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(54) **SUBLINGUAL AND BUCCAL FILM COMPOSITIONS**

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(57) **ABSTRACT**

The present invention relates to products and methods for treatment of narcotic dependence in a user. The invention more particularly relates to self-supporting dosage forms which provide an active agent for treating narcotic dependence while providing sufficient buccal adhesion of the dosage form.

SUBLINGUAL AND BUCCAL FILM COMPOSITIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is a continuation of U.S. application Ser. No. 13/923,749, filed Jun. 21, 2013, which is a continuation of U.S. application Ser. No. 12/537,571 filed Aug. 7, 2009, now U.S. Pat. No. 8,475,832, issued Jul. 2, 2013.

FIELD OF THE INVENTION

[0002] The present invention relates to compositions, methods of manufacture, products and methods of use relating to films containing therapeutic actives. The invention more particularly relates to self-supporting film dosage forms which provide a therapeutically effective dosage, essentially matching that of currently-marketed tablets containing the same active. Such compositions are particularly useful for treating narcotic dependence while providing sufficient buccal adhesion of the dosage form.

BACKGROUND OF THE RELATED TECHNOLOGY

[0003] Oral administration of two therapeutic actives in a single dosage form can be complex if the intention is to have one active absorbed into the body and the other active remain substantially unabsorbed. For example, one active may be relatively soluble in the mouth at one pH, and the other active may be relatively insoluble at the same pH. Moreover, the absorption kinetics of each therapeutic agent may be substantially different due to differing absorption of the charged and uncharged species. These factors represent some of the challenges in appropriately co-administering therapeutic agents.

[0004] Co-administration of therapeutic agents has many applications. Among such areas of treatment include treating individuals who suffer from narcotic dependence. Such individuals have a tendency to suffer from serious physical dependence on the narcotic, resulting in potentially dangerous withdrawal effects when the narcotic is not administered to the individual. In order to help individuals addicted to narcotics, it is known to provide a reduced level of a drug, which provides an effect of satisfying the body's urge for the narcotic, but does not provide the "high" that is provided by the misuse of the narcotic. The drug provided may be an agonist or a partial agonist, which provides a reduced sensation and may help lower dependence on the drug. However, even though these drugs provide only a low level of euphoric effect, they are capable of being abused by the individuals parenterally. In such cases, it is desirable to provide a combination of the drug with a second drug, which may decrease the likelihood of diversion and abuse of the first drug. For example, it is known to provide a dosage of an antagonist in combination with the agonist or partial agonist. The narcotic antagonist binds to a receptor in the brain to block the receptor, thus reducing the effect of the agonist.

[0005] One such combination of drugs has been marketed under the trade name Suboxone® as an orally ingestible tablet. However, such combinations in tablet form have the potential for abuse. In some instances, the patient who has been provided the drug may store the tablet in his mouth [illegible] Although certain antagonists (such as highly water-soluble antagonists) may be used to help reduce the ability to separate the agonist, the potential for abuse still exists. It is desired to provide a dosage that cannot be easily removed from the mouth once it has been administered.

[0006] There is currently a need for an orally dissolvable film dosage form that provides the desired absorption levels of the agonist and antagonist, while providing an adhesive effect in the mouth, rendering it difficult to remove once placed in the mouth, thereby making abuse of the agonist difficult.

SUMMARY OF THE INVENTION

[0007] In one embodiment of the present invention, there is provided a film dosage composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffer in an amount to provide a pH of the composition of a value sufficient to optimize absorption of the buprenorphine.

[0008] In another embodiment of the present invention, there is provided a film dosage composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffer in an amount sufficient to inhibit the absorption of the naloxone when administered orally.

[0009] In still other embodiments, there may be provided a film dosage composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffering system; where the buffering system includes a buffer capacity sufficient to maintain the ionization of naloxone during the time which the composition is in the oral cavity of a user.

[0010] In another embodiment of the invention, there is provided a method of treating narcotic dependence of a user, including the steps of: providing a composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffer in an amount to provide a pH of the composition of a value sufficient to optimize absorption of the buprenorphine; and administering the composition to the oral cavity of a user.

[0011] In still another embodiment of the invention, there is provided a process of forming a film dosage composition including the steps of: casting a film-forming composition, the film-forming composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffer in an amount to provide a pH of the composition of a value sufficient to optimize absorption of the buprenorphine and drying the film-forming composition to form a self-supporting film dosage composition.

