with or without certain types of food, and in particular quantities. As such, it may be difficult for a patient to remember and comply with the administration instructions for a drug or a group of drugs. Failure to comply with such administration instructions can result in suboptimal efficacy.

SUMMARY

[3a] In one aspect, provided herein is a multi-drug delivery system comprising a first capsule comprising: a first capsule body comprising a first interior; a first tablet within the first interior, the first tablet comprising a first drug; and a second tablet within the first interior, the second tablet comprising at least a second drug different from the first drug, and a third drug different from the first and second drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within a patient; and a second capsule, co-packaged with the first capsule, comprising: a second capsule body comprising a second interior; and a third tablet within the second interior, the third tablet comprising the first drug, wherein using USP apparatus 2 at 50 rpm, pH 6.8, and 37.5±0.5°C, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second and third drugs in the second tablet dissolve after 30 minutes; wherein the first tablet comprises between about 175 mg to about 325 mg of elagolix and the second tablet comprises between about 0.75 mg and about 1.25 mg of estradiol; and wherein the second tablet further comprises between about 0.1 mg and about 1 mg of norethindrone acetate.

[3b] In one aspect, provided herein is an oral multi-drug capsule composition comprising: (a) 300 mg of free acid equivalent of elagolix; (b) 1 mg of estradiol which is administered once daily; and (c) 0.5 mg of norethindrone acetate; wherein administration of a single dose of the composition to healthy adult subjects results in a mean peak concentration, Cmax for said elagolix of about 1218.4 ng/ml to about 2185 ng/mL; a mean peak concentration, Cmax for

said estradiol of about 0.0424 ng/ml to about 0.0775 ng/ml; and a mean peak concentration, Cmax for said norethindrone acetate of about 4.56 ng/ml to about 8.0 ng/ml.

[3c] In one aspect, provided herein is a multi-drug delivery system as described herein or the oral multi-drug capsule composition as described herein for use in therapy.

[3d] In one aspect, provided herein is a use of the multiple-drug delivery system as described herein or the oral multi-drug capsule composition as described herein in the manufacture of a medicament for reducing uterine fibroid volume prior to surgery for removal of uterine fibroids, treating pain associated with endometriosis or treating heavy menstrual bleeding associated with uterine leiomyomas.

[4] In one example, a multi-drug delivery system is provided. The system includes a first capsule including a first capsule body having a first interior, and a first tablet and a second tablet included within the first interior. The first tablet includes a first drug, and the second tablet includes at least a second drug different from the first drug. For example, the second tablet may include a second and third drug, each of which are different from the first drug and each other. The first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within a patient. The system also includes a second capsule, co-packaged with the first capsule, including a second capsule body having a second interior, and a third tablet included within the second interior. The third tablet may include either the first drug, the second drug and/or one or more other drugs. At least 75%±10% of the first drug in the first tablet dissolves after 60 minutes and at least 70%±10% or 70%±20% or 70%±30% or

70%±40% of the second and third drugs in the second tablet dissolve after 30 minutes when using USP apparatus 2 at 50 rpm, pH 6.8, and 37.5±0.5°C.

[5] In some examples, the first tablet may include a gonadotropin-releasing hormone antagonist. For example, the first tablet may include elagolix, relugolix, another gonadotropin-releasing hormone antagonist and/or a combination of gonadotropin-releasing hormone antagonists. In some examples, the first tablet may include elagolix.

[6] In some examples, the first tablet may include between about 175 mg to about 325 mg of the gonadotropin-releasing hormone antagonist and

the second tablet may include between about 0.75 mg and about 1.25 mg of estradiol; the second tablet may further include between about 0.1 mg and about 1 mg of norethindrone acetate; after about 15 minutes, the release of estradiol is equal to or greater than 70%±10% or 70%±20% or 70%±30% or 70%±40%.

