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(54) **TRANSDERMAL ESTROGEN DEVICE AND DELIVERY**

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(58) **Field of Classification Search**

None

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,390,520	A		6/1983	Nagai et al.
4,559,222	A		12/1985	Enscore et al.
4,584,355	A		4/1986	Blizzard et al.
4,585,836	A		4/1986	Homan et al.
4,591,622	A		5/1986	Blizzard et al.
4,624,665	A	*	11/1986	Nuwayser 604/307
4,655,767	A		4/1987	Woodard et al.
4,746,515	A		5/1988	Cheng et al.
4,769,028	A		9/1988	Hoffmann et al.
4,814,168	A		3/1989	Sablotsky et al.
4,911,707	A		3/1990	Heiber et al.
4,915,950	A		4/1990	Miranda et al.
4,938,759	A		7/1990	Enscore et al.
4,983,395	A		1/1991	Chang et al.
4,994,267	A		2/1991	Sablotsky
5,271,940	A		12/1993	Cleary et al.
5,300,291	A		4/1994	Sablotsky et al.
5,350,581	A		9/1994	Kochinke
5,446,070	A		8/1995	Mantelle
5,474,783	A		12/1995	Miranda et al.
5,474,787	A		12/1995	Grey et al.
5,505,956	A		4/1996	Kim et al.
5,567,488	A		10/1996	Allen et al.
RE35,474	E		3/1997	Woodard et al.
5,656,286	A		8/1997	Miranda et al.
5,665,377	A		9/1997	Gonella
5,730,999	A		3/1998	Lehmann et al.
5,762,952	A		6/1998	Barnhart et al.
5,837,280	A		11/1998	Kenealy et al.
5,902,603	A		5/1999	Chen et al.
5,904,931	A		5/1999	Lipp et al.
5,906,830	A		5/1999	Farinas et al.
5,928,666	A		7/1999	Farinas et al.
5,958,446	A		9/1999	Miranda et al.
6,024,976	A		2/2000	Miranda et al.
6,156,335	A		12/2000	Rovati et al.
6,221,383	B1		4/2001	Miranda et al.
6,235,306	B1		5/2001	Miranda et al.
6,337,086	B1		1/2002	Kanios et al.
6,562,363	B1		5/2003	Mantelle et al.
6,638,528	B1	*	10/2003	Kanios 424/449
6,808,739	B2		10/2004	Sitz et al.
7,456,159	B2		11/2008	Houze et al.
8,231,906	B2		7/2012	Mantelle
8,343,538	B2		1/2013	Kanios et al.
2002/0100185	A1		8/2002	Sitz et al.
2003/0099695	A1		5/2003	Mueller
2003/0228354	A1		12/2003	Muraoka et al.
2005/0129749	A1		6/2005	Strauss
2005/0169977	A1		8/2005	Kanios et al.

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0 887 075 A2	12/1998

OTHER PUBLICATIONS

Vaughan, "Using Solubility Parameters in Cosmetics Formulation," *J. Soc. Cosmet. Chem.*, vol. 36, pp. 319-333 (1985).

Sobieski et al., "Silicone Pressure Sensitive Adhesives," *Handbook of Pressure-Sensitive Adhesive Technology*. 2nd ed., pp. 508-517 (D. Satas, ed.), Van Nostrand Reinhold, New York (1989).

"Acrylic Adhesives," *Handbook of Pressure-Sensitive Adhesive Technology*, 2nd ed., pp. 396-456 (D. Satas, ed.), Van Nostrand Reinhold, N.Y. (1989).

International Preliminary Report on Patentability and Written Opinion issued Apr. 19, 2007.

International Search Report issued on Apr. 6, 2005 in application No. PCT/US2004/029789.

International Search Report issued on Feb. 24, 2011 in application No. PCT/US2009/050069.

(Continued)

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(57) **ABSTRACT**

Described are transdermal drug delivery systems for the transdermal administration of estrogen, comprising a polymer matrix and estrogen. Methods of making and using such systems also are described.

