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(54) **BUPRENORPHINE-WAFER FOR DRUG
SUBSTITUTION THERAPY**

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(57) **ABSTRACT**

The present invention relates to oral pharmaceutical dosage forms comprising buprenorphine with the dosage form releasing buprenorphine instantly upon oral, preferably sublingual, application of the dosage form. The present invention also relates to the use of such dosage forms for treating pain in a human or animal or for drug substitution therapy in drug-dependent human subjects.

BUPRENORPHINE-WAFER FOR DRUG SUBSTITUTION THERAPY

[0001] The present invention relates to oral pharmaceutical dosage forms comprising buprenorphine with the dosage form releasing buprenorphine instantly upon oral, preferably sublingual, application of the dosage form. The present invention also relates to the use of such dosage forms for treating pain in a human or animal or for drug substitution therapy in drug-dependent human subjects.

BACKGROUND OF THE INVENTION

[0002] Chronic pain, which may be due to idiopathic reasons, cancer or other diseases such as rheumatism and arthritis, is typically treated with strong opioids.

[0003] Over the last decades prejudices in the medical community as to the use of strong opioids for treating chronic pain in patients has significantly decreased. Many of the se prejudices were due to some of the characteristics being inherent to opioids.

[0004] While opioids have always been known to be useful in pain treatment, they also display an addictive potential in view of their euphorogenic activity. Thus, if opioids are taken by healthy human subjects with a drug seeking behaviour they may lead to psychological as well as physical dependence.

[0005] These usually undesired characteristics of opioids can however become important in certain scenarios such as drug substitution therapies for drug addicts. One of the fundamental problems of illicit drug abuse by drug addicts ("junkies") who are dependent on the constant intake of illegal drugs such as heroin is the drug-related criminal activities resorted to by such addicts in order to raise enough money to fund their addiction. The constant pressures upon addicts to procure money for buying drugs and the concomitant criminal activities have been increasingly recognised as a major factor that counteracts efficient and long-lasting withdrawal and abstinence from drugs.

[0006] Therefore, programmes have been developed, particularly in the United States and western European countries, in which drug addicts are allowed to take prescription drugs under close supervision of medical practitioners instead of illegal drugs such as street heroin.

[0007] The aim of drug substitution theory is thus to first enable addicts to lead a regular life by administering legal drugs to prevent withdrawal symptoms, but because of their legal character and prescription by medical practitioners do not lead to the aforementioned described drug-related criminal activities. In a second and/or alternate step in the treatment of drug addiction may be to slowly make the drug addict less dependent on the drug by gradually reducing the dose of the substitution drug or to bridge the time until a therapy place in a withdrawal programme is available.

[0008] The standard drug used in drug substitution therapy programmes has for a long time been methadone. However, in recent years the potential of other opioids as substitution drugs in substitution therapy has been recognised. A particularly suitable drug for that purpose is the opioid buprenorphine, which is a mixed opioid agonist/antagonist.

[0009] Nowadays, buprenorphine preparations are administered in drug substitution programmes in the form of a tablet

this the preferred route of administration for buprenorphine. Furthermore, if a patient swallows such tablets they will not provide euphorogenic activity.

[0010] One example of sublingual tablets for drug substitution therapy is the preparation Subutex® (being marketed in Germany by Essex Pharma).

[0011] Nevertheless, drug addicts sometimes still try to divert these sublingual buprenorphine tablets by removing them from the mouth when the supervising healthcare professional's attention is directed to other activities. Later the tablets may be sold or the active agent buprenorphine isolated/extracted to apply it parenterally.

[0012] Another buprenorphine preparation aimed at preventing this potential possibility of abuse has recently gained administrative approval in the United States (Suboxone®). The Suboxone® preparation comprises buprenorphine hydrochloride and the opioid antagonist naloxone hydrochloride dihydrate. The presence of naloxone is intended to prevent parenteral abuse of buprenorphine as parenteral co-administration of buprenorphine and naloxone in e.g. an opioid-dependent addict will lead to serious withdrawal symptoms.

