinchocaine hydrochloride per 1 g of ULTRAPROCT®

Each suppository contains 0.612 mg fluocortolone pivalate, 0.63 mg fluocortolone hexanoate, and 1 mg cinchocaine hydrochloride.

What is in this leaflet

Please read this leaflet carefully before you start using ULTRAPROCT®. It will advise you about how to use ULTRAPROCT® properly and when to tell your doctor about health-related conditions. If you have any questions or need more advice, ask your doctor, professional health care provider, or pharmacist.

This preparation has been prescribed for you personally, and you should not pass it on to others. It may harm them.

What is ULTRAPROCT® used for

ULTRAPROCT® is used for patients suffering from haemorrhoids, superficial anal fissures, and proctitis.

Before you use ULTRAPROCT®

When you must not use it

Do not use ULTRAPROCT® if:

- You are pregnant or think you might be pregnant. Corticosteroid preparations such as ULTRAPROCT® should not be applied during the first three months of pregnancy.
- You are allergic to any of the ingredients of ULTRAPROCT®.
- You suffer from tuberculous or syphilitic processes in the area to be treated; virus diseases (e.g. vaccinia, chickenpox).

If any of these conditions appear while using ULTRAPROCT®, stop using it at once and consult your doctor.

If you are not sure whether you should start using ULTRAPROCT®, talk to your doctor.

Before you start to use it

Tell your doctor if:

- You have or have had any medical conditions, especially fungal infections such as thrush, in the area of the anus. ULTRAPROCT® does not treat this condition. Your doctor may need to provide additional treatment for this condition.
- You are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits of using ULTRAPROCT® during pregnancy or breast-feeding.
- You have allergies to any of the ingredients listed at the end of this leaflet or any other substances, such as foods, preservatives or dyes.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are using ULTRAPROCT®.

How to use ULTRAPROCT®

How to use it

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

For best results, first go to the toilet and empty your bowels. Do not strain. Wash and dry the anal area.

Before and after use, wash your hands thoroughly with soap and water.

Ointment

Smear a little ointment (about the size of a pea) around the anus and in the anal ring with a finger, using the fingertip to overcome the resistance of the sphincter. Before applying within the rectum, the enclosed nozzle should be screwed on to the tube. However, for very inflamed and painful lesions, it is advisable initially to apply the ointment internally with the finger. Protruding lumps should be smeared thickly and pressed carefully back with the finger.

Suppository

1. Remove the foil wrapper from the suppository. The consistency of suppositories that have become soft due to warmth should be restored by placing them in cold water before the covering is removed.
2. Lie on your side and raise your knee to your chest.
3. Push the suppository gently and slowly, pointed end first, into the rectum (back passage).
4. Try not to go to the toilet for at least one hour to allow the suppository time to work.

How much to use and when to use it

Ointment

Unless otherwise prescribed by the doctor, generally apply twice daily. On the first day, ointment can be applied up to four times for faster symptomatic relief.

Suppository

In general, insert one suppository daily high into the rectum. If symptoms are severe, insert one suppository two to three times on the first day.

How long to use it

There is usually a rapid improvement, but this should not mislead one into stopping treatment too soon.

To avoid relapses, ULTRAPROCT® should be continued for at least one week, though less frequently (ointment once a day or one suppository every other day), even when the symptoms have completely disappeared. However, the duration of treatment should, as far as possible, not exceed four weeks.

If you forget to use it

If it is almost time for your next dose (e.g., within 2 or 3 hours), skip the dose you missed and use the next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

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

If you have trouble remembering when to use your medicine, ask your doctor or pharmacist for some hints.

While you are using ULTRAPROCT®

Things you must do

Tell your doctor or pharmacist if you begin taking any other medicine while you are using ULTRAPROCT®. This applies to all medicines obtained with or without a doctor's prescription.

If you find that your condition persists despite using ULTRAPROCT®, seek advice from your doctor or pharmacist.

Things you must not do

Do not use more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Things to be careful of

Avoid contact of the preparation with the eyes. Careful handwashing after use is recommended.

The duration of treatment should, as far as possible, not exceed four weeks.

Prolonged use may lead to local concomitant symptoms, such as thinning of the skin (skin atrophy).

In case of overdose

There has been no report of toxicity even after an inadvertent overdose.

ULTRAPROCT® should not be swallowed. Swallowing ULTRAPROCT® could cause side effects that affect your heart, circulation, or brain. These could reduce or prevent the functioning of your heart or your lungs, or cause convulsions.

If ULTRAPROCT® is swallowed immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ULTRAPROCT®.

Tell your doctor if you notice any unwanted side effects, especially if severe or persistent, or if there is a change in your health that you think might be caused by ULTRAPROCT®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

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

Applying ULTRAPROCT® for long periods of time (more than four weeks) can be linked with symptoms such as thinning of the skin in the area being treated.

Allergic skin reactions may occur in rare cases.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by the list of possible adverse effects. You may not experience any of them.

After using ULTRAPROCT®

Storage

Store all medicines properly and keep them out of reach of children. Ultraproct® ointment should be stored below 25°C.

Ultraproct® suppositories should be stored in the fridge (at 2°C to 8°C). Do not freeze.

Disposal

If your doctor tells you to stop using Ultraproct® or you find that it has passed the expiry date, ask your pharmacist what to do with any medicine you have leftover.

Do not use after the expiry date stated on the package.

Product description

What it looks like

Ultraproct® comes in two presentations:

- Ultraproct® ointment is colorless to faintly yellowish color ointment. It is available as tubes containing 30 g of ointment.
- Ultraproct® suppositories are yellowish-white suppositories contained in a blister strip. The suppositories are available in packs of 12 suppositories.

Ingredients

Active ingredient(s):

- Ointment: every gram of ULTRAPROCT® ointment contains 0.92 mg fluocortolone pivalate, 0.95 mg fluocortolone hexanoate, and 5 mg cinchocaine hydrochloride.
- Suppository: each suppository contains 0.612 mg fluocortolone pivalate, 0.63 mg fluocortolone hexanoate, and 1 mg cinchocaine hydrochloride.

Inactive ingredients:

- Ointment: 2-Octyldodecanol, castor oil, hydrogenated castor oil, macrogol 400-monoricinoleate, and citrus-rose perfume oil.
- Suppositories: hard fat.

Sponsor Details

ULTRAPROCT® is supplied in New Zealand by:

AFT Pharmaceuticals Ltd

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Takapuna

Auckland 0740

Phone: 0800 423 823

Email: customer.service@aftpharm.com

Date of Preparation

This leaflet was revised in August 2020.