

Consent form for off-label use of Bactroban (Mupirocin)

I understand and agree to the off-label use of a specific medication – Bactroban (Mupirocin) ointment - in the management of my nasal/sinus condition. I understand that Off-label prescribing, also known as unapproved use, is the physician practice of prescribing a drug or medical device for a purpose different from one of the indications for which the product is approved by the Food and Drug Administration (FDA). Because there has not been sufficient testing by the FDA, my physician does not have tested information on use, dosage, and route of administration that is provided in product labeling for approved indications. Furthermore, the safety and efficacy of the unapproved use has not have been established by adequate and well-controlled clinical trials. I also understand that I have other alternatives – medical and surgical – to this off-label use. Risks vary widely and may include topical reactions (rash, burning, itching, dryness), pharyngitis, upper respiratory tract infection, nausea, pain, diarrhea, change or loss of sense of smell and/or taste, increase in over-growth of antibiotic-resistant organisms including but not limited to bacteria and fungi. Other risks may exist, including serious and long-lasting risks. With this knowledge of the potential risks, benefits, alternatives, and complications, I request that my doctor proceed with the off-label prescription of Bactroban (Mupirocin) ointment. I also acknowledge that the doctor has reviewed the use of this medication with me in detail, answered all of my questions on the subject of the use of this medication, and given me a copy of this consent form (which is also posted on the web site – www.noseandsinus.com).

Patient name (printed)

Date

Patient signature

I confirm that I have reviewed in detail the reasons for my recommendation of the off-label prescription of Bactroban (Mupirocin) ointment for this patient. I have reviewed with the patient the meaning of “off-label” prescription of medication, and discussed at length the risks and potential complications – known and unknown – to this usage. I have also reviewed in detail the alternatives to this usage of Bactroban (Mupirocin) ointment. I affirm that that patient expresses understanding of these risks, benefits, alternatives, and complications and would like to proceed with off-label usage of Bactroban (Mupirocin) ointment.

Physician name (printed)

Date

Physician signature

Directions for off-label use of Bactroban (Mupirocin)

1. Wash your hands with soap and warm water before mixing the solution and before irrigation.
2. Mix the Neil Med sinus rinse bottle per the directions (using Distilled Water, and the Sodium Chloride/Sodium Bicarbonate Packets).
3. Squirt 1 inch of Bactroban ointment into the rinse bottle and tightly cap the bottle. Shake slowly and methodically to dissolve the ointment. Let the bottle sit at room temperature, shaking it occasionally until the ointment is dissolved.
4. Now use the Sinus Rinse bottle per your usual nasal routine. To minimize the amount that goes into your throat, stand upright over a sink. (Some patients prefer to do the irrigations in the shower.) One to three good squirts should be sufficient on each side, depending upon how much mucus is flushed out.
5. Perform this irrigation 1-2 times daily for the number of days agreed upon with Dr. Becker (Typically 3-7 days).
6. Call with any questions or concerns.