[0012] In another embodiment, there is provided a film dosage composition including a therapeutically sufficient [illegible]

one or a pharmaceutically acceptable salt thereof, the film dosage composition having a bioequivalent release profile as compared to a Suboxone® tablet containing about 2 times the amount of buprenorphine or a pharmaceutically acceptable salt thereof.

[0013] Still other embodiments of the present invention provide an orally dissolving film formulation including buprenorphine and naloxone, where the formulation provides an in-vivo plasma profile having a Cmax of between about 0.624 ng/ml and about 5.638 ng/ml for buprenorphine and an in-vivo plasma profile having a Cmax of between about 41.04 pg/ml to about 323.75 pg/ml for naloxone.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Definitions

[0014] As used herein, the term Cmax refers to the mean maximum plasma concentration after administration of the composition to a human subject. As also used herein, the term AUC refers to the mean area under the plasma concentration-time curve value after administration of the compositions formed herein. As will be set forth in more detail below, the term "optimizing the absorption" does not refer to reaching the maximum absorption of the composition, and rather refers to reaching the optimum level of absorption at a pH of about 2 to about 4. The "optimum" absorption may be, for example, a level that provides a bioequivalent absorption as administration of the currently available Suboxone® tablet. An "optimum" Cmax of buprenorphine is about 0.67 to about 5.36 mg/ml at dosages of from 2-16 mg buprenorphine at a given pH. Similarly, an "optimum" AUC of buprenorphine may be about 7.43 to about 59.46 hr*ng/ml at dosages of from 2-16 mg buprenorphine at a given pH. As will be described in more detail below, it has been surprisingly discovered that the absorption of one particular agonist, buprenorphine, can provide an optimum absorption at a pH of about 2-4 as well as about 5.5-6.5. Thus, one may "optimize" the absorption of buprenorphine by providing a pH of about 2-4 or about 5.5-6.5.

[0015] "Maximizing the absorption" refers to the maximum in vivo absorption values achieved at a pH of about 4 to about 9.

[0016] The term "local pH" refers to the pH of the region of the carrier matrix immediately surrounding the active agent as the matrix hydrates and/or dissolves, for example, in the mouth of the user.

[0017] By "inhibiting" the absorption of an active, it is meant achieving as complete an ionization state of the active as possible, such that little to none of the active is measurably absorbable. For example, at a pH of 3-3.5, the Cmax of an active such as naloxone for dosage of 0.5 mg to 4.0 mg ranges from 32.5 to 260 pg/ml, and an AUC of naloxone for dosage of 0.5 mg to 4.0 mg ranges from 90.55 to 724.4 hr*pg/ml. It is understood that at a pH lower than 3.0, further ionization would be expected and thus result in lower absorption.

[0018] The term "bioequivalent" means obtaining 80% to 125% of the Cmax and AUC values for a given active in a different product. For example, assuming Cmax and AUC values of buprenorphine for a commercially-available Suboxone® tablet (containing 2 mg buprenorphine and 0.5 mg [illegible]) are in the range of 0.624-0.975 ng/ml, and an AUC value of buprenorphine of 5.431-8.486 hr*ng/ml.

[0019] It will be understood that the term "film" includes thin films and sheets, in any shape, including rectangular, square, or other desired shape. The films described herein may be any desired thickness and size such that it may be placed into the oral cavity of the user. For example, the films may have a relatively thin thickness of from about 0.1 to about 10 mils, or they may have a somewhat thicker thickness of from about 10 to about 30 mils. For some films, the thickness may be even larger, i.e., greater than about 30 mils. Films may be in a single layer or they may be multi-layered, including laminated films.

[0020] Oral dissolving films generally fall into three main classes: fast dissolving, moderate dissolving and slow dissolving. Fast dissolving films generally dissolve in about 1 second to about 30 seconds in the mouth. Moderate dissolving films generally dissolve in about 1 to about 30 minutes in the mouth, and slow dissolving films generally dissolve in more than 30 minutes in the mouth. Fast dissolving films may consist of low molecular weight hydrophilic polymers (i.e., polymers having a molecular weight between about 1,000 to 9,000, or polymers having a molecular weight up to 200,000). In contrast, slow dissolving films generally have high molecular weight polymers (i.e., having a molecular weight in the millions).

[0021] Moderate dissolving films tend to fall in between the fast and slow dissolving films. Moderate dissolving films dissolve rather quickly, but also have a good level of mucoadhesion. Moderate dissolving films are also flexible, quickly wettable, and are typically non-irritating to the user. For the instant invention, it is preferable to use films that fall between the categories of fast dissolving and moderate dissolving. Such moderate dissolving films provide a quick enough dissolution rate, most desirably between about 1 minute and about 20 minutes, while providing an acceptable mucoadhesion level such that the film is not easily removable once it is placed in the oral cavity of the user.

