

PRESCRIBING INFORMATION
INCLUDING PATIENT MEDICATION INFORMATION

PrSANDOZ PROCTOMYXIN HC

(Hydrocortisone, Framycetin Sulfate, Cinchocaine Hydrochloride and Esculin)

Ointment

PrSANDOZ PROCTOMYXIN HC SUPPOSITORIES

(Hydrocortisone, Framycetin Sulfate, Cinchocaine Hydrochloride and Esculin)

Suppositories

Antibacterial – Corticosteroid – Anorectal Therapy

Sandoz Canada Inc.
110 Rue de Lauzon
Boucherville, QC
J4B 1E6

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PRESCRIBING INFORMATION

Sandoz Proctomyxin HC **Sandoz Proctomyxin HC Suppositories**

(Hydrocortisone, Framycetin Sulfate, Cinchocaine Hydrochloride and Esculin)
Suppositories and Ointment

THERAPEUTIC CLASSIFICATION

Antibacterial – Corticosteroid – Anorectal Therapy

ACTIONS AND CLINICAL PHARMACOLOGY

Framycetin sulfate, also known as neomycin B, is an aminoglycoside antibiotic which forms the major component of neomycin sulfate and has similar actions and uses.

Aminoglycosides are taken up into sensitive bacterial cells by an active transport process which is inhibited in anaerobic, acidic, or hyperosmolar environments. Within the cell, they bind to the 30S and to some extent to the 50S subunits of the bacterial ribosome, inhibiting protein synthesis and generating errors in the transcription of the genetic code. The manner in which cell death is brought about is imperfectly understood, and other mechanisms may contribute, including effects on membrane permeability.

In general, neomycin is active against many aerobic gram-negative bacteria and some aerobic gram-positive bacteria. Bacterial strains susceptible to neomycin include: *Escherichia coli*, *Haemophilus influenzae*, *Moraxella lacunata*, indole-positive and indole-negative *Proteus*, *Staphylococcus aureus*, *S. epidermidis* and *Serratia*. Neomycin is only minimally active against streptococci. *Pseudomonas aeruginosa* is generally resistant to the drug. The drug is inactive against fungi, viruses, and most anaerobic bacteria.

Natural and acquired resistance to neomycin have been demonstrated in both gram-negative and gram-positive bacteria. There is partial cross-resistance between neomycin and other aminoglycosides; cross-resistance occurs frequently between kanamycin, neomycin and paromomycin.

Hydrocortisone is the main glucocorticoid secreted by the adrenal cortex. Whereas cortisone must be converted in the liver to hydrocortisone, hydrocortisone is already pharmacologically active.

When it is administered by topical application or as a rectal enema, sufficient hydrocortisone may be absorbed to give systemic effects. Factors that may influence absorption include the site of application and the degree of skin damage.

Corticosteroids in the circulation are extensively bound to plasma proteins, mainly to globulin and to a lesser extent albumin. The corticosteroid binding globulin has a high affinity but a low binding capacity, while the albumin has a low affinity but a high binding capacity. Only unbound corticosteroid has pharmacological effects or is metabolized. Corticosteroids are metabolized mainly in the liver but also in the kidney, and are excreted in the urine.

Cinchocaine is a local anesthetic of the amide type with a long duration of action. It is used topically for the temporary relief of pain, itching and burning caused by hemorrhoids.

Local anesthetics are weak bases and at tissue pH can diffuse through connective tissue and cellular membranes to reach the nerve fibre where ionization can occur.

Most local anesthetics are readily absorbed through mucous membranes and through damaged skin.

Amide-type anesthetics are metabolized in the liver and, in some cases, the kidneys; they are considerably protein-bound.

Local anesthetics act by preventing generation and transmission of impulses along nerve fibres and at nerve endings; depolarization and ion-exchange are inhibited. The effects are reversible. The lipid-soluble anesthetic base must penetrate the lipoprotein nerve sheath before it can act. The effectiveness of an anesthetic depends on the concentration attained at the nerve fibre. There is a latent period before the onset of action which varies according to the agent used, the concentration used and the method of administration.

INDICATIONS

The reduction of swelling, pain and inflammation of hemorrhoids and other rectal lesions. The management of acute and chronic nonspecific proctitis, acute internal hemorrhoids, cryptitis, fissures and incomplete fistulas, internal and external pruritus ani. May be used in pre- and postoperative hemorrhoidectomy and repair of fissures.

Sandoz Proctomyxin HC and Sandoz Proctomyxin HC Suppositories contains an antibacterial ingredient, framycetin. To reduce the development of drug-resistant bacteria and maintain the effectiveness of framycetin, Sandoz Proctomyxin HC and Sandoz Proctomyxin HC Suppositories should only be used for the authorized indication and clinical use.