(56) **References Cited**

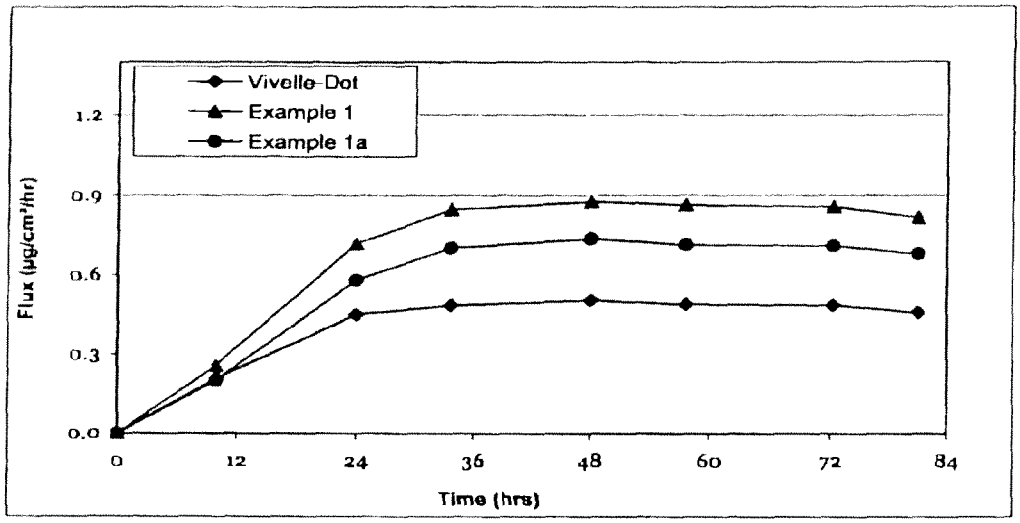
U.S. PATENT DOCUMENTS

2005/0202073	A1	9/2005	Jackson et al.	
2006/0233870	A1	10/2006	Houze et al.	
2006/0240087	A1	10/2006	Houze et al.	
2009/0041831	A1*	2/2009	Miller et al.	424/448
2013/0156815	A1	6/2013	Mantelle	