[7] In some examples, the first capsule may be marked with a first identifier and the second capsule may be marked with a second identifier different from the first identifier such that the first capsule and the second capsule are visually distinguishable; the first identifier may be configured to indicate the first capsule is intended for administration within a first time window in the day, and the second identifier may be configured to indicate the second capsule is intended for administration within a second time window in the day different from the first time window. In some examples, the first identifier may be configured to indicate the first capsule is intended for administration at the first time window that is before noon, and the second identifier may be configured to indicate the second capsule is intended for administration at the second time window that is after noon; the first identifier may be a first color included on the first capsule, and the second identifier may be a second color included on the second capsule.

[8] In some examples, the system may include a package having a plurality of compartments configured to house the first capsule and the second capsule. The package may include a blister card that defines the plurality of compartments, wherein the first capsule and the second capsule housed in the plurality of compartments are accessible by puncturing a seal in the blister card; the package may have information printed thereon related to when to administer the first capsule and the second capsule to the patient; the blister card may have a first row of the plurality of compartments and a second row of the plurality of compartments, wherein the first capsule is housed in the first row, wherein the second capsule is housed in the second row, and wherein the first row and the second row are visually distinct.

[9] In another example, a capsule for use in delivering drugs to a patient is provided. The capsule includes a capsule body having an interior, and at least one first tablet and a second tablet included within the interior. The at least one first tablet includes a first drug, and the second tablet includes at least a second drug different from the first drug. The at least one first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule body within the patient.

[10] In some examples, the first tablet may include between about 175 mg and about 325 mg of a gonadotropin-releasing hormone antagonist, such as elagolix, and the second tablet comprises between about 0.75 mg and about 1.25 mg of estradiol; the second tablet may further comprise between about 0.1 mg and about 1.0 mg of norethindrone acetate. In some examples, wherein after 16 minutes, the release of estradiol is equal to or greater than 70%±10% or 70%±20% or 70%±30% or 70%±40%; the capsule body may be oblong to define a longitudinal axis, wherein the at least one first tablet and the second tablet are arranged in a serial relationship along the longitudinal axis within the interior; the at least one first tablet and the second tablet may be distinct tablets that have been formed separately from each other and then secured within the interior; the capsule body may not contain drugs in powder form; the capsule body may not include a barrier extending between the first tablet and the second tablet, and wherein the first tablet and the second tablet are not bonded together within the interior; the first capsule may include gelatin.

[11] In yet another example, a method of delivering drugs to a patient is provided. The method includes delivering a first capsule to the patient, wherein the first capsule includes a first capsule body having a first interior, and a first tablet and a second tablet included within the first interior. The first tablet includes a first drug, and the second tablet includes at least a second drug different from the first drug. The first tablet and the second tablet are configured for

simultaneous release upon dissolution of the first capsule body within a patient. The method also includes delivering a second capsule, which is co-packaged with the first capsule, to the patient after a predetermined amount of time has elapsed after administration of the first capsule. The second capsule includes a second capsule body having a second interior, and a third tablet included within the second interior. The third tablet includes the first drug.

[12] In some examples, the first tablet comprises the first tablet comprises between about 175 and 325 mg of gonadotropin-releasing hormone antagonist and the second tablet comprises between about 0.75 mg and 1.25 mg of estradiol and between about 0.1 mg and 1.0 mg of norethindrone; after 20 minutes, the release of estradiol is equal to or greater than 70%±10% or 70%±20% or 70%±30% or 70%±40%; delivering a second capsule includes delivering the second capsule at least 5 hours after administration of the first capsule; includes providing a package comprising a plurality of compartments configured to house the first capsule and the second capsule therein; and/or further includes housing a plurality of first capsules and a plurality of second capsules within the package, such that the number of first capsules and the number of second capsules housed within the package are each a multiple of the number of days in a week.

[13] In some examples, a multi-drug tablet includes a first tablet and a second tablet coated on the first tablet; the second tablet may be positioned in the center of the first tablet; and/or the multi-tablet includes crospovidone.