[0013] However, there remains a need for other diversion and/or abuse-resistant dosage forms of buprenorphine, which can be used in drug substitution therapy as described above. Additionally, it would be desirable to have a buprenorphine preparation available which is diversion and/or abuse-resistant in cases where the preparation is used for drug substitution therapy and which could also provide efficient analgesia in cases where the preparation is administered to alleviate pain in a patient.

OBJECT AND SUMMARY OF THE INVENTION

[0014] It is an object of the present invention to provide an oral pharmaceutical dosage form of the active agent buprenorphine that is less prone to diversion and/or abuse in drug substitution therapy. It is another object of the present invention to provide an oral dosage form of the active agent buprenorphine that can be used for drug substitution therapy and/or pain treatment.

[0015] In one embodiment the present invention relates to an oral pharmaceutical dosage form comprising at least buprenorphine or a pharmaceutically acceptable salt thereof with a dosage form releasing buprenorphine or said pharmaceutically acceptable salt thereof instantly upon or oral, preferably sublingual, application of the dosage form. It is, however, understood that the invention and its various embodiments which are set out below, can be extended to any opioid or analgesic whose preferred route of administration is oral, preferably sublingual, as is the case for buprenorphine.

[0016] An instant release of buprenorphine or a pharmaceutically acceptable salt thereof upon oral, preferably sublingual, application means that substantially all of the buprenorphine or said pharmaceutically acceptable salt thereof will be released within less than three minutes, preferably within less than two minutes or less than one minute. Even more preferably, substantially all of the buprenorphine or said pharmaceutically acceptable salt thereof will be released within less than thirty seconds, twenty seconds, ten seconds or even within less than five seconds after oral, preferably sublingual, application of the dosage form. In one of the preferred embodiments these oral dosage forms will comprise between approximately 0.1 mg and approximately 16

[0017] In a further preferred embodiment these oral pharmaceutical dosage forms will achieve an average C_{max} of between 1.5 ng/ml and approximately 2.25 ng/ml in the case of a dose of 0.4 mg buprenorphine hydrochloride being administered. In the case of a dose of 8 mg buprenorphine HCl being administered, the C_{max} will typically be between approximately 2.5 and 3.5 ng/ml and if a dose of 16 mg buprenorphine hydrochloride is administered the C_{max} will preferably be between 5.5 to 6.5 ng/ml.

[0018] Yet another preferred embodiment of the invention relates to oral pharmaceutical dosage forms which may provide for the above-mentioned characteristics and/or an average T_{max} of from approximately 45 to approximately 90 minutes.

[0019] In a particularly preferred embodiment the dosage forms will additionally comprise an opioid antagonist, preferably naloxone or a pharmaceutically acceptable salt thereof.

[0020] In yet a further preferred embodiment, the pharmaceutical dosage form will comprise buprenorphine and the opioid antagonist, which preferably is naloxone, in a weight ratio of from approximately 1:1 to approximately 10:1.

[0021] One embodiment of the present invention also relates to oral pharmaceutical dosage forms, which may have some or all of the aforementioned characteristics and wherein the dosage form has a film-like or wafer-like shape.

[0022] Another embodiment relates to a method of manufacturing the afore-mentioned described dosage forms.

[0023] Embodiments of the present invention also relate to the use of the afore-described oral, preferably sublingual, pharmaceutical dosage forms in the manufacture of a medicament for treating pain in a human or animal and/or for drug substitution therapy in drug-dependent human subjects.

[0024] One aspect of the invention also relates to a method of drug substitution therapy in drug-dependent human subjects wherein the aforementioned oral pharmaceutical dosage forms are administered to a drug-dependent subject in need thereof.

DETAILED DESCRIPTION OF THE INVENTION

[0025] From the prior art, sublingual tablets are known under the trade names Subutex® or Suboxone® both of which comprise the active agent buprenorphine hydrochloride for drug substitution therapy.

