

Identification for adhesive sheet-like dermal and transdermal therapeutic administration forms using an adhesive plaster as information carrier, and process for its production.

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Adhesive sheet-like systems are known for the therapy of a large number of disorders and have been outstandingly successful in many therapeutic application areas.

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Systems of this type have long been known as superficially acting systems for application to the skin with a surface (topical) action as antirheumatic plasters or as plasters for treating precancerous states with the active ingredient 5-fluorouracil. Transdermal therapeutic systems (TTS) with a systemic action are also achieving increasing importance. Their advantage comprises, for example, controlled, relatively long-term delivery of active ingredients through the skin. A transdermal system of this type has an impermeable and nonadhesive backing layer to prevent unwanted emergence of active ingredients to the outside, and a pressure-sensitive adhesive layer, for the required adhesion to the skin, which may simultaneously contain active ingredient, and a detachable protective layer, which normally has an adhesive finish, to prevent loss of active ingredient during storage of a TTS.

As the result of medical and pharmacological research and, in particular, to improve the possibilities of medicinal treatment of patients, novel active ingredient combinations and administration forms are continually being developed and proposed for medical application. According to a study at the University of Ottawa and, in particular, the Heart Institute there, documented in Mussivand et al., ASAIO Journal 1995; 41:

M253-M258, it is reported that 25,000 novel medical articles are launched on the market each year.

Hence modern medicine confronts both the physician
5 and the patients with an immense number of medicines, of
which it is still possible to acquire without prescription
a comparatively large proportion (for example
antirheumatic plasters, nicotine plasters for stopping
smoking etc.). Many patients are dependent on long-term
10 medication, for example for lowering high blood pressure
etc. They are thus often exposed to the reaction of one or
more medicinal substances. One disadvantage of the use and
of the often inadvertent misuse of numerous medicines
consists of the possible interactions with other medicinal
15 substances or particular consumables (for example alcohol)
and an increase in side effects with the risk of harmful
levels of active ingredient in a patient's body. In some
cases, a critical problem may arise from this if a patient
declines into a helpless, for example comatose unconscious
20 state, for example because of excessive alcohol
consumption, drug use or such an acute interaction, and
there is no information available to the attending
emergency physician about all the medicinal substances or
active ingredients taken by the patient. Such information
25 about the nature of the harmful pharmaceuticals acting
inside the patient can in such a case be obtained only by
blood analysis, which is time-consuming and requires
elaborate apparatus, which would in an acute case be
available much too late, if at all. As a consequence, in
30 such a case, the physician has no possibility of correctly
assessing, and for example determining with antidotes, the
effect of a harmful active ingredient, or supplementing
the intake of a medicinal substance which is vital for the
patient in a controlled manner. The physician is equally
35 unable to decide in such cases whether the maintenance and
possible renewal of the medication is also indicated in
such cases. It is obvious to expect there to be a need for

precise identification of active ingredient plasters in respect of constitution and ingredients so that, for the purposes of disposal, they can be graded into pure grades, disposed of correspondingly appropriately or passed on for recovery of active ingredients.

In view of the increasingly large number of different systems already on the market now - there are more than 40 different basic types of active ingredient patterns - it is a particularly important necessity to be able to identify comprehensively each one, especially when the information from pack insert and other accompanying information is unavailable.

DE 195 19 593 C1 discloses a transdermal therapeutic system with a backing layer of thermoplastic material consisting of a laminate of a low-melting thermoplastic located on the outside and of a higher-melting thermoplastic facing the skin, of a permanent identifying coding applied to this backing layer and consisting of locally varying surface characteristics, surface thickness or surface roughness of this backing layer, and of an active part containing the active ingredient. In this case, the invention consists of producing this coding of the backing layer by the action of pressure, heat, ultrasound or abrasion.

Limits of utilizability of the application of the known identifying coding emerge from the fact that the action of pressure or heat may be harmful for many active ingredient-containing plasters. In addition, there are comparatively narrow limits on the capacity of a coding which can be produced by varying the surface characteristics of the backing layer of a plaster. In addition, production thereof requires an additional concluding operation, for example on the fabricating system.

The abovementioned article from the University of Ottawa Heart Institute discloses a transcutaneous energy and information system with which implants, defibrillators, circulatory stabilizers, biosensors etc. can be supplied with energy using a remote-controlled connection system and can be monitored with respect to the information generated by these implants. The range of applications of such devices and methods is, however, restricted to stationary facilities and is unsuitable, because of the great complexity both of the apparatus and of the overall technique, for identifying transdermal therapeutic systems.

The invention is based on the object, starting from the abovementioned state of the art, of indicating an identification for both transdermal therapeutic and non-transdermal administration forms using a plaster as information carrier, and processes for producing it, which provides information about properties, amount, risks and/or side effects without difficulty and with a comparatively large range of information.

The object is achieved by an identification in which the plaster is provided with an electronically identifiable coding.

Such a coding has the advantage that it can be performed or applied by known means and it has a comparatively large storage capacity for information and can be decoded with available electronic readers which are possessed by or can be carried by every physician, every pharmacy, every ambulance or every hospital ward.

One embodiment provides for the coding being designed in the form of electronically readable numbers or letters or in the form of a barcode on the side of the

plaster facing away from the skin. It is possible to store comparatively extensive information texts on a coding field which is, for example, of the size of a normal postage stamp. The coding is decoded without difficulty using an optical IR reading device.

It is, however, also possible advantageously to make sure that the coding on the side of the plaster facing away from the skin is designed in the form of a microchip like one applied, for example, to cards given to those insured by health insurance offices. The latter have, for example, dimensions corresponding to about half the area of a postage stamp, can be produced at low cost and can be applied to a plaster.