[14] In some examples, a medication container assembly includes a first set of a plurality of compartments each compartment configured to support a first capsule; a second set of a plurality of compartments each compartment configured to support a second capsule; wherein, the first capsule comprises a first interior; a first tablet within the first interior, the first tablet comprising a first drug; and a second tablet within the first interior, the second tablet comprising at

least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within a patient; and the second capsule comprises a second capsule body comprising a second interior; and a third tablet within the second interior, the third tablet comprising the at least one drug selected from the group consisting of: the first drug, the second drug, or a third drug.

[15] In some examples, a multi-drug capsule includes a first tablet, the first tablet comprising a first drug; a second tablet co-packaged with the first tablet and, the second tablet comprising at least a second drug different from the first drug; and a third drug different from the first and second drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule within a patient; wherein using USP apparatus 2 at 50 rpm, pH 6.8, and 37.5±0.5°C, at least 75%±10% of the first drug in the first tablet dissolves after 60 minutes and at least 70%±10% or 70%±20% or 70%±30% or 70%±40% of the second and third drugs in the second tablet dissolve after 30 minutes.

[16] In some examples, a multi-drug capsule includes a first tablet, the first tablet comprising a first drug; a second tablet co-packaged with the first tablet and, the second tablet comprising at least a second drug different from the first drug; and a third drug different from the first and second drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule within a patient; wherein using USP apparatus 1 at 100 rpm, pH 6.8, and 37.5±0.5°C, at least 75%±10% of the first drug in the first tablet dissolves after 45 minutes and at least 90%±10% or 90%±20% or 90%±30% or 90%±40% of the second and third drugs in the second tablet dissolve after 30 minutes.

[17] In some examples, the first tablet comprises elagolix, the first tablet has between about 175 mg to about 325 mg of elagolix and the second tablet has between about 0.75 mg and about 1.25 mg of estradiol.

[18] In another example, an oral multi-drug capsule composition includes 300 mg of free acid equivalent of elagolix; 1 mg of estradiol; and 0.5 mg of norethindrone acetate; and following administration of a single dose of the composition to healthy adult subjects results in a mean peak concentration (Cmax) for said elagolix of about 1218.4 ng/mL to about 2185 ng/mL; a mean peak concentration (Cmax) for said estradiol of about 0.0424 ng/mL to about 0.0775 ng/mL; a mean peak concentration (Cmax) for said norethindrone acetate of about 4.56 ng/mL to about 8.0 ng/mL; a mean Area Under the Curve ($AUC_{(t)}$) for said elagolix of about 3293.6 ng.hr/mL to about 5892.5 ng.hr/mL; a mean Area Under the Curve ($AUC_{(t)}$) for said estradiol of about 0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and a mean Area Under the Curve ($AUC_{(t)}$) for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

[19] In another example, a multi-drug capsule composition includes 300 mg of free acid equivalent of elagolix; 1 mg of estradiol; and 0.5 mg of norethindrone acetate; and administration of a single dose of the composition to healthy adult subjects results in a mean peak concentration, Cmax for said elagolix of about 1218.4 ng/ml to about 2185 ng/mL; a mean peak concentration, Cmax for said estradiol of about 0.0424 ng/ml to about 0.0775 ng/ml; and a mean peak concentration, Cmax for said norethindrone acetate of about 4.56 ng/ml to about 8.0 ng/ml.

[20] In one example, the multi-drug composition has a mean Area Under the Curve, $AUC_{(t)}$ for said elagolix of about 3296.6 ng.hr/mL to about 5892.5 ng.hr/mL; a mean Area Under the Curve, $AUC_{(t)}$ for said estradiol of about 0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and a mean Area Under the Curve, $AUC_{(t)}$ for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

