What is claimed is:

[Claim 1]

A pharmaceutical formulation for applying as an external application to the surface of the human body, wherein the formulation contains:
(a) sofpironium bromide,
(b) one or more kinds of water-soluble polymers,
(c) ethanol, and
(d) a pH adjuster,
wherein the formulation has a pH of the range of 2.5 to 5.2 and is a uniformly dispersed, and non-aqueous formulation or low water content formulation with a water content of 5 w/w% or lower, and
wherein the pH adjuster is an acid selected from the group consisting of tartaric acid, acetic acid, and citric acid, or a salt thereof, and
wherein the pH is measured at any one or more time points selected within 6 months after preparation of the formulation, the pH is determined by measuring pH of the formulation stored at room temperature, and the pH is a value obtained after a pH electrode for non-aqueous solvent is immersed in the formulation for 5 minutes.

[Claim 2]

The formulation according to claim 1, wherein content of sofpironium bromide is 1 to 20 w/w% based on the total weight of the formulation.

[Claim 3]

The formulation according to claim 1 or 2, wherein ingredients in the formulation are uniformly dissolved.

[Claim 4]

The formulation according to any one of claims 1 to 3, wherein the water-soluble polymer or polymers consist of a water-soluble vinyl polymer or a water-soluble cellulose polymer.

[Claim 5]

The formulation according to any one of claims 1 to 3, wherein the water-soluble polymer or polymers are selected from the group consisting of hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxyethylmethylcellulose, hydroxypropylmethylcellulose, methylcellulose, ethylcellulose, carboxymethylcellulose, a carboxyvinyl polymer, polyvinyl alcohol, a polyvinyl copolymer, polyvinylpyrrolidone, and copovidone.

[Claim 6]

The formulation according to any one of claims 1 to 3, wherein the water-soluble polymer or polymers consist of hydroxypropylcellulose or a carboxyvinyl polymer.

[Claim 7]

The formulation according to any one of claims 1 to 6, wherein content of the water-soluble polymer or polymers is 0.01 to 5.0 w/w% based on the total weight of the formulation.

[Claim 8]

The formulation according to any one of claims 1 to 7, wherein content of ethanol is 50 to 99 w/w% based on the total weight of the formulation.

[Claim 9]

The formulation according to claim 1, wherein the amount of the pH adjuster is 0.015 to 5 w/w% based on the total weight of the formulation.

[Claim 10]

The formulation according to any one of claims 1 to 9, further containing a non-volatile oil (except for formulation containing Dimethiconol Blend 20).

[Claim 11]

The formulation according to claim 10, wherein the non-volatile oil is selected from the group consisting of a non-volatile ester, a non-volatile ether, a non-volatile silicone, and a non-volatile alcohol.

[Claim 12]

The formulation according to claim 10, wherein the non-volatile oil is a non-volatile ester selected from the group consisting of a monoester, a diester, and a trimester, and wherein the non-volatile oil is represented as R_1COOR_2, wherein one of R_1 and R_2 is a C_4-C_{40} straight chain alkyl group that may be substituted, or a C_4-C_{40} branched chain alkyl group that may be substituted, and the other of R_1 and R_2 is a C_1-C_{40} alkyl group that may be substituted.

[Claim 13]

The formulation according to claim 10, wherein the non-volatile oil is a non-volatile fatty acid ester selected from the group consisting of ethyl myristate, 2-octyldodecyl myristate, butyl stearate, isocetyl stearate, 2-octyldodecyl stearate, hexyl laurate, 2-hexyldecyl laurate, 2-ethylhexyl palmitate, 2-octyldecyl palmitate, cetearyl octanoate, isononyl isononanoate, octyldodecyl neopentanoate, 2-octyldodecyl erucate, 2-octyldodecyl benzoate, a decanoic acid ester, a ricinoleic acid ester, isopropyl myristate, diisopropyl adipate, a medium chain fatty acid triglyceride, isopropyl