However, the coding can also be designed on the side of the plaster facing away from the skin in the form of a magnetic strip, similar to the magnetic strip provided on a bank card. Finally, the coding may be present on the adhesive-free side of an adhesive film which can be stuck onto the plaster before or after its application to a patient's skin.

The identification according to the invention provides for the coding to comprise information about the nature and amount of the active ingredient present in the plaster and, appropriately, all the other materials. The coding provided for identifying the administration forms can, however, also advantageously contain further information about, for example, side effects of the therapeutic active ingredient, incompatibilities with other active ingredients and other noteworthy peculiarities. Finally, it is also possible to apply information required for disposal - grading, processing, landfilling or thermal treatment. The identification can very advantageously be supplemented, for example, by the coding containing instructions for administration of

antidote in the case of evident occurrence of hazardous symptoms, such as overdosage of the active ingredient or acute side effects. A particular advantage of the identification is that personal data about the wearer of the dermal or transdermal system can be stored in coded form. It is possible specifically for patients at risk with an extensive medical history to include data about existing allergies, intolerance of medicines, etc. as patient-specific information content in the coding.

The general structure of basic TTS types is described, for example, by Y.W. Chien, "Developmental Concepts and Practice in Transdermal Therapeutic Systems" in Transdermal Controlled Systemic Medications, ed. by Y.W. Chien, Marcel Dekker, New York (1987), p. 25-81. The coding can be present in an active ingredient-containing or active ingredient-free layer of the TTS.

A preferred embodiment contains the coding in a separate layer located on the backing layer of a TTS consisting of backing layer and active ingredient-containing self-adhesive matrix layer.

Another preferred embodiment contains the coding in the backing layer of a TTS consisting of backing layer and active ingredient-containing self-adhesive matrix layer.

Another preferred embodiment contains the coding in a separate layer which is located between the backing layer and the active ingredient-containing self-adhesive matrix layer of a TTS.

Another preferred embodiment contains the coding in a separate layer located on the backing layer of a TTS consisting of backing layer, active ingredient-containing

reservoir, membrane controlling the rate of release of the active ingredient, and a self-adhesive layer.

Another preferred embodiment contains the coding
5 in the backing layer of a TTS consisting of backing layer, active ingredient-containing reservoir, membrane controlling the rate of release of the active ingredient, and a self-adhesive layer.

10 Another preferred embodiment contains the coding in a separate layer located underneath the backing layer of a TTS consisting of backing layer, active ingredient-containing reservoir, membrane controlling the rate of release of the active ingredient and a self-adhesive
15 layer.

A process for producing an identification of the generic type according to the precharacterizing clause of Claim 1 is characterized in that the coding is
20 incorporated into or applied to the plaster during preparation thereof. It is possible and advantageous to apply the coding to the plaster, for example, in a printing process such as screen printing or tampon printing or the like. The coding can also be applied to
25 the plaster using a self-adhesive carrier provided with the coding.

Finally, an advantageous process for producing an identification of the plaster provides for storing the
30 coding in a separate layer of a multilayer plaster or in the active ingredient-containing layer or in the outer covering layer.

The identification for both transdermal
35 therapeutic and non-transdermal administration forms using a plaster as information carrier eliminates in a very advantageous manner risk factors which are not always

recognizable sufficiently rapidly, for example from active ingredient combinations which react together to give harmful side effects, or associated with a first-pass effect as a consequence of a damaged TTS or an overdosage,
5 furthermore from allergic reactions or the consequences of the use of an active ingredient after its expiry date. The identification according to the invention makes it possible in such cases for the physician to remedy serious complications with specific remedial procedures,
10 especially in cases of life-threatening conditions.

To this extent the invention achieves the object stated at the outset in an optimal manner.



PATENT CLAIMS

1. Identification for sheet-like adhesive systems - dermal and transdermal therapeutic administration forms - using a plaster as information carrier, characterized in
5 that the plaster is provided with an electronically identifiable coding.
2. Identification according to Claim 1, characterized
10 in that the coding is designed in the form of a barcode on the side of the plaster facing away from the skin.
3. Identification according to Claim 1, characterized
15 in that the coding is designed in the form of a microchip on the side of the plaster facing away from the skin.
4. Identification according to Claim 1, characterized
20 in that the coding is designed in the form of a magnetic strip on the side of the plaster facing away from the skin.
5. Identification according to Claim 1, characterized
25 in that the coding is present on the adhesive-free side of an adhesive film which can be stuck onto the plaster before or after its application to a patient's skin.
6. Identification according to one or more of Claims
30 1 - 5, characterized in that the coding contains information about the nature and amount of the active ingredient present in the plaster.
7. Identification according to one or more of Claims
35 1 - 6, characterized in that the coding contains further information about, for example, side effects of the transdermal active ingredient, incompatibilities with other active ingredients and other noteworthy peculiarities.

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8. Identification according to one or more of Claims 1 - 7, characterized in that the coding contains instructions for administration of antidote in the case of evident occurrence of hazardous symptoms.

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9. Identification according to one or more of Claims 1 - 5, characterized in that the coding contains information about the justifiability of maintaining the administration.

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10. Identification according to one or more of Claims 1 - 5, characterized in that the coding contains information about the constitution and composition in connection with disposal, especially data for grading, for recovering ingredients and for final destruction.

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11. Identification according to one or more of Claims 1 - 5, characterized in that the coding contains information with patient-specific data such as, for example, about existing allergies and intolerance of medicines.

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12. Process for the production of an identification for sheet-like adhesive systems, characterized in that the coding is applied to the plaster using a self-adhesive carrier provided with the coding.

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13. Process for the production of an identification for sheet-like adhesive systems, characterized in that the coding is introduced into a separate layer of a multilayer plaster or into the active ingredient-containing layer or into the outer covering layer.

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