[21] In one example, multi-drug capsule composition includes 300 mg of free acid equivalent of elagolix; 1 mg of estradiol; and 0.5 mg of norethindrone acetate; and administration of a single dose of the composition to healthy adult subjects results in a mean Area Under the Curve, $AUC_{(t)}$ for said elagolix of about 3293.6 ng.hr/mL to about 5892.5 ng.hr/mL; a mean Area Under the Curve, $AUC_{(t)}$ for said estradiol of about 0.0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and a mean Area Under the Curve, $AUC_{(t)}$ for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

[22] In one example, administration of the multi-drug capsule to healthy adult subjects results in a mean peak concentration, Cmax for said elagolix of about 1218.4 ng/mL to about 2185 ng.hr/mL; a mean peak concentration, Cmax for said estradiol of about 0.0424 ng.hr/mL to about 0.0775 ng/mL ng/ml; and a mean peak concentration, Cmax for said norethindrone acetate of about 4.56 ng.hr/mL to about 8.0 ng/ml.

[23] In another example, an oral multi-drug capsule composition includes 300 mg of free acid equivalent of elagolix; 1 mg of estradiol; and 0.5 mg of norethindrone acetate; and using USP apparatus 2 at 50 rpm, pH 6.8, and 37.5±0.5°C, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second and third drugs in the second tablet dissolve after 30 minutes. In another example, a method of safely treating heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in a pre-menopausal female patient is provided. The method comprising once daily oral administration to said patient of: (a) 300 mg of free acid equivalent of elagolix; (b) 1 mg of estradiol; and (c) 0.5 mg of norethindrone acetate, wherein said method results in a mean Cmax for said elagolix of about 1218.4 ng.hr/mL to about 2185 ng/mL; for said estradiol of about 0.0424 ng/mL to about 0.0775 ng/mL; for said norethindrone acetate of about 4.56 ng/mL to about 8.0 ng/mL, and a mean $AUC_{(t)}$ for said elagolix of about 3293.6ng.hr/mL to about 5892.5 ng.hr/mL; for

said estradiol of about 0.0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL, and wherein, after a treatment duration of about 6 months, said patient achieves equal to or greater than about 2 g/dL increase in hemoglobin as compared to baseline where the patient did not receive elagolix, estradiol, and norethindrone.

[24] In another example, an oral capsule for use in delivering drugs to a patient comprises: a capsule body comprising an interior; a first tablet within the interior, the at least one first tablet comprising a first drug; and a second tablet within the interior, the second tablet comprising at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the capsule body within the patient, wherein using USP apparatus 1 at 100 rpm, pH 6.8, and 37.5±0.5°C, at least 75% of the first drug in the first tablet dissolves after 45 minutes and at least 90% of the second and third drugs in the second tablet dissolve after 30 minutes.

[25] In another example, an oral multi-drug capsule composition is provided that is bioequivalent to any of the foregoing compositions.

[26] In another example, a method of delivering co-packaged drugs to a patient for oral use is provided. The method comprises delivering a first capsule to the patient, wherein the first capsule includes: a first capsule body including a first interior; a first tablet within the first interior, the first tablet including a first drug; and a second tablet within the first interior, the second tablet including at least a second drug different from the first drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within the patient; and delivering a second capsule, co-packaged with the first capsule, to the patient after a predetermined amount of time has elapsed after administration of the first capsule, wherein the second capsule includes: a second capsule body including a second interior; and a third tablet within the second interior, the third tablet including the first drug.

WHAT IS CLAIMED IS:

1. A multi-drug delivery system comprising

a first capsule comprising:

a first capsule body comprising a first interior;

a first tablet within the first interior, the first tablet comprising a first drug; and

a second tablet within the first interior, the second tablet comprising at least a second drug different from the first drug, and a third drug different from the first and second drug, wherein the first tablet and the second tablet are configured for simultaneous release upon dissolution of the first capsule body within a patient; and

a second capsule, co-packaged with the first capsule, comprising:

a second capsule body comprising a second interior; and

a third tablet within the second interior, the third tablet comprising the first drug,

wherein using USP apparatus 2 at 50 rpm, pH 6.8, and 37.5±0.5°C, at least 75% of the first drug in the first tablet dissolves after 60 minutes and at least 70% of the second and third drugs in the second tablet dissolve after 30 minutes;

wherein the first tablet comprises between about 175 mg to about 325 mg of elagolix and the second tablet comprises between about 0.75 mg and about 1.25 mg of estradiol; and

wherein the second tablet further comprises between about 0.1 mg and about 1 mg of norethindrone acetate.