palmitate, an alkyl (C_{14}-C_{18}) ethylhexanoate, myristyl myristate, ethyl oleate, oleyl oleate, ethylhexyl palmitate, cetyl palmitate, 2-hexyldecyl myristate, 2-hexyldecyl palmitate, PPG-3 benzyl ether myristate, isotridecyl isononanoate, triethylhexyl trimellitate, an alkyl (C_{12}-C_{15}) benzoate, diethoxyethyl succinate, propylene glycol dicaprate, propylene glycol dicaprylate, glyceryl tri(caprylate/caprate), triethylhexanoin, triisostearin, isopropyl isostearate, isostearyl isostearate, polyglyceryl-2 triisostearate, diethylhexyl succinate, PPG-2 myristyl propionate, pentaerythrityl tetraisostearate, diethyl sebacate, PPG-3 benzyl ether ethylhexanoate, glyceryl tribehenate, cetyl 2-ethylhexanoate, diisostearyl malate, 2-ethylhexyl stearate, triethylhexyl citrate, and an alkyl lactate such as ethyl lactate.

[Claim 14]

The formulation according to claim 10, wherein the non-volatile oil is a non-volatile fatty acid ester selected from the group consisting of isopropyl myristate, diisopropyl adipate, and a medium chain fatty acid triglyceride.

[Claim 15]

The formulation according to claim 10, wherein the non-volatile oil is a non-volatile silicone selected from the group consisting of a medical grade silicone oil, methylphenyl silicone, methyl terminated hydrogen branched silicone, decamethyl pentacyclosiloxane, octamethyl tetracyclosiloxane, cyclomethicone 5-NF, PEG-12 dimethicone, dimethicone 20cSt, dimethicone 100cSt, dimethicone 350cSt, dimethicone 500cSt, dimethicone 1000cSt, and dimethicone 12500cSt.

[Claim 16]

The formulation according to claim 10, wherein the non-volatile oil is a non-volatile silicone selected from the group consisting of cyclomethicone 5-NF, PEG-12 dimethicone, dimethicone 20cSt, and dimethicone 350cSt.

[Claim 17]

The formulation according to any one of claims 10 to 16, wherein content of the non-volatile oil is 0.5 to 10 w/w% based on the total weight of the formulation.

[Claim 18]

The formulation according to any one of claims 1 to 17, further containing a polyhydric alcohol.

[Claim 19]

The formulation according to claim 18, wherein the polyhydric alcohol is selected from the group consisting of hexylene glycol, propylene glycol, ethylene glycol, glycerol, and butylene glycol.

[Claim 20]

The formulation according to claim 18 or 19, wherein content of the polyhydric alcohol is 1.0 to 30 w/w% based on the total weight of the formulation.

[Claim 21]

The formulation according to any one of claims 1 to 20, wherein viscosity of the formulation is 10 to 2000 mPa・s at 25°C.

[Claim 22]

The formulation according to any one of claims 1 to 21, wherein viscosity of the formulation is 10 to 1000 mPa・s at 25°C after storage at room temperature for 36 months from preparation of the formulation or after storage at 40°C for 3 months from preparation of the formulation.

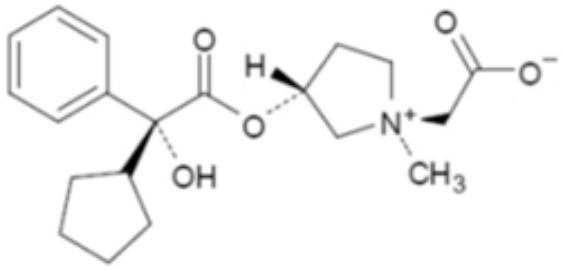
[Claim 23]

The formulation according to any one of claims 1 to 22, which is for medical care, therapeutic treatment, or prevention of a disease selected from the group consisting of hyperhidrosis, overactive bladder, chronic obstructive pulmonary disease, cardiac disease, salivation, ocular disease, and bronchial asthma.

[Claim 24]

The formulation according to any one of claims 1 to 23, wherein content of a compound (II) represented by the following formula (II):

[Formula 1]



and epimer at N^+

is 1.5 w/w% or lower based on the content of sofpironium bromide, and purity of sofpironium bromide is 90 w/w% or higher after storage at room temperature for 36 months from preparation of the formulation, or after storage at 40°C for 3 months from preparation of the formulation.