[0022] Inventive films described herein may include one or more agonists or partial agonists used for the treatment of drug addiction. As used herein, the term "agonist" refers to a chemical substance that is capable of providing a physiological response or activity in the body of the user. The films described herein may further include one or more antagonists. As used herein, the term "antagonist" refers to any chemical substance that acts within the body of the user to reduce the physiological activity of another chemical substance. In some embodiments, an antagonist used herein may act to reduce and/or block the physiological activity of the agonist. The actives may be water-soluble, or they may be water-insoluble. As used herein, the term "water-soluble" refers to substances that are at least partially dissolvable in a solvent, including but not limited to water. The term "water-soluble" does not necessarily mean that the substance is 100% dissolvable in the solvent. The term "water-insoluble" refers to substances that are not dissolvable in a solvent, including but not limited to water. Solvents may include water, or alternatively may include other polar solvents by themselves or in combination with water.

Inventive Films

[0023] The present invention relates to methods of treating [illegible]

individual, while using a formulation and delivery that hinders misuse of the narcotic. Currently, treatment of opioid dependence is aided by administration of Suboxone®, which is an orally dissolvable tablet. This tablet which provides a combination of buprenorphine (an opioid agonist) and naloxone (an opioid antagonist). Therefore, the present invention provides a method of treating narcotic dependence by providing an orally dissolvable film dosage, which provides a bioequivalent effect to Suboxone®. The film dosage preferably provides buccal adhesion while it is in the user's mouth, rendering it difficult to remove after placement.

[0024] The film dosage composition preferably includes a polymeric carrier matrix. Any desired polymeric carrier matrix may be used, provided that it is orally dissolvable. Desirably, the dosage should have enough bioadhesion to not be easily removed and it should form a gel like structure when administered. The orally consumable films are preferably moderate-dissolving in the oral cavity and particularly suitable for delivery of actives, although both fast and sustained release compositions are also among the various embodiments contemplated.

[0025] The films used in the pharmaceutical products may be produced by a combination of at least one polymer and a solvent, optionally including other fillers known in the art. The solvent may be water, a polar organic solvent including, but not limited to, ethanol, isopropanol, acetone, or any combination thereof. In some embodiments, the solvent may be a non-polar organic solvent, such as methylene chloride. The film may be prepared by utilizing a selected casting or deposition method and a controlled drying process. For example, the film may be prepared through controlled drying processes, which include application of heat and/or radiation energy to the wet film matrix to form a visco-elastic structure, thereby controlling the uniformity of content of the film. Such processes are described in more detail in commonly assigned U.S. application Ser. No. 10/074,272, filed on Feb. 14, 2002, and published as U.S. Patent Publication No. 2003/0107149 A1, the contents of which are incorporated herein by reference in their entirety. Alternatively, the films may be extruded as described in commonly assigned U.S. application Ser. No. 10/856,176, filed on May 28, 2004, and published as U.S. Patent Publication No. 2005/0037055 A1, the contents of which are incorporated herein by reference in their entirety.

[0026] The polymer included in the films may be water-soluble, water-swellable, water-insoluble, or a combination of one or more either water-soluble, water-swellable or water-insoluble polymers. The polymer may include cellulose or a cellulose derivative. Specific examples of useful water-soluble polymers include, but are not limited to, polyethylene oxide, pullulan, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, polyvinyl pyrrolidone, carboxymethyl cellulose, polyvinyl alcohol, sodium alginate, polyethylene glycol, xanthan gum, tragancanth gum, guar gum, acacia gum, arabic gum, polyacrylic acid, methylmethacrylate copolymer, carboxyvinyl copolymers, starch, gelatin, and combinations thereof. Specific examples of useful water-insoluble polymers include, but are not limited to, ethyl cellulose, hydroxypropyl ethyl cellulose, cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate and combinations thereof. For higher dosages, it may be desirable to incorporate a polymer that provides a high level of viscosity as compared to lower dosages.

soluble in water, and desirably fully or predominantly soluble in water, or absorbs water. Polymers that absorb water are often referred to as being water-swellable polymers. The materials useful with the present invention may be water-soluble or water-swellable at room temperature and other temperatures, such as temperatures exceeding room temperature. Moreover, the materials may be water-soluble or water-swellable at pressures less than atmospheric pressure. Desirably, the water-soluble polymers are water-soluble or water-swellable having at least 20 percent by weight water uptake. Water-swellable polymers having a 25 or greater percent by weight water uptake are also useful. In some embodiments, films formed from such water-soluble polymers may be sufficiently water-soluble to be dissolvable upon contact with bodily fluids.

