

Such a concentrated application of an active pharmaceutical ingredient directly onto the mucous membrane can be achieved with dosage forms which contain the active pharmaceutical ingredient in a sheet like, in particular film shaped, foil shaped or wafer shaped preparation, in particular as a so-called wafer. Drawbacks of conventional wafers are, particularly, that known wafers dissolve partially or completely before the site of action and in particular for e.g. intestinal, rectal or vaginal wafers no contact with the mucous membrane can be guaranteed. Moreover, for e.g. intestinal, rectal and vaginal multilayered wafers no contact with the correct site of the wafer and in particular no sufficiently long contact with the mucous membrane can be guaranteed.

Summary

In one aspect, the present invention refers to a pharmaceutical dosage form for the application to a mucous membrane, comprising at least one sheet-like preparation comprising an active pharmaceutical ingredient, a release mechanism and a trigger mechanism, wherein the trigger mechanism is adapted to trigger, at a predetermined site of action of the gastrointestinal tract, of the rectum or of the vagina, the release of the sheet-like preparation by the release mechanism, wherein the pharmaceutical dosage form further comprises a shell, wherein the shell contains at least the sheet-like preparation comprising the active pharmaceutical ingredient, wherein the shell or the trigger mechanism comprises at least one aperture through which a fluid surrounding the shell can come into contact with an inner space of the shell, wherein the aperture is formed as a slit and/or the aperture is at least partially covered by the trigger mechanism, wherein the shell contains a gas-forming agent as the release mechanism and as an expansion mechanism, and the gas-forming agent is arranged in a part of the shell that is opposed to the part of the shell containing the preparation, or wherein the shell and a mechanical expansion system comprise at least a first joint or lever element and/or wherein the shell and the mechanical expansion system comprise at least one spring element, or wherein the shell (2) at least comprises a first tube element, and the shell at least comprises a further tube element, wherein the second tube element has a smaller tube diameter than the first tube element, and wherein the second tube element is arranged at least partially in the first tube element, and the shell further comprises a spring element, wherein the spring element is arranged such that the spring element can move the at least one second tube element longitudinally relative to the first tube element, or wherein the shell (2) comprises at least a joint or lever element, and wherein the shell and a mechanical expansion system comprise at least a further joint or lever element, wherein the first joint or lever element and/or the further joint or lever element is arranged at a free end of the shell, or wherein the trigger mechanism is a holding device that is a part of or is attached to the sheet-like preparation.

It is an object of the present invention to provide a pharmaceutical dosage form that overcomes the aforementioned drawbacks.

It is a further object of the present invention to provide a pharmaceutical dosage form that enhances the bioavailability of active pharmaceutical ingredients contained in dosage forms which are administered, in particular orally, vaginally or rectally.

It is yet a further object of the present invention to provide a pharmaceutical dosage form, in particular a dosage form containing the active pharmaceutical ingredient in a sheet like, in particular film shaped, foil shaped or wafer shaped, preparation, preferably a wafer, in which a release of the active pharmaceutical ingredient at its predetermined site of action is achieved and the amount of the active pharmaceutical ingredient available for resorption is increased, and/or an enhanced bioavailability and/or an enhanced rate of resorption is achieved.

In particular, it is an object of the present invention to provide a rapidly releasing dosage form with a systemic effect. Finally, it is yet a further object of the invention to provide a dosage form that makes it possible to apply active pharmaceutical ingredients, which cannot be administered orally due to poor bioavailability, at a predetermined site of action.

Especially, the present invention relates to a pharmaceutical dosage form for the application, preferably to an upper gastrointestinal tract such as throat, esophagus, cardia and/or stomach, and particularly to the respective mucous membranes, that

Claims:

1. A pharmaceutical dosage form for the application to a mucous membrane, comprising at least
- 5 one sheet-like preparation comprising an active pharmaceutical ingredient, a release mechanism and a trigger mechanism, wherein the trigger mechanism is adapted to trigger, at a predetermined site of action of the gastrointestinal tract, of the rectum or of the vagina, the release of the sheet-like
- 10 preparation by the release mechanism, wherein the pharmaceutical dosage form further comprises a shell, wherein the shell contains at least the sheet-like preparation comprising the active pharmaceutical ingredient, wherein the shell or the trigger mechanism comprises at least one aperture through which a fluid surrounding the shell can come into contact with an inner space of
- 15 the shell, wherein the aperture is formed as a slit and/or the aperture is at least partially covered by the trigger mechanism, wherein the shell contains a gas-forming agent as the release mechanism and as an expansion mechanism, and the gas-forming agent is arranged in a part of the shell that is opposed to the part of the shell containing the preparation,
- 20 or wherein the shell and a mechanical expansion system comprise at least a first joint or lever element and/or wherein the shell and the mechanical expansion system comprise at least one spring element,
- or
- 25 wherein the shell (2) at least comprises a first tube element, and the shell at least comprises a further tube element, wherein the second tube element has a smaller tube diameter than the first tube element, and wherein the second tube element is arranged at least partially in the first tube element, and the shell further comprises a spring element, wherein the spring element is arranged such that the spring element can move the at
- 30 least one second tube element longitudinally relative to the first tube element,
- or wherein the shell (2) comprises at least a joint or lever element, and wherein the shell and a mechanical expansion system comprise at least a further joint or lever element, wherein the first joint or lever element and/or the further joint or lever element is arranged
- 35 at a free end of the shell,