[0026] The suitability of particularly buprenorphine for drug substitution therapy had been recognised early on in view of buprenorphine's very long elimination half-life (reported as approximately 20 to 37 hours), which allows a reduced frequency of administration. As a consequence drug addicts who participate in drug substitution therapy have to report less frequently to the medical agency or healthcare professional supervising the substitution programme.

[0027] Furthermore, the sublingual absorption of buprenorphine has the advantage that an abuse by swallowing tablets of buprenorphine is less likely to occur. The tablets that are currently on the market in the form of Subutex® and Suboxone® preparations are both for sublingual administration and typically disintegrate over a time period of five to ten minutes. However, within that time period the drug addict may be able to divert the tablet before subsequently either selling the tablets on the street or isolating the active agents therefrom.

which comprise the active agent buprenorphine and which release buprenorphine instantly after oral, preferably sublingual, administration of the drug.

[0029] It is understood that if reference is made in the context of this invention to the term "buprenorphine" this refers to the free base as well as to any pharmaceutically acceptable salt thereof such as the hydrochloride, sulfate, bisulfate, tartrate, nitrate, citrate, bitartrate, phosphate, malate, maleate, hydrobromide, hydroiodide, fumarate, succinate salts and the like.

[0030] A particularly preferred pharmaceutically acceptable salt of buprenorphine is buprenorphine hydrochloride.

[0031] The provision of a pharmaceutical dosage form comprising buprenorphine or a pharmaceutically acceptable salt thereof in e.g. film-like or wafer-like shapes which allows for instant release of the active agent upon oral, preferably sublingual, administration of the dosage form should prevent the type of abuse resulting from illicit diversion of the tablets by drug addicts participating in drug substitution therapy programmes.

[0032] In the context of the present invention instant release means that substantially the whole amount of the buprenorphine or the respective pharmaceutically acceptable salt thereof will be released in less than five minutes. Preferably, substantially all of the buprenorphine or its pharmaceutically acceptable salt thereof will be released within less than four, within less than three, within less than two and more preferably within less than one minute.

[0033] In a particularly preferred embodiment, instant release refers to the situation that substantially all of the buprenorphine or the respective pharmaceutically acceptable salt thereof will be released within less than thirty seconds, within less than twenty seconds, or within less than ten seconds. In an even more preferred embodiment, the term "instant release" means that substantially all of the buprenorphine will be released from the dosage form within less than five seconds or within less than three seconds.

[0034] The term "substantially all" means that approximately 95% of the drug will have been released.

[0035] The term "approximately" in the context of the present invention describes a deviation from the indicated value of 10% and preferably of 5%.

[0036] Such efficient release of the drug is hard to achieve with a sublingual tablet which generally requires a greater amount of time to melt or to disintegrate.

[0037] Fast-dissolving or rapidly disintegrating dosage forms for other pharmaceutically active compounds are known which disintegrate within seconds upon contact with the mucosal saliva of the mouth and particularly the sublingual mucosa.

[0038] These pharmaceutical dosage forms and formulation principles are well known to the person skilled in the art and will be described in more detail below.

[0039] As regards the dosage amount, the pharmaceutical compositions in accordance with the present invention will typically comprise between approximately 0.1 mg and approximately 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof such as buprenorphine hydrochloride. Preferred dosage amounts will be in the range of between approximately 0.4 mg and approximately 12 mg or between approximately 2 mg and approximately 8 mg buprenorphine or a pharmaceutically acceptable salt thereof.

of providing a C_{max} of approximately 1.5 to 2.5 ng/ml in the case of a dose of 4 mg buprenorphine hydrochloride being administered. A preferred C_{max} in the case of a dose of 4 mg of buprenorphine hydrochloride being administered may be approximately between 1.7 ng/ml to 2 ng/ml.