[0028] Other polymers useful for incorporation into the films include biodegradable polymers, copolymers, block polymers and combinations thereof. It is understood that the term "biodegradable" is intended to include materials that chemically degrade, as opposed to materials that physically break apart (i.e., bioerodable materials). Among the known useful polymers or polymer classes which meet the above criteria are: poly(glycolic acid) (PGA), poly(lactic acid) (PLA), polydioxanes, polyoxalates, poly(α-esters), polyanhydrides, polyacetates, polycaprolactones, poly(orthoesters), polyamino acids, polyaminocarbonates, polyurethanes, polycarbonates, polyamides, poly(alkyl cyanoacrylates), and mixtures and copolymers thereof. Additional useful polymers include, stereopolymers of L- and D-lactic acid, copolymers of bis(p-carboxyphenoxy) propane acid and sebacic acid, sebacic acid copolymers, copolymers of caprolactone, poly(lactic acid)/poly(glycolic acid)/polyethyleneglycol copolymers, copolymers of polyurethane and (poly(lactic acid), copolymers of polyurethane and poly(lactic acid), copolymers of α-amino acids, copolymers of α-amino acids and caproic acid, copolymers of α-benzyl glutamate and polyethylene glycol, copolymers of succinate and poly(glycols), polyphosphazene, polyhydroxy-alkanoates and mixtures thereof. Binary and ternary systems are contemplated.

[0029] Other specific polymers useful include those marketed under the Medisorb and Biodel trademarks. The Medisorb materials are marketed by the Dupont Company of Wilmington, Del. and are generically identified as a "lactide/glycolide co-polymer" containing "propanoic acid, 2-hydroxy-polymer with hydroxy-polymer with hydroxyacetic acid." Four such polymers include lactide/glycolide 100 L, believed to be 100% lactide having a melting point within the range of 338°-347° F. (170°-175° C.); lactide/glycolide 100 L, believed to be 100% glycolide having a melting point within the range of 437°-455° F. (225°-235° C.); lactide/glycolide 85/15, believed to be 85% lactide and 15% glycolide with a melting point within the range of 338°-347° F. (170°-175° C.); and lactide/glycolide 50/50, believed to be a copolymer of 50% lactide and 50% glycolide with a melting point within the range of 338°-347° F. (170°-175° C.).

[0030] The Biodel materials represent a family of various polyanhydrides which differ chemically.

[0031] Although a variety of different polymers may be used, it is desired to select polymers that provide mucoadhesive properties to the film, as well as a desired dissolution and/or disintegration rate. In particular, the time period for which it is desired to maintain the film in contact with the

for delivery through the mucosal tissue, whereas other actives may require up to several hours or even longer. Accordingly, in some embodiments, one or more water-soluble polymers, as described above, may be used to form the film. In other embodiments, however, it may be desirable to use combinations of water-soluble polymers and polymers that are water-swellable, water-insoluble and/or biodegradable, as provided above. The inclusion of one or more polymers that are water-swellable, water-insoluble and/or biodegradable may provide films with slower dissolution or disintegration rates than films formed from water-soluble polymers alone. As such, the film may adhere to the mucosal tissue for longer periods or time, such as up to several hours, which may be desirable for delivery of certain active components.

[0032] Desirably, the individual film dosage has a small size, which is between about 0.5-1 inch by about 0.5-1 inch. Most preferably, the film dosage is about 0.75 inches×0.5 inches. The film dosage should have good adhesion when placed in the buccal cavity or in the sublingual region of the user. Further, the film dosage should disperse and dissolve at a moderate rate, most desirably dispersing within about 1 minute and dissolving within about 3 minutes. In some embodiments the film dosage may be capable of dispersing and dissolving at a rate of between about 1 to about 1.5 minutes.