CONTRAINDICATIONS

Hydrocortisone must not be used in the presence of tuberculosis, fungal and viral infections. Sensitivity to any of the components.

PRECAUTIONS

Discontinue use if sensitization occurs. Hydrocortisone should not be used until an adequate proctologic examination is completed and a diagnosis made. Other specific measures against infections, allergy, and other causal factors must not be neglected. The possibility, however rare, that prolonged use of this preparation might produce systemic corticosteroid effects, should be borne in mind. Patients should be advised to inform subsequent physicians of the previous use of hydrocortisone.

The safe use of topical corticosteroids during pregnancy has not been fully established. Therefore, during pregnancy, they should not be used unnecessarily on extended areas, in large amounts or for prolonged periods of time.

Susceptibility/Resistance

Development of Drug Resistant Bacteria

Prescribing Sandoz Proctomyxin HC and Sandoz Proctomyxin HC Suppositories in the absence of the authorized indications is unlikely to provide benefit to the patient and risks the development of drug-resistant bacteria.

ADVERSE EFFECTS

Certain patients may experience the following adverse effects:

Gastrointestinal disorders: anal pruritus, anorectal discomfort, proctalgia.

General disorders and administration site conditions: burning, irritation and pain at the application site.

Immune system disorders: hypersensitivity manifested as pruritus, rash and/or urticaria.

DOSAGE AND ADMINISTRATION

Ointment: For external treatment: apply a small quantity morning and evening and after each bowel movement to the affected area. For internal application: attach rectal cannula to tube, insert to full extent and squeeze tube gently from lower end while withdrawing.

Suppositories: One suppository morning and evening and after each bowel movement.

AVAILABILITY OF DOSAGE FORMS

Suppositories: Each rectal suppository contains: hydrocortisone 5 mg (0.5%), framycetin sulfate 10 mg (1%, equivalent to 7 mg of framycetin base), cinchocaine hydrochloride 5 mg (0.5%), esculin 10 mg (1%). Available in boxes of 12, individually wrapped in aluminum foil shells.

Store between 15 and 25°C.

Ointment: Each gram contains: hydrocortisone 5 mg (0.5%), framycetin sulfate 10 mg (1%, equivalent to 7 mg of framycetin base), cinchocaine hydrochloride 5 mg (0.5%), esculin 10 mg (1%). Also contains 10% w/w anhydrous lanolin. Tubes of 15 and 30 g with rectal cannula.

Store between 15 and 30°C

REFERENCES

Aptalis Pharma Canada ULC. Prescribing Information: PROCTOSEDYL® (Hydrocortisone BP, Framycetin sulfate BP, Cinchocaine hydrochloride BP, Aesculin), ointment / suppositories. Control Number: 216051, Date of Revision: August 10, 2018.

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrSANDOZ PROCTOMYXIN HC

Hydrocortisone, Framycetin Sulfate, Cinchocaine Hydrochloride and Esculin
Ointment

Read this carefully before you start taking Sandoz Proctomyxin HC and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sandoz Proctomyxin HC.

What is Sandoz Proctomyxin HC used for?

- To reduce the swelling and pain of hemorrhoids.
- To reduce the swelling and pain of sores on your rectum or anus.
- To treat swelling irritation, itching and cracking of the rectum and anus.
- Sandoz Proctomyxin HC contains an antibacterial ingredient called framycetin sulfate, and it should be used exactly as directed by your healthcare professional.

How does Sandoz Proctomyxin HC work?

Sandoz Proctomyxin HC contains the following medicinal ingredients: hydrocortisone, framycetin sulfate, cinchocaine hydrochloride and esculin. Hydrocortisone is a steroid medicine. Framycetin sulfate is an antibiotic. Cinchocaine hydrochloride is a pain medicine. Esculin protects the blood vessels. These work together to reduce swelling and pain and to relieve itching.

What are the ingredients in Sandoz Proctomyxin HC?

Medicinal ingredients: hydrocortisone, framycetin sulfate, cinchocaine hydrochloride, esculin.

Non-medicinal ingredients: 10% w/w anhydrous lanolin

Sandoz Proctomyxin HC comes in the following dosage forms:

5 mg hydrocortisone, 10 mg framycetin sulfate, 5 mg cinchocaine HCl, 10 mg esculin per gram of ointment.