[0041] In the case of a dose of 8 mg buprenorphine hydrochloride being administered, the C_{max} may be approximately between 2.5 and 3.5 ng/ml. In a preferred embodiment the C_{max} may be approximately between 2.75 ng/ml and 3.25 ng/ml in the case of a dose of 8 mg buprenorphine hydrochloride being administered.

[0042] In case of a dose of 16 mg buprenorphine hydrochloride being administered, the C_{max} may preferably be in the range of approximately 5 to 7 ng/ml. In a preferred embodiment the C_{max} may be between 5.5 and 6.5 ng/ml if 16 mg of buprenorphine hydrochloride are administered.

[0043] The AUC_{0-48} (i.e. the Area under the Curve for 48 hours after administration) may in the case of administration of 4 mg of buprenorphine hydrochloride be in the range of approximately 10 to 15 hours×ng/ml. In a preferred embodiment the AUC_{0-48} may be approximately 12 to 13 hours×ng/ml. In the case of 8 mg buprenorphine hydrochloride being administered the AUC_{0-48} may be approximately in the range of 15 to 25 hours×ng/ml. In a preferred embodiment the AUC_{0-48} in this case may be between approximately 20 to 22 hours×ng/ml. In the case of 16 mg buprenorphine hydrochloride being administered, the AUC_{0-48} may be in the range of 25 to 40 hours×ng/ml. In a preferred embodiment the AUC_{0-48} in this case may be in the range of approximately 30 to 35 hours×ng/ml.

[0044] The average T_{max} values for such preparations will preferably be from approximately 45 to approximately 90 minutes.

[0045] It is understood that the aforementioned pharmacokinetic parameters C_{max} and AUC_{0-48} are average values that are obtained by measuring the blood plasma levels in a group of eight to approximately twenty-four patients. These patients will be selected according to inclusion and exclusion criteria, as they are common for drug substitution programmes. It is understood that such patients typically will be of average weight and Caucasian origin.

[0046] The pharmaceutical dosage form in accordance with the invention will be administered such that the maximal dosage per day is 32 mg of buprenorphine. Once a patient is enrolled in substitution therapy, the initial dosage will be typically between 2 mg to 4 mg of buprenorphine. The formulations may be administered once a day, every two days, preferably every three days or even less frequently.

[0047] In a preferred embodiment, the oral dosage forms of the invention will additionally comprise an opioid antagonist. Such antagonists may be selected from the group comprising naltrexone, naloxone, nalmefene, nalorphine, nalbuphine, naloxoneazinen, methylnaltrexone, ketylcyclazocine, norbinaltorphimine, naltrindol, 6-β-naloxol and 6-β-naltrexol or the pharmaceutically acceptable salts thereof.

[0048] Especially preferred antagonists comprise naltrexone, nalmefene and naloxone. Specifically preferred as an antagonist is naloxone and its hydrochloride salt.

[0049] It is understood, that if in the context of the present invention reference is made to an opioid antagonist, this also not only refers to the free base but also to pharmaceutically

[0050] A particularly preferred antagonist is naloxone. Of the naloxone salts, naloxone hydrochloride dihydrate may be particularly preferable in combination with buprenorphine hydrochloride.

[0051] The pharmaceutical dosage forms in accordance with the invention will comprise buprenorphine and the antagonist, which preferably is naloxone, in a weight ratio of from 1:1 to 10:1. A weight ratio of from 2:1 to 8:1 may be preferred, with a weight ratio of 4:1 being particularly preferred.

[0052] Thus, if an oral dosage form in accordance with the present invention for example comprises 2 mg buprenorphine hydrochloride it will comprise approximately 0.5 mg naloxone. If the dosage form comprises 0.4 mg buprenorphine hydrochloride, it will comprise 0.1 mg naloxone and if the dosage form comprises 8 mg buprenorphine hydrochloride it will comprise e.g. 2 mg naloxone hydrochloride.