[0033] For instance, in some embodiments, the films may include polyethylene oxide alone or in combination with a second polymer component. The second polymer may be another water-soluble polymer, a water-swellable polymer, a water-insoluble polymer, a biodegradable polymer or any combination thereof. Suitable water-soluble polymers include, without limitation, any of those provided above. In some embodiments, the water-soluble polymer may include hydrophilic cellulosic polymers, such as hydroxypropyl cellulose and/or hydroxypropylmethyl cellulose. In accordance with some embodiments, polyethylene oxide may range from about 20% to 100% by weight in the polymer component, more specifically about 30% to about 70% by weight, and even more specifically about 40% to about 60% by weight. In some embodiments, one or more water-swellable, water-insoluble and/or biodegradable polymers also may be included in the polyethylene oxide-based film. Any of the water-swellable, water-insoluble or biodegradable polymers provided above may be employed. The second polymer component may be employed in amounts of about 0% to about 80% by weight in the polymer component, more specifically about 30% to about 70% by weight, and even more specifically about 40% to about 60% by weight.

[0034] The molecular weight of the polyethylene oxide also may be varied. In some embodiments, high molecular weight polyethylene oxide, such as about 4 million, may be desired to increase mucoadhesivity of the film. In some other embodiments, the molecular weight may range from about 100,000 to 900,000, more specifically from about 100,000 to 600,000, and even more specifically from about 100,000 to 300,000. In some embodiments, it may be desirable to combine high molecular weight (600,000 to 900,000) with low molecular weight (100,000 to 300,000) polyethylene oxide in the polymer component.

[0035] A variety of optional components and fillers also may be added to the films. These may include, without limitation: surfactants; plasticizers; polyalcohols; anti-foaming

film; thermo-setting gels such as pectin, carageenan, and gelatin, which help in maintaining the dispersion of components; inclusion compounds, such as cyclodextrins and caged molecules; coloring agents; and flavors. In some embodiments, more than one active components may be included in the film.

[0036] Additives may be included in the films. Examples of classes of additives include excipients, lubricants, buffering agents, stabilizers, blowing agents, pigments, coloring agents, fillers, bulking agents, sweetening agents, flavoring agents, fragrances, release modifiers, adjuvants, plasticizers, flow accelerators, mold release agents, polyols, granulating agents, diluents, binders, buffers, absorbents, glidants, adhesives, anti-adherents, acidulants, softeners, resins, demulcents, solvents, surfactants, emulsifiers, elastomers and mixtures thereof. These additives may be added with the active ingredient(s).

[0037] Useful additives include, for example, gelatin, vegetable proteins such as sunflower protein, soybean proteins, cotton seed proteins, peanut proteins, grape seed proteins, whey proteins, whey protein isolates, blood proteins, egg proteins, acrylated proteins, water-soluble polysaccharides such as alginates, carrageenans, guar gum, agar-agar, xanthan gum, gellan gum, gum arabic and related gums (gum ghatti, gum karaya, gum tragancanth), pectin, water-soluble derivatives of cellulose: alkylcelluloses hydroxyalkylcelluloses and hydroxyalkylalkylcelluloses, such as methylcelulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxyethylmethylcellulose, hydroxypropylmethylcellulose, hydroxybutylmethylcellulose, cellulose esters and hydroxyalkylcellulose esters such as cellulose acetate phthalate (CAP), hydroxypropylmethylcellulose (HPMC); carboxyalkylcelluloses, carboxyalkylalkylcelluloses, carboxyalkylcellulose esters such as carboxymethylcellulose and their alkali metal salts; water-soluble synthetic polymers such as polyacrylic acids and polyacrylic acid esters, polymethacrylic acids and polymethacrylic acid esters, polyvinylacetates, polyvinylalcohols, polyvinylacetatephthalates (PVAP), polyvinylpyrrolidone (PVP), PVY/vinyl acetate copolymer, and polycrotonic acids; also suitable are phthalated gelatin, gelatin succinate, crosslinked gelatin, shellac, water-soluble chemical derivatives of starch, cationically modified acrylates and methacrylates possessing, for example, a tertiary or quaternary amino group, such as the diethylaminoethyl group, which may be quaternized if desired; and other similar polymers.

[0038] Such extenders may optionally be added in any desired amount desirably within the range of up to about 80%, desirably about 3% to 50% and more desirably within the range of 3% to 20% based on the weight of all film components.

[0039] Further additives may flow agents and opacifiers, such as the oxides of magnesium aluminum, silicon, titanium, etc. desirably in a concentration range of about 0.02% to about 3% by weight and desirably about 0.02% to about 1% based on the weight of all film components.

[0040] Further examples of additives are plasticizers which include polyalkylene oxides, such as polyethylene glycols, polypropylene glycols, polyethylene-propylene glycols, organic plasticizers with low molecular weights, such as glycerol, glycerol monoacetate, diacetate or triacetate, triacetin, polysorbate, cetyl alcohol, propylene glycol, sorbitol,

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