Do not use Sandoz Proctomyxin HC if you:

- Have tuberculosis
- Have a fungal infection
- Have a viral infection
- Are sensitive to any of the ingredients in Sandoz Proctomyxin HC

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Proctomyxin HC. Talk about any health conditions or problems

you may have, including if you:

- Have been using another product that contains hydrocortisone
- Are pregnant

Other warnings you should know about:

Tell your healthcare professional if you get any sensitivity while using Sandoz Proctomyxin HC.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Sandoz Proctomyxin HC:

- External treatment:
- Apply a small quantity to the affected area in the morning and in the evening and after every bowel movement

- Internal treatment:
- Attach the rectal cannula to the tube
- Insert cannula into rectum to full extent
- Squeeze the tube gently from the lower end while removing it from your rectum
- Apply in the morning and evening and after every bowel movement.

- Misuse or overuse of Sandoz Proctomyxin HC could lead to the growth of bacteria that will not be killed by framycetin sulfate. This means that Sandoz Proctomyxin HC or other medicines containing framycetin sulfate may not work for you in the future.

- Do not share your medicine.

Usual dose:

A small quantity of ointment in the morning and evening and after each bowel movement.

Overdose:

If you think you have taken too much Sandoz Proctomyxin HC, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

- If you forget to apply Sandoz Proctomyxin HC, apply it when you remember.
- Then, continue to apply in the morning and evening and after every bowel movement.

What are possible side effects from using Sandoz Proctomyxin HC?

These are not all the possible side effects you may feel when taking Sandoz Proctomyxin HC. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Discomfort, irritation or pain of the anus
- Discomfort or pain of the rectum
- Burning, irritation or pain at the application site
- Itching
- Rash

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/healthcanada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15 and 30°C.

Keep out of reach and sight of children.

If you want more information about Sandoz Proctomyxin HC:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://www.sandoz.ca> or by calling 1-800-361-3062.

This leaflet was prepared by Sandoz Canada Inc.

Last Revised: November 16, 2018

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrSANDOZ PROCTOMYXIN HC Suppositories

Hydrocortisone, Framycetin Sulfate, Cinchocaine Hydrochloride and Esculin
Suppositories

Read this carefully before you start taking Sandoz Proctomyxin HC Suppositories and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Sandoz Proctomyxin HC Suppositories.

What is Sandoz Proctomyxin HC Suppositories used for?

- To reduce the swelling and pain of hemorrhoids.
- To reduce the swelling and pain of sores on your rectum or anus.
- To treat swelling irritation, itching and cracking of the rectum and anus.
- Sandoz Proctomyxin HC Suppositories contains an antibacterial ingredient called framycetin sulfate, and it should be used exactly as directed by your healthcare professional.

How does Sandoz Proctomyxin HC Suppositories work?

Sandoz Proctomyxin HC Suppositories contains the following medicinal ingredients: hydrocortisone, framycetin sulfate, cinchocaine hydrochloride and esculin. Hydrocortisone is a steroid medicine. Framycetin sulfate is an antibiotic. Cinchocaine hydrochloride is a pain medicine. Esculin protects the blood vessels. These work together to reduce swelling and pain and to relieve itching.

What are the ingredients in Sandoz Proctomyxin HC Suppositories?

Medicinal ingredients: hydrocortisone, framycetin sulfate, cinchocaine hydrochloride, esculin.
Non-medicinal ingredients: hard fat.

Sandoz Proctomyxin HC Suppositories comes in the following dosage forms:

5 mg hydrocortisone, 10 mg framycetin sulfate, 5 mg cinchocaine HCl, 10 mg esculin per suppository.

Do not use Sandoz Proctomyxin HC Suppositories if you:

- Have tuberculosis
- Have a fungal infection
- Have a viral infection
- Are sensitive to any of the ingredients in Sandoz Proctomyxin HC Suppositories

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Proctomyxin HC Suppositories. Talk about any health conditions or problems you may have, including if you:

- Have been using another product that contains hydrocortisone
- Are pregnant

Other warnings you should know about:

Tell your healthcare professional if you get any sensitivity while using Sandoz Proctomyxin HC Suppositories.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Sandoz Proctomyxin HC Suppositories:

- Insert one suppository into your rectum in the morning and in the evening and after every bowel movement.
- Misuse or overuse of Sandoz Proctomyxin HC Suppositories could lead to the growth of bacteria that will not be killed by framycetin sulfate. This means that Sandoz Proctomyxin HC Suppositories or other medicines containing framycetin sulfate may not work for you in the future.
- Do not share your medicine.

Usual dose:

One suppository in the morning and evening and after each bowel movement.

Overdose:

If you think you have taken too much Sandoz Proctomyxin HC Suppositories, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

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