OTHER PUBLICATIONS

"Acrylic and Methacrylic Ester Polymers," *Polymer Science and Engineering*, vol. 1, 2nd ed., pp. 234-269, John Wiley & Sons (1984).
Office Action issued on Sep. 9, 2010 by the Examiner in U.S. Appl. No. 12/216,811 (U.S. 8,231,906).
Office Action issued on Jan. 20, 2011 by the Examiner in U.S. Appl. No. 12/216,811 (U.S. 8,231,906).
Office Action issued on Jun. 30, 2011 by the Examiner in U.S. Appl. No. 12/216,811 (U.S. 8,231,906).
Office Action issued on Sep. 13, 2011 by the Examiner in U.S. Appl. No. 12/216,811 (U.S. 8,231,906).
Office Action issued on Nov. 8, 2011 by the Examiner in U.S. Appl. No. 12/216,811 (U.S. 8,231,906).
Office Action issued on May 29, 2012 by the Examiner in U.S. Appl. No. 12/216,811 (U.S. 8,231,906).
Notice of Allowance issued on Jun. 19, 2012 by the Examiner in U.S. Appl. No. 12/216,811 (US 8,231,906).
Office Action issued on Dec. 29, 2010 by the Examiner in U.S. Appl. No. 11/245,084 (US 8,343,538).
Office Action issued on Apr. 14, 2010 by the Examiner in U.S. Appl. No. 11/245,084 (U.S. 8,343,538).
Office Action issued on Jun. 10, 2009 by the Examiner in U.S. Appl. No. 11/245,084 (U.S. 8,343,538).
Office Action issued on Oct. 26, 2011 by the Examiner in U.S. Appl. No. 11/245,084 (U.S. 8,343,538).
Office Action issued on May 13, 2011 by the Examiner in U.S. Appl. No. 11/245,084 (U.S. 8,343,538).
Office Action issued on Jun. 13, 2012 by the Examiner in U.S. Appl. No. 11/245,084 (U.S. 8,343,538).
Notice of Allowance issued on Aug. 22, 2012 by the Examiner in U.S. Appl. No. 11/245,084 (US 8,343,538).
Office Action issued on Apr. 12, 2013 by the Examiner in U.S. Appl. No. 13/553,972 (US 2013/0156815).
Office Action issued on Sep. 4, 2013 by the Examiner in U.S. Appl. No. 13/553,972 (US 2013/0156815).
Office Action issued on Mar. 5, 2014 by the Examiner in U.S. Appl. No. 13/553,972 (US 2013/0156815).
Nagai et al., "New Drug Delivery Systems," Kurashiki Printing Co. Ltd., Academic Document 2009-00984-005, published Jan. 31, 2000.
Sekine et al., "New Cosmetic Handbook," Nikko Chemical Co. Ltd., et al., Academic Documents 2008-02180-001, published Oct. 30, 2006.
Novartis Pharmaceuticals Corporation, "Vivelle-Dot® (estradiol transdermal system)," prescription labeling, Aug. 2004.
Benson, "Transdermal Drug Delivery: Penetration Enhancement Techniques," Current Drug Delivery, vol. 2, pp. 23-33, 2005.
Office Action issued on May 5, 2015 in U.S. Appl. No. 13/553,972 (US 2013/0156815).
Feldmann et al., "Percutaneous Penetration of Steroids in Man," The Journal of Investigative Dermatology, vol. 52, No. 1, pp. 89-94, 1969.
Schaefer et al., "Contraception via Topical Application? A Review," Contraception, vol. 20, No. 3, pp. 225-236, Sep. 1979.
Rietschel et al., "Effects of harvesting techniques on hydration dynamics: gravimetric studies of stratum corneum," J. Soc. Cosmet. Chem., vol. 29, pp. 777-782, Dec. 1978.
Feldstein et al., "Modeling of percutaneous drug transport in vitro using skin-imitating Carbosil membrane," Journal of Controlled Release, vol. 52, pp. 25-40, 1998.
Pfister, "Transdermal and Dermal Therapeutic Systems: Current Status," Transdermal and Topical Drug Delivery Systems, Ghosh et al., eds., Chapter 2, pp. 33-112, 1997.
Dow Corning, :"Dow Corning® BIO-PSA Standard Silicone Adhesives," Product Information, Jul. 28, 2008.
Janisch et al., Email correspondence, Mar. 10, 2016.
Manngold, Apr. 28, 2004 letter to Angela Nwaneri re: Duro-Tak® 87-4287 and 87-2287.
Noven Pharmaceuticals, Inc., Response filed in European application No. 09790211.8 on Dec. 19, 2014.
Mantelle, "DOT Matrix® Technology," Modified-Release Drug Delivery Technology, Rathbone et al., eds., Chapter 30, pp. 405-415, May 28, 2008.
Office Action dated on May 5, 2016 in U.S. Appl. No. 13/553,972 (U.S. 2013-0156815).
Notice of Allowance dated on Oct. 2, 2015 in U.S. Appl. No. 13/553,972 (U.S. 2013-0156815).
Office Action dated on Apr. 29, 2016 in U.S. Appl. No. 14/738,255 (U.S. 2015-0272905).
Office Action dated on Oct. 26, 2015 in U.S. Appl. No. 14/738,255 (U.S. 2015-0272905).
Toole et al., "Evaluation of irritation and sensitisation of two 50 µg/day oestrogen patches," Maturitas, vol. 43, pp. 257-263, Dec. 2002.
Marty, "New trends in transdermal technologies: Development of the skin patch, Menorest®," International Journal of Gynecology & Obstetrics, vol. 52, Suppl. 1, pp. S17-S20, Mar. 1996.
Novartis, "Estraderm®," Prescribing information, Jun. 2004.
Novartis, "Vivelle®," Prescribing information, Jun. 2004.
Novartis, "Vivelle-Dot®," Prescribing information, Jun. 2004.
Bayer Healthcare, "Climara®," Prescribing information, 2007.
3M Pharmaceuticals, "Menostar™," Prescribing information, Jun. 2004.
Watson Pharma, Inc., "Alora®," Prescribing information, May 2005.
Serono Laboratories, Inc., "Esclim®," Prescribing information, Aug. 1998.
Office Action dated on Sep. 7, 2016 in U.S. Appl. No. 14/870,574 (U.S. 2016-0015655).
Notice of Allowance dated on Dec. 9, 2016 in U.S. Appl. No. 13/553,972 (U.S. 2013-0156815).
Notice of Allowance dated on Mar. 23, 2017 in U.S. Appl. No. 13/553,972 (U.S. 2013-0156815).
European Office Action dated on Feb. 14, 2017 in application No. EP 09790211.8.
Mantelle et al., "Effect of Silicone/Acrylic PSA Blends on Skin Permation," Procced. Int'l Symp. Control. Rel. Bioact. Mater., Jun. 20-23, 1999.
Notice of Allowance dated on Mar. 23, 2017 in U.S. Appl. No. 13/553,972 (U.S. 2013/0156815).
Office Action dated on Jun. 15, 2017 in U.S. Appl. No. 14/870,574 (U.S. 2016/0015655).