[0053] A particularly preferred embodiment thus relates to an oral dosage form comprising buprenorphine, preferably buprenorphine hydrochloride, and naloxone, preferably naloxone hydrochloride, wherein the dosage form releases said active agents within less than one minute, preferably within less than thirty seconds and more preferably within less than ten seconds after sublingual application of the dosage form. In addition, the dosage forms may provide the preferred values of the aforementioned pharmacokinetic parameters C_{max} and AUC_{0-48} .

[0054] Thus, the person skilled in the art will have to ensure that indeed an oral dosage form is used which is able to allow for incorporation of sufficient amounts of buprenorphine and preferably also of naloxone and which at the same time disintegrates rapidly enough to release the active agents instantly.

[0055] In one embodiment one may use non-gelatin film materials, e.g. films of modified cellulose materials as dosage forms. In this case, buprenorphine and optionally opioid antagonists such as naloxone are incorporated into the film matrix and films thus prepared may be administered orally.

[0056] In accordance with this aspect of the invention, the active ingredients may be dissolved in a hydrophilic, organic system to form a homogenous solution or dispersion. The solution or dispersion can then be applied to one or more surfaces of a non-gelatin polymeric film, e.g. a dry cellulose ether film, resulting in the active ingredient(s) and/or liquid carrier phase being transported through the surface of the "dry" film resulting in a new film composition.

[0057] The film substrate may remain completely intact or relatively physically unchanged immediately following the incorporation process. It can, however, be converted to any size or shape of unit dosage form. Alternatively, the film substrate may liquefy or dissolve partly or fully during the incorporation process, but nevertheless finally forming a single discrete film, after curing. Films according to this aspect of the invention are typically made up of one or more soluble polymer or polymers which will otherwise degrade at the intended site of release after administration in the mouth, e.g. sublingual administration, in order to provide the instant release of the active agents. Suitable cellulose ether film bases include e.g. hydroxypropylmethylcellulose (HPMC), hydroxypropylcellulose (HPC), hydroxyethylmethylcellulose (HEMC), hydroxyethylcellulose (HEC), methylcellulose (MC), carboxymethylcellulose (CMC) and salts and

[0058] Optional ingredients may be added including colorants, emulsifiers, humectants, and anti-blocking agents.

[0059] Once one has a film being based on a cellulose ether available, in a next step the active ingredient(s) will be applied in the form of a liquid to the film. Appropriate means of liquid application onto the film substrate include extrusion, roller application, pouring, spraying, brush painting or whipping. Further details of the preparation of such films can be taken e.g. from WO 2005/079750 A2 which is incorporated by reference herewith.

[0060] Another possible technology in order to provide the afore-described pharmaceutical dosage forms of buprenorphine and preferably naloxone is described in WO 03/030883. In this latter embodiment of the present invention, a thin film drug delivery composition includes (i) a flowable water-soluble film-forming matrix and (ii) the active agent(s) uniformly stationed therein. Optionally a taste-masking agent may be coated or intimately associate with the active agent(s) to provide taste masking of the active agent(s). The flowable water-soluble film-forming matrix together with the active agent(s) is formable into a dry film of less than about 380 microns in thickness, for example less than about 250 microns in thickness.

[0061] The matrix may be a cellulosic material, a gum, a protein, a starch, a glucan and combinations thereof. For example one may use the already aforementioned methylcellulose, HMC, HEC, HC, HPC, HPMC, HMPC, gum Arabic, xanthan gum etc. The films are prepared according to standard technology and the active agents are displaced thereon and therein as described in WO 03/030883.

[0062] Yet another interesting technology relates to immediate release drug delivery forms as described in WO 99/17744, which is also incorporated by reference herein as far as it describes fast releasing oral dosage forms. The person skilled in the art will understand that the processes and dosage forms in WO 99/17744 may be used to obtain the aforementioned described pharmaceutical dosage forms of buprenorphine and preferably also naloxone.

[0063] One may of course also use fast disintegrating tablets that disintegrate upon contacting the saliva, e.g. under the tongue, following oral administration. Such fast-disintegrating tablets are described e.g. in WO 99/44580 and are well known to the person skilled in the art.

