CLAIMS

1. Use of a hyaluronidase PH20 enzyme formulation comprising recombinant human hyaluronidase PH20 enzyme comprising a sequence having at least 95% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7 and SEQ ID NO: 15, and having an activity of about 500 U/mL to about 5,000 U/mL in the manufacture of a medicament for treating a disease by subcutaneous administration to a subject in need thereof, wherein the subcutaneous administration occurs at a volume of about 3 mL to about 50 mL and a rate of about 0.10 mL/sec to about 1.0 mL/sec.

2. Use of a formulation comprising recombinant human hyaluronidase PH20 enzyme comprising a sequence having at least 95% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7 and SEQ ID NO: 15, and having an activity of about 500 U/mL to about 5,000 U/mL in the manufacture of a medicament for reducing one or more side effects of a high-volume subcutaneous injection in a subject in need thereof, wherein the high-volume subcutaneous administration occurs at a volume of about 3 mL to about 50 mL and a rate of about 0.10 mL/sec to about 1.0 mL/sec and the one or more side effects are selected from pain and discomfort at the injection site, back leakage at the injection site, swelling volume at the injection site, swelling height at the injection site, bleb swelling size, bleb induration, and bleb resolution time.

3. The use of claim 1 or 2, wherein the formulation further comprises an active ingredient selected from a small molecule, a peptide, a nanoparticle, an antibody, and an antibody fragment.

4. The use of any one of claims 1-3, wherein the high-volume subcutaneous administration occurs at a volume of about 10 mL to about 20 mL.

5. The use of claim 4, wherein the high-volume subcutaneous administration occurs at a volume of about 3 mL to about 15 mL.

6. The use of any one of claims 1-5, wherein the subcutaneous administration occurs with a starting delivery force of about 3 lbf to about 50 lbf, and/or with an ending delivery force of about 5 lbf to about 20 lbf.

7. The use of any one of claims 1-6, wherein the subcutaneous administration occurs with a starting pressure of about 50 psi to about 200 psi, and/or with an ending pressure of about 20 psi to about 75 psi.

8. The use of any one of claims 1-7, wherein the subcutaneous administration occurs via a high volume autoinjector.

9. The use of claim 8, wherein the high volume autoinjector comprises a prefilled syringe containing the formulation.

10. The use of claim 9, wherein the prefilled syringe comprises a needle having a gauge of about 20 to about 33.

11. The use of claim 8, wherein the subcutaneous administration occurs via the high volume autoinjector using a compressed-gas cylinder as an energy source.

12. The use of any one of claims 1-11, wherein the formulation has a viscosity of about 1 cP to about 50 cP.

13. The use of any one of claims 1-12, wherein after the subcutaneous administration, one or more side effects are reduced in the subject compared to the one or more side effects from a high-volume subcutaneous injection of a similar formulation that does not comprise the recombinant human hyaluronidase PH20 enzyme.

14. The use of any one of claims 1-13, wherein at least one of i) to vi) applies:

i) administration of the formulation requires less applied force when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

ii) administration of the formulation is faster when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

iii) administration of the formulation causes fewer side effects, less pain, and less discomfort in the subject when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

iv) administration of the formulation causes less back leakage at the injection site when compared to a similar formulation that does not comprise a hyaluronidase enzyme;

v) administration of the formulation causes less swelling volume and/or swelling height at the injection site when compared to a similar formulation that does not comprise a hyaluronidase enzyme; and

vi) administration of the formulation comprises self-administration of the formulation to the subject.

15. A pharmaceutical kit comprising a high volume injector and about 3 mL to about 50 mL of a formulation comprising recombinant human hyaluronidase PH20 enzyme comprising a sequence having at least 95% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7 and SEQ ID NO: 15, and having an activity of about 500 U/mL to about 5,000 U/mL, and an active ingredient selected from a small molecule, a peptide, a nanoparticle, an antibody, an antibody fragment, and a small molecule antiviral.

16. The pharmaceutical kit of claim 15, wherein at least one of i) to v) applies:

i) the high volume injector is configured to subcutaneously administer the formulation to a subject at a rate of about 0.10 mL/sec to about 1.0 mL/sec;

ii) the high volume injector is configured to subcutaneously administer the formulation to a subject with a starting delivery force of about 3 lbf to about 50 lbf and an ending delivery force of about 5 lbf to about 20 lbf;

iii) the subcutaneous administration occurs via the high volume injector using a compressed-gas cylinder as an energy source;

iv) the high volume injector is configured to subcutaneously administer the formulation to a subject with a starting pressure of about 50 psi to about 200 psi and an ending pressure of about 20 psi to about 75 psi;

v) the high volume injector is configured for self-administration of the formulation by the subject; and

vi) the high volume injector is a high volume autoinjector.

17. The use of any one of claims 1-14 or the pharmaceutical kit of claim 15 or 16, wherein the active ingredient is an antibody.

18. The use of any one of claims 1-14 or the pharmaceutical kit of claim 15 or 16, wherein the active ingredient is an antibody fragment.

19. The use of any one of claims 1-14 or the pharmaceutical kit of claim 15 or 16, wherein the active ingredient is a small molecule.

20. The use of any one of claims 1-14 or the pharmaceutical kit of claim 15 or 16, wherein the active ingredient is a peptide.

21. The use of any one of claims 1-14 or 17-20 or the pharmaceutical kit of any one of claims 15-20, wherein the recombinant human hyaluronidase PH20 enzyme comprises a sequence having at least 98% amino acid sequence identity to an amino acid sequence selected from any of SEQ ID NO: 1 through 7.

22. The use of any one of claims 1-14 or 17-20 or the pharmaceutical kit of any one of claims 15-20, wherein the recombinant human hyaluronidase PH20 enzyme comprises a sequence having at least 98% amino acid sequence identity to an amino acid sequence of SEQ ID NO: 15.

23. The use of any one of claims 1-14 or 17-20 or the pharmaceutical kit of any one of claims 15-20, wherein the recombinant human hyaluronidase PH20 enzyme comprises an amino acid sequence of SEQ ID NO: 2.