* cited by examiner



TRANSDERMAL ESTROGEN DEVICE AND DELIVERY

This application is a continuation of U.S. patent application Ser. No. 13/553,972, filed Jul. 20, 2012, which is a continuation of U.S. patent application Ser. No. 12/216,811, filed Jul. 10, 2008 (now U.S. Pat. No. 8,231,906), which are incorporated herein by reference in their entirety.

FIELD OF THE INVENTION

Described herein are compositions and methods for the transdermal delivery of estrogen.

BACKGROUND

This invention relates generally to transdermal drug delivery systems, and more particularly, to transdermal drug delivery systems for the delivery of estrogen. The use of a transdermal system, for example, a patch comprising a pressure-sensitive adhesive containing a drug, as a means of delivering drug through the skin is well known. However, there remains a need for transdermal drug delivery systems designed for the delivery of specific drugs, such as estrogen, and there remains a particular need for smaller transdermal drug delivery systems that exhibit desired pharmacokinetic properties.

Transdermal delivery systems (adhesive patches) as dosage forms have been the subject of a vast number of patent applications over the last 25 years, yielding many patents but few commercial products in comparison. To those working in the field, the relatively small number of commercial products is not surprising. Although regulatory, economic, and market hurdles play a role in limiting the number of products on the market, the task of developing a transdermal delivery system that achieves desired physical and pharmacokinetic parameters to satisfy physician and patient demand is more daunting. Parameters to be considered during commercial product development may include drug solubility, drug stability (e.g., as may arise from interaction with other component materials and/or the environment), delivery of a therapeutic amount of drug at a desired delivery rate over the intended duration of use, adequate adhesion at the anatomical site of application, integrity (e.g., minimal curling, wrinkling, delaminating and slippage) with minimal discomfort, irritation and sensitization both during use and during and after removal, and minimal residual adhesive (or other components) after removal. Size also may be important from a manufacturing and patient viewpoint, and appearance may be important from a patient viewpoint. The physical manufacturing and production aspects of commercial product development (e.g., the identity and costs of materials, equipment, and labor) and supporting analytical methods required for regulatory compliance also can be significant.

Of the physical parameters that are considered when developing a commercial transdermal drug delivery system, size, e.g., surface area at the site of application, is often dictated and limited by other physical and pharmacokinetic requirements, such as desired drug delivery rates and daily dosages. In general, it is easier to develop a relatively "large" transdermal drug delivery system that will achieve drug delivery at target therapeutic levels over an intended duration of therapy, than it is to develop a smaller transdermal drug delivery system that still exhibits acceptable pharmacokinetic properties. Still, because size directly impacts

ment, labor costs relative to product yield per run time, etc.) and patients generally prefer smaller systems to larger ones (both for aesthetic reasons and comfort, since a smaller surface may permit the use of less aggressive adhesives), there is a need for smaller transdermal drug delivery systems.