[0064] A particularly interesting technology for fast-releasing dosage forms that may be used for the purpose of the present invention to provide an oral dosage form of buprenorphine and preferably an opioid antagonist such as naloxone can be taken from WO 96/26720.

[0065] Therein it is described how the active agent selegiline is formulated into a rapidly releasing dosage form that can be used e.g. for sublingual administration. WO 96/26720 describes in detail a "fast-dispersing dosage form" with the term encompassing all types of dosage forms being described in U.S. Pat. No. 5,120,549, U.S. Pat. No. 5,079,018, WO 93/12769, U.S. Pat. No. 5,298,261 and WO 91/04757.

[0066] As for WO 96/26720 in the case of the active agent selegiline, the present invention contemplates particularly using fast-dispersing dosage forms as described in UK patent number 1548022, that is, a solid fast-dispersing dosage form comprising a network of the active ingredient(s) and a water-

soluble dispersing agent, the active ingredient(s) being in a liming solvent from a composition in the solid state, that composition comprising the active ingredient and a solution of the carrier in a solvent.

[0067] It is preferred that such a composition in accordance with the invention disintegrates within one to ten seconds, and particularly within two to eight seconds of being placed in the oral cavity and particularly sublingually.

[0068] The composition will preferably contain in addition to the active ingredient, matrix forming agents and secondary components.

[0069] Matrix forming agents suitable for use in this aspect of the present invention include materials derived from animal or vegetable proteins, such as gelatins, dextrans and soy, wheat and psyllium seed proteins, gums such as acacia, guar, agar, and xanthan, polysaccharides, alginates, carboxymethylcelluloses, carrageenans, dextrans, pectins, synthetic polymers such as polyvinylpyrrolidone, and polypeptide/protein or polysaccharide complexes such as gelatin-acacia complexes.

[0070] Other matrix forming agents suitable for use in the present invention include sugars such as mannitol, dextrose, lactose, galactose and trehalose; cyclic sugars such as cyclodextrin; inorganic salts such as sodium phosphate, sodium chloride and aluminium silicates; and amino acids having from 2 to 12 carbon atoms such as a glycine, L-alanine, L-aspartic acid, L-glutamic acid, L-hydroxyproline, L-isoleucine, L-leucine and L-phenylalanine.

[0071] One or more matrix forming agents may be incorporated into the solution or suspension prior to solidification. The matrix forming agent may be present in addition to a surfactant or to the exclusion of a surfactant. In addition to forming the matrix, the matrix forming agent may aid in maintaining the dispersion of any active ingredient within the solution or suspension.

[0072] Secondary components such as preservatives, anti-oxidants, surfactants, viscosity enhancers, colouring agents, flavouring agents, pH modifiers, sweeteners or taste-masking agents may also be incorporated into the composition. Suitable colouring agents include red, black and yellow iron oxides. Suitable flavouring agents include mint, raspberry, liquorice, orange, lemon, grapefruit, caramel, vanilla, cherry and grape flavours and combinations of these. Suitable pH modifiers include citric acid, tartaric acid, phosphoric acid, hydrochloric acid and maleic acid. Suitable sweeteners include aspartame and thaumatin. Suitable taste-masking agents include sodium bicarbonate, ion-exchange resins, cyclodextrin inclusion compounds, adsorbates or microencapsulated actives.

[0073] Such fast-dispersing dosage forms containing buprenorphine and preferably an opioid antagonist such as naloxone may be similarly obtained as described in GB 1548022B or WO 96/26720, in particular Example 1 of the latter, which are incorporated herein in their entirety.

[0074] A particularly preferred embodiment of the present invention relates to dosage forms, which are produced along the lines described in WO 03/070227 A1.

[0075] This prior art reference describes taste-masked, film-type or wafer-type medicinal preparations. It is to be understood that the dosage forms in accordance with the present invention may preferably be such film-type or wafer-type medicinal preparations with the taste-masking being only an optional feature.

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