CLAIMS

1. A ~~P~~package for administration of medicinal or nutritional substances, comprising:

an outer bag (1) with a ~~sterile or~~ sterilized inner chamber (2) ~~and, within said chamber (2)~~,

a bottle (5) of medicinal or nutritional substance (6) set in an overturned position and disposed within the inner chamber (2) of the outer bag (1), the bottle (5) comprising ~~with~~ a neck (7) and a pierceable cap (8), ~~set in an overturned position and~~

a device (9) ~~for the~~ configured to withdraw~~al and/or~~or reconstitut~~eion of the~~ substance (6) contained in the bottle (5), the device (9) is ~~which may be~~ hooked to the neck (7) of the bottle (5), and the device (9) comprises a perforation needle (13) configured to move in an axial direction relative to the bottle (5) and to perforate ~~for the perforation of~~ the cap (8) of the bottle (5) and a bottom shank (34) extending from a base of the needle (13) ~~which is axially movable with respect to the bottle (5)~~, and

an outflow tube (15) extending out of the outer bag (1) and ~~equipped with~~comprising an openable closure element (17) disposed in a passage of the outflow tube (15),

characterized in that said perforation needle (13) comprises: ~~is passed through longitudinally by~~

a first channel (18) extending longitudinally through the perforation needle (13) such that first channel (18) establishes fluid communication between ~~connecting after perforation of the cap (8) and with the closure element (17) set open the inside~~an interior of the bottle (5) ~~to said~~ and the passage of the outflow tube (15) when the perforation needle (13) perforates the cap (8) and the closure element (17) is opened, ~~and~~

a second channel (19) ~~with~~ extending from a side opening (20) of the perforation needle (13) to a tip of the perforation needle (13), wherein the side opening (20) is disposed at the base of the needle (13) above the bottom shank (34) and opens directly into the inner chamber of the outer bag (1), and ~~equipped with~~

a hydrophobic filter (21) disposed within the perforation needle (13) at the side opening (20) and configured to allow~~, after perforation of the cap (8),~~ only air or other gaseous fluid to flow ~~from inside~~between the interior of the

bottle (5) ~~into~~ and the inner chamber (2) of the bag (1) when the perforation needle (13) perforates the cap (8) ~~or vice versa~~.

2. The ~~P~~package according to claim 1, characterized in that ~~said withdrawal and/or~~the reconstitution device (9) ~~consists of~~comprises an upper body (10) equipped with flaps ~~that may~~configured to be hooked to the neck (7) of the bottle (5) and a lower body (12) ~~which may be~~slidably coupled to the upper body (10) ~~with an axially sliding motion~~the lower body (12) ~~and~~ comprises said perforation needle (13) and a bottom shank (34) ~~passed through lengthways by said first channel (18) of the perforation needle (13) until said openable closure (17) and~~ housed hermetically within said outflow tube (15), and the first channel (18) extends in a longitudinal direction through the bottom shank.

3. The ~~P~~package according to claim 1 or 2, characterized in that said outflow tube (15) ~~terminates with an end open/close~~includes an end connector (16) disposed at an end of the outflow tube (15) and configured to open and close the end of the outflow tube (15).

4. The ~~P~~package according to claim 3, characterized in that said end connector (16) ~~may be~~configured to be coupled to an opening syringe (22, 24).

5. The p~~P~~ackage according to any one of the preceding claims, characterized in that said bag (1) is made of a flexible material.

6. The p~~P~~ackage according to any one of claims 1-5, characterized in that said bag (1) comprises a tube (3) with an airtight ~~open/close~~ connector (4) ~~for the introduction of~~configured to open and close to introduce a mixture of ozone or any other sterilizing gas into said inner chamber (2) of the bag (1).

7. The p~~P~~ackage according to any one of claims 1-6, characterized by comprising: a ~~further~~ second bag (31) positioned below said outer bag (1) and designed to contain a liquid substance (35) to be mixed with said medicinal or nutritional substance (6), and a two-way tap (29) ~~placed~~ disposed between the outer bag (1) and the second bag (31), ~~said bags (1 and 31) and equipped with~~ the two-way tap (29) comprising a side open/close connector (32) configured to be coupled to ~~which~~ an opening syringe (40)

with a sliding plunger (41) ~~may be coupled~~, characterized in that said tap (29) ~~being adjustable~~is configured to be adjusted between a first position inhibiting communications between said side connector (32) and said ~~further~~ second bag (31), and a second position inhibiting communications between said side connector (32) and said outflow tube (15) of said outer bag (1).

8. The p~~P~~ackage according to claim 7, characterized in that said two-way tap (29) ~~is~~ comprises a first connector (36) secured to an end connector (16) of the outflow tube (15) of the outer bag (1) and a second connector (38) secured to an end connector (30) of a second outflow tube of the second bag (31) ~~said bags (1, 31) through connectors (36, 38) of said tap (29) being coupled to corresponding connectors (16, 30) of said bags (1, 31)~~.

9. The p~~P~~ackage according to claim 7, characterized in that said tap (29) is permanently secured to the outflow tube (15) of the outer bag (1) and a second outflow tube of the second bag (31)~~said bags (1, 31) by means of permanent connections~~.

10. The p~~P~~ackage according to any one of claims 1-3 and 5-6, ~~characterized in that it~~ further comprisinge~~s~~ a collection bag (27) positioned below said outer bag (1) and ~~communicating~~ in communication with the ~~same~~outer bag (1).