SUMMARY

In accordance with one embodiment, there is provided a transdermal drug delivery system comprising a drug containing layer defusing an active surface area and comprising a polymer matrix comprising estradiol, wherein the system includes greater than 0.156 mg/cm^2 estradiol and achieves an estradiol flux that is greater than 0.01 mg/cm^2/day, based on the active surface area. In some embodiments, the polymer matrix comprises a polymer blend comprising an acrylic adhesive, a silicone adhesive, and soluble PVP. In some embodiments, the polymer matrix comprises about 2-25% by weight acrylic adhesive, about 45-70% by weight silicone adhesive, about 2-25% by weight soluble PVP, about 5-15% penetration enhancer, and about 0.1-10% by weight estradiol, all based on the total dry weight of the polymer matrix. In some embodiments, the polymer matrix comprises about 20% by weight acrylic adhesive, about 56.9% by weight silicone adhesive, about 7.5% by weight soluble PVP, about 6.0% by weight oleyl alcohol, about 8.0% by weight dipropylene glycol, and about 1.6% by weight estradiol. In some embodiments, the acrylic adhesive and silicone adhesive are present in a ratio of from about 1:2 to about 1:6, based on the total weight of the acrylic and silicone adhesives.

In some embodiments, the penetration enhancer comprises oleyl alcohol or dipropylene glycol, or both.

In some embodiments, the polymer matrix comprises an amount of estradiol effective to deliver a therapeutically effective amount of estradiol over a period of time selected from the group consisting of at least 1 day, at least 2 days, at least 3 days, at least 4 days, at least 5 days, at least 6 days and at least 7 days. In some embodiments, the polymer matrix comprises an amount of estradiol effective to deliver an amount of estradiol selected from the group consisting of about 0.025, 0.0375, 0.05, 0.075 and 0.1 mg/day.

In some embodiments, the polymer matrix has a coat weight of greater than about 10 mg/cm^2. In some embodiments, the polymer matrix has a coat weight selected from the group consisting of about 12.5 and about 15 mg/cm^2.

In accordance with some embodiments, there is provided a transdermal drug delivery system comprising a polymer matrix comprising estradiol, wherein the system has an active surface area that is about 60% of a size selected from the group consisting of 2.5, 3.75, 5.0, 7.5 and 10.0 cm^2 and is effective to deliver an amount of estradiol per day of about 0.025, 0.0375, 0.05, 0.075 and 0.1 mg/day, respectively.

In accordance with some embodiments, there is provided a method for administering estradiol, comprising applying to the skin or mucosa of a subject in need thereof a transdermal drug delivery system comprising a drug-containing layer defining an active surface area and comprising a polymer matrix comprising estradiol, wherein the system includes greater than 0.156 mg/cm^2 estradiol and achieves an estradiol flux that is greater than 0.01 mg/cm^2/day, based on the active surface area. In some embodiments, the system has an active surface area that is about 60% of a size selected from the group consisting of 2.5, 3.75, 5.0, 7.5 and 10.0 cm^2 and

In accordance with some embodiments, there is provided a method of making a transdermal drug delivery system for administering estrogen, comprising forming a polymer matrix comprising estrogen and a polymer blend comprising an acrylic adhesive, a silicone adhesive, and soluble PVP, and applying the polymer matrix to a support layer such that the system includes greater than 0.156 mg/cm^2 estradiol. In some embodiments, the system has an active surface area that is about 60% of a size selected from the group consisting of 2.5, 3.75, 5.0, 7.5 and 10.0 cm^2. In some embodiments, the polymer matrix comprises about 20% by weight acrylic adhesive, about 56.9% by weight silicone adhesive, about 7.5% by weight soluble PVP, about 6.0% by weight oleyl alcohol, about 8.0% by weight dipropylene glycol, and about 1.6% by weight estradiol. In some embodiments, the polymer matrix is applied to the support layer at a coat weight of greater than about 10 mg/cm^2. In some embodiments, the polymer matrix coat weight is selected from the group consisting of about 12.5 and about 15 mg/cm^2.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates the estradiol flux (μg/cm^2/hr) over time (0-81 hours) from transdermal delivery systems according to the invention (▲ & ●), as compared to Vivelle-Dot® (♦).

DETAILED DESCRIPTION

The field of transdermal delivery systems suffers from the problem of needing to balance many different competing factors to develop a commercial product that exhibits, for example both clinical efficacy and satisfactory wear properties while remaining acceptable to patients. For example, when selecting the size of a transdermal delivery system, it is necessary to balance factors that favor a smaller size (such as lower cost, better adhesive performance and improved aesthetics) against factors that favor a larger size (such as the target delivery rate (flux) and daily dose). The Vivelle-Dot® transdermal estradiol product (manufactured by Noven Pharmaceutcials Inc.) is available in five different active surface areas (2.5, 3.75, 5.0, 7.5 and 10.0 cm^2) which each deliver different amounts of drug per day (0.025, 0.0375, 0.05, 0.075 and 0.1 mg/day, respectively). Each of the Vivelle-Dot® products include 0.156 mg/cm^2 estradiol.