2. The multi-drug delivery system in accordance with claim 1, wherein after about 15 minutes, the release of estradiol is equal to or greater than 70%.

3. The multi-drug delivery system in accordance with Claim 1, wherein the first capsule is marked with a first identifier and the second capsule is marked with a second identifier

different from the first identifier such that the first capsule and the second capsule are visually distinguishable.

4. The multi-drug delivery system in accordance with Claim 3, wherein the first identifier is configured to indicate the first capsule is intended for administration within a first time window in the day, and the second identifier is configured to indicate the second capsule is intended for administration within a second time window in the day different from the first time window.

5. The multi-drug delivery system in accordance with Claim 4, wherein the first identifier is configured to indicate the first capsule is intended for administration at the first time window that is before noon, and the second identifier is configured to indicate the second capsule is intended for administration at the second time window that is after noon.

6. The multi-drug delivery system in accordance with any of Claims 3-5, wherein the first identifier is a first color included on the first capsule, and the second identifier is a second color included on the second capsule.

7. The multi-drug delivery system in accordance with any of Claims 1-6 further comprising a package comprising a plurality of compartments configured to house the first capsule and the second capsule.

8. The multi-drug delivery system in accordance with Claim 7, wherein the package comprises a blister card that defines the plurality of compartments, wherein the first capsule and the second capsule housed in the plurality of compartments are accessible by puncturing a seal in the blister card.

9. The multi-drug delivery system in accordance with Claim 7 or 8, wherein the package comprises information printed thereon related to when to administer the first capsule and the second capsule to the patient.

10. The multi-drug delivery system in accordance with Claim 7, wherein the blister card comprises a first row of the plurality of compartments and a second row of the plurality of compartments, wherein the first capsule is housed in the first row, wherein the second capsule is housed in the second row, and wherein the first row and the second row are visually distinct.

11. An oral multi-drug capsule composition comprising:

(a) 300 mg of free acid equivalent of elagolix;

(b) 1 mg of estradiol which is administered once daily; and

(c) 0.5 mg of norethindrone acetate;

wherein administration of a single dose of the composition to healthy adult subjects results in a mean peak concentration, Cmax for said elagolix of about 1218.4 ng/ml to about 2185 ng/mL;

a mean peak concentration, Cmax for said estradiol of about 0.0424 ng/ml to about 0.0775 ng/ml; and

a mean peak concentration, Cmax for said norethindrone acetate of about 4.56 ng/ml to about 8.0 ng/ml.

12. The oral multi-drug capsule composition of claim 11, wherein

a mean Area Under the Curve, $AUC_{(t)}$ for said elagolix of about 3296.6 ng.hr/mL to about 5892.5 ng.hr/mL;

a mean Area Under the Curve, $AUC_{(t)}$ for said estradiol of about 0.688 ng.hr/mL to about 1.1375 ng.hr/mL; and

a mean Area Under the Curve, $AUC_{(t)}$ for said norethindrone acetate of about 17.6 ng.hr/mL to about 33.125 ng.hr/mL.

13. The multi-drug delivery system in accordance with any one of claims 1 to 10 or the oral multi-drug capsule composition in accordance with claims 11 or 12 for use in therapy.

14. Use of the multiple-drug delivery system in accordance with any one of claims 1 to 10 or the oral multi-drug capsule composition in accordance with claims 11 or 12 in the manufacture of a medicament for reducing uterine fibroid volume prior to surgery for removal of uterine fibroids, treating pain associated with endometriosis or treating heavy menstrual bleeding associated with uterine leiomyomas.