[0017] In a further aspect, a dissolving film comprising a therapeutically effective amount of a Clostridial toxin active ingredient is described. In embodiments, the film further comprises at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; at least one mucosal permeation enhancer; and at least one dissolution controller. In embodiments, the film comprises about 0.0056 to 560 ng of the Clostridial toxin active ingredient. In some embodiments, the Clostridial toxin active ingredient is selected from the group consisting of botulinum toxin types A, B, C, D, E, F and G.

[0018] In embodiments, the film comprises about 20 to 95% (w/w) of the at least one polymer. In some embodiments, the at least one polymer is selected from at least one of a hydrophilic polymer and a mucoadhesive polymer. In embodiments, the hydrophilic polymer is selected from the group consisting of polysaccharides, hydroxyalkyl starch derivatives, polyvinyl acetates, polyvinyl pyrrolidones, polyethylene glycols, and a poloxamer. In embodiments, the mucoadhesive polymer is selected from the group consisting of polyacrylic acids, polyacrylates, poly(meth)acrylates, poly(ethylene oxide), pectin, sodium alginate, carrageenan, cellulose derivatives, hyaluronic acid, chitosan, alginates, pectin, gelatin, and poloxamers.

[0019] In embodiments, the film comprises about 0.1 to 15 % (w/w) of the at least one dissolution controller. In some embodiments, the at least one dissolution controller is selected from sugars, glycerin, and propylene glycol.

[0020] In embodiments, the film comprises about 0.0001 to 15% (w/w) of the at least one mucosal permeation enhancer. In some embodiments, the at least one mucosal permeation enhancer is selected from the group consisting of diethylene glycol monoethyl ether, glyceryl monooleate, and cell penetrating peptides.

[0020a] In a further aspect, described is a use of a biodegradable or biocompatible film in the manufacture of a medicament for treating rhinitis or a symptom of rhinitis, wherein the medicament is to be administered to a nasal cavity of a subject thereby relieving one or more symptoms of rhinitis, the film comprising:
a therapeutically effective amount of a Clostridial toxin active ingredient;
at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; and
at least one of:
(a) at least one mucosal permeation enhancer; and
(b) at least one dissolution controller.

[0020b] In a further aspect, described is a biodegradable or biocompatible film for use in therapy, the film comprising:
a therapeutically effective amount of a Clostridial toxin active ingredient;
at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; and
at least one of:
(a) at least one mucosal permeation enhancer; and
(b) at least one dissolution controller.

[0021] Certain methods, compositions and formulations are described herein to provide a dissolvable film for delivery of an active agent such as a Clostridial toxin derivative. It will be appreciated that the film compositions as described below may refer to the film composition as a whole or to a layer of a film that includes the active agent. The film compositions may further comprise one or more excipients including, but not limited to, a disaccharide, a surfactant, and/or an antioxidant.

[0022] In addition to the exemplary aspects and embodiments described above, further aspects and embodiments will become apparent by reference to the examples and by study of the following descriptions.

IT IS CLAIMED:

1. Use of a biodegradable or biocompatible film in the manufacture of a medicament for treating rhinitis or a symptom of rhinitis, wherein the medicament is to be administered to a nasal cavity of a subject thereby relieving one or more symptoms of rhinitis, the film comprising:

a therapeutically effective amount of a Clostridial toxin active ingredient;

at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; and

at least one of:

(a) at least one mucosal permeation enhancer; and

(b) at least one dissolution controller.

2. The use of claim 1, wherein the film dissolves at the administration site in less than about 10 minutes.

3. The use of claim 1 or 2, further comprising:

coating the tip of a delivery device with the biodegradable film prior to application; and wherein said application comprises the delivery device to be inserted into a nasal cavity of a subject and a mucosal membrane of the subject to be contacted with the film.

4. A biodegradable film, comprising:

about 0.0056 to 560 ng of a therapeutically effective amount of a Clostridial toxin active ingredient;

about 20 to 95% (w/w) of at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; and

at least one of a mucosal permeation enhancer and at least one dissolution controller.

5. The film of claim 4, wherein the film comprises about 0.0001 to 15% (w/w) of the at least one mucosal permeation enhancer.

6. The film of claim 4 or 5, wherein the film comprises about 0.1 to 15 % (w/w) of the at least one dissolution controller.

7. The film of any one of claims 4 to 6, wherein the hydrophilic polymer is selected from the group consisting of polysaccharides, hydroxyalkyl starch derivatives, polyvinyl acetates, polyvinyl pyrrolidones, polyethylene glycols, and a poloxamer.

8. The film of any one of claims 4 to 7, wherein the mucoadhesive polymer is selected from the group consisting of polyacrylic acids, polyacrylates, poly(meth)acrylates, poly(ethylene oxide), pectin, sodium alginate, carrageenan, cellulose derivatives, hyaluronic acid, chitosan, alginates, pectin, gelatin, and poloxamers.

9. The film of any one of claims 4 to 8, wherein the at least one mucosal permeation enhancer is selected from the group consisting of diethylene glycol monoethyl ether, glyceryl monooleate, and a cell penetrating peptide.

10. The film of any one of claims 4 to 9, wherein the dissolution controller is selected from the group consisting of sugars, glycerin, and propylene glycol.

11. A biodegradable film, comprising:

a therapeutically effective amount of a Clostridial toxin active ingredient;

at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; at least one mucosal permeation enhancer; and

at least one dissolution controller.

12. The film of claim 11, wherein the film comprises about 20 to 95% (w/w) of the at least one polymer.

13. The film of claim 11 or 12, wherein the film comprises about 0.1 to 15 % (w/w) of the at least one dissolution controller.

14. The film of any one of claims 11 to 13, wherein the at least one dissolution controller is selected from sugars, glycerin, and propylene glycol.

15. The film of any one of claims 11 to 14, wherein at least one of the at least one polymers is a hydrophilic polymer.

16. The film of claim 15, wherein the hydrophilic polymer is selected from the group consisting of polysaccharides, hydroxyalkyl starch derivatives, polyvinyl acetates, polyvinyl pyrrolidones, polyethylene glycols, and a poloxamer.

17. The film of any one of claims 11 to 16, wherein at least one of the at least one polymers is a mucoadhesive polymer.

18. The film of claim 17, wherein the mucoadhesive polymer is selected from the group consisting of polyacrylic acids, polyacrylates, poly(meth)acrylates, poly(ethylene oxide), pectin, sodium alginate, carrageenan, cellulose derivatives, hyaluronic acid, chitosan, alginates, pectin, gelatin, and poloxamers.

19. The film of any one of claims 11 to 18, wherein the film comprises about 0.0001 to 15% (w/w) of the at least one mucosal permeation enhancer.

20. The film of any one of claims 11 to 19, wherein the at least one mucosal permeation enhancer is selected from the group consisting of diethylene glycol monoethyl ether, glyceryl monooleate, and a cell penetrating peptide.

21. A biodegradable or biocompatible film for use in therapy, the film comprising:

a therapeutically effective amount of a Clostridial toxin active ingredient;

at least one polymer selected from a hydrophilic polymer and a mucoadhesive polymer; and

at least one of:

(a) at least one mucosal permeation enhancer; and
(b) at least one dissolution controller.