or

wherein the trigger mechanism is a holding device that is a part of or is attached to the sheet-like preparation.

5 2. The pharmaceutical dosage form for the application to a mucous membrane according to claim 1, wherein the mucous membrane is a buccal, nasopharyngeal, or a gastrointestinal mucous membrane.

10 3. The pharmaceutical dosage form according to claim 2, wherein the gastrointestinal mucous membrane is an esophageal mucous membrane.

4. The pharmaceutical dosage form for the application to a mucous membrane according to claim 1, wherein the mucous membrane is a rectal mucous membrane.

15 5. The pharmaceutical dosage form for the application to a mucous membrane according to claim 1, wherein the mucous membrane is a vaginal mucous membrane.

6. The pharmaceutical dosage form according to any one of the preceding claims, wherein
20 the trigger mechanism is adapted to trigger the release of the sheet-like preparation by the release mechanism after a contact of the pharmaceutical dosage form with a key stimulus and/or
the trigger mechanism is adapted to trigger the release of the sheet-like preparation by the release mechanism in a time controlled manner or immediately and/or
25 the release mechanism is adapted to release the sheet-like preparation in a time controlled manner or immediately after triggering of the trigger mechanism.

7. The pharmaceutical dosage form according to claim 1, wherein the release mechanism is an expansion mechanism, wherein the expansion mechanism is selected
30 from the group comprising mechanical expansion system, gas driven expansion system, compressed foam or compressed tissue, and wherein an expansion of the expansion mechanism results in an opening of the shell.

8. The pharmaceutical dosage form according to any one of the preceding claims, wherein the dosage form contains the preparation in a folded form and the expansion of the expansion mechanism results in an unfolding of the preparation.

5 9. The pharmaceutical dosage form according to any one of the preceding claims, wherein the preparation comprises a swelling agent wherein the swelling agent is selected from the group comprising sponge and fibers.

10 10. The pharmaceutical dosage form according to any one of the preceding claims, wherein the first joint or lever element and/or the further joint or lever element is at least partially covered by the trigger mechanism and/or wherein the at least one first joint or lever element or the at least one further joint or lever element is arranged such that a joint or lever element of one end is arranged adjacent to a respective joint or lever element of the other end.

15 11. The pharmaceutical dosage form according to any one of the preceding claims, wherein:

the sheet-like preparation provides, after its release by the release mechanism, a relatively large surface area, and comes into contact with a relatively large surface area;
20 and/or

the release mechanism is adapted to release, at least partially, the sheet-like preparation while moving along the mucous membrane.

25 12. The pharmaceutical dosage form according to any one of the claims 1 or 11, wherein:

the release mechanism comprises a string member;
the string member being expandable from a compact form, which is a folded, collapsed, rolled or coiled up form, to an expanded form, which is an unfolded, spread out, opened up, elongated, stretched, unrolled or oblong form, upon activation of the release
30 mechanism; and

the string member comprises, at least in the compact form, the sheet-like preparation, or wherein the release mechanism is an expansion mechanism and an elongation mechanism adapted to unfold, elongate, uncoil, unroll or unwind the sheet-like preparation by leveraging an external movement, force or pressure.

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13. The pharmaceutical dosage form according to any one of the claims 1 or 10 to 12, for the oral administration, wherein the trigger mechanism and the holding device are adapted to be fixed in an oral cavity and/or to be held in a hand during administration of the pharmaceutical dosage form.

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14. The pharmaceutical dosage form according to any one of the preceding claims for the oral administration, wherein, at least during the release of the sheet-like preparation, the released portion of the sheet-like preparation and the dosage form move relative to each other thereby defining a movement path (PM) of the dosage form, and the
10 enveloping cross-sectional area (AD) of the dosage form, viewed in the direction of the movement path is larger than the enveloping cross-sectional area (AP) of the released part of the sheet-like preparation.