In accordance with some embodiments, the present invention provides transdermal drug delivery systems for the transdermal delivery of estrogen that have a smaller active surface area than Vivelle-Dot® but achieve daily dosages that are about equal to or greater than the Vivelle-Dot® products. For example, the present invention includes transdermal drug delivery systems that achieve daily dosages that are about equal to a Vivelle-Dot® product, in a smaller sized system. The ability to provide a smaller system without sacrificing daily dosage represents a significant advance.

Applicant surprisingly discovered that increasing the coat weight of the drug-containing adhesive layer resulted in an increased flux per unit area, and thus permitted the development of smaller transdermal drug delivery systems that achieve comparable daily dosages. This result was surprising because coat weight is typically selected to control the duration of delivery, but is not generally understood to impact delivery rate. Thus, while it is known in the art to increase coat weight to provide delivery over a longer period of time, it was not known that increasing coat weight could

In accordance with some aspects, there are provided transdermal drug delivery systems and methods for the transdermal delivery of estrogen. In specific embodiments, the systems exhibit increased flux than other known estrogen devices (such as Vivelle-Dot®, manufactured by Noven Pharmaceutcials Inc.) and, therefore, exhibit increased drug delivery per unit area. For example, in some embodiments, the systems exhibit a flux greater than the 0.01 mg/cm^2/day exhibited by the Vivelle-Dot® products, such as a flux that is about 1.25, 1.33, 1.5, 1.67, 1.75, 2, 3, 4, or 5 times the flux of the Vivelle-Dot® products. In some embodiments, the systems have a greater coat weight than other known estrogen devices. For example, in some embodiments, the systems have a coat weight such that the amount of estradiol per unit area is greater than the 0.156 mg/cm^2 estradiol of the Vivelle-Dot® products, such as a coat weight that is about 1.25, 1.33, 1.5, 1.67, 1.75, 2, or 3 times the coat weight of the Vivelle-Dot® products, or greater. Thus, in accordance with some aspects, the invention permits the use of smaller devices to achieve comparable drug delivery.

DEFINITIONS

Technical and scientific terms used herein have the meanings commonly understood by one of ordinary skill in the art to which the present invention pertains, unless otherwise defined. Reference is made herein to various methodologies known to those of ordinary skill in the art. Publications and other materials setting forth such known methodologies to which reference is made are incorporated herein by reference in their entireties as though set forth in full. Any suitable materials and/or methods known to those of ordinary skill in the art can be utilized in carrying out the present invention. However, specific materials and methods are described. Materials, reagents and the like to which reference is made in the following description and examples are obtainable from commercial sources, unless otherwise noted.

As used herein, the singular forms "a," "an," and "the" designate both the singular and the plural, unless expressly stated to designate the singular only.

The term "about" and the use of ranges in general, whether or not qualified by the term about, means that the number comprehended is not limited to the exact number set forth herein, and is intended to refer to ranges substantially within the quoted range while not departing from the scope of the invention. As used herein, "about" will be understood by persons of ordinary skill in the art and will vary to some extent on the context in which it is used. If there are uses of the term which are not clear to persons of ordinary skill in the art given the context in which it is used, "about" will mean up to plus or minus 10% of the particular term.

The phrase "substantially free" as used herein generally means that the described composition (e.g., transdermal drug delivery system, polymer matrix, etc.) comprises less than about 5%, less than about 3%, or less than about 1% by weight, based on the total weight of the composition at issue, of the excluded component.

As used herein "subject" denotes any animal in need of drug therapy, including humans. For example, a subject may be suffering from or at risk of developing a condition that can be treated or prevented with estrogen, or may be taking estrogen for health maintenance purposes.

As used herein, the phrases "therapeutically effective amount" and "therapeutic level" mean that drug dosage or

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