

Annex III

Amendments to the relevant sections of the summaries of product characteristics and package leaflets

Amendments to be included in the relevant sections of the summary of product characteristics and package leaflets for Dianeal PD4 and Extraneal, as applicable.
Changes are shown as **greyed boxed wording**

Summary of Product Characteristics

DIANEAL PD4

6.3 Shelf life

The shelf life of the product as packaged for sale is 24 months
12 months (for medicinal products manufactured at Alliston, Canada and North Cove, USA only).
The product, once removed from its overpouch, should be used immediately

EXTRANEAL

6.3 Shelf Life

2 years
12 months (for medicinal products manufactured at Alliston, Canada and North Cove, USA only).
The product, once removed from its overpouch should be used immediately.

6.5 Nature and Contents of Container

Flexible PVC container holding 1.5, 2.0 or 2.5 litres.

The lineo connector that may equip the Y transfer line of the twin bag, contains 10.5% of Povidone iodine ointment

1.5 L	8 units per box	Single bag Sy II (luer connector)
1.5 L	8 units per box	Single bag Sy III (spike connector)
1.5 L	8 units per box	Twin bag Sy II (luer connector)
1.5 L	8 units per box	Twin bag Sy III (spike connector)
1.5 L	6 units per box	Single bag Sy II (luer connector)
1.5 L	6 units per box	Single bag Sy III (spike connector)
1.5 L	6 units per box	Twin bag Sy II (luer connector)
1.5 L	6 units per box	Twin bag Sy III (spike connector)
1.5 L	6 units per box	Twin bag (lineo connector)
2.0 L	8 units per box	Single bag Sy II (luer connector)
2.0 L	8 units per box	Single bag Sy III (spike connector)
2.0 L	8 units per box	Twin bag Sy II (luer connector)
2.0 L	8 units per box	Twin bag Sy III (spike connector)
2.0 L	6 units per box	Single bag Sy II (luer connector)
2.0 L	6 units per box	Single bag Sy III (spike connector)
2.0 L	6 units per box	Twin bag Sy II (luer connector)
2.0 L	6 units per box	Twin bag Sy III (spike connector)
2.0 L	5 units per box	Single bag Sy II (luer connector)
2.0 L	5 units per box	Single bag Sy III (spike connector)
2.0 L	5 units per box	Twin bag Sy II (luer connector)
2.0 L	5 units per box	Twin bag Sy III (spike connector)
2.0 L	5 units per box	Twin bag (lineo connector)
2.5 L	5 units per box	Single bag Sy II (luer connector)
2.5 L	5 units per box	Single bag Sy III (spike connector)
2.5 L	5 units per box	Twin bag Sy II (luer connector)
2.5 L	5 units per box	Twin bag Sy III (spike connector)
2.5 L	4 units per box	Single bag Sy II (luer connector)
2.5 L	4 units per box	Single bag Sy III (spike connector)
2.5 L	4 units per box	Twin bag Sy II (luer connector)
2.5 L	4 units per box	Twin bag Sy III (spike connector)
2.5 L	4 units per box	Twin bag (lineo connector)

Not all pack sizes may be marketed.

Patient Information Leaflet

EXTRANEAL

5. How to store EXTRANEAL

- Keep out of the reach and sight of children.
- Store in the original package.
- Do not store below 4°C.
- Do not use EXTRANEAL after the expiry date. The date is stated on the carton label and on the bag after the abbreviation Exp. and the symbol ☞. The expiry date refers to the last day of that month.
- Dispose EXTRANEAL as you have been trained

Patient Information Leaflet

Volume	Number of units per box	Product configuration	Type of connector(s)
1.5L	8	Single bag (APD)	luer /spike
1.5L	8	Twin bag (CAPD)	luer / spike
1.5L	6	Single bag (APD)	luer /spike
1.5L	6	Twin bag (CAPD)	luer / spike /lineo
2.0L	8	Single bag (APD)	luer/spike
2.0L	8	Twin bag (CAPD)	luer/spike
2.0L	6	Single bag (APD)	luer/spike
2.0L	6	Twin bag (CAPD)	luer/spike
2.0L	5	Single bag (APD)	luer / spike
2.0L	5	Twin bag (CAPD)	luer / spike / lineo
2.5L	5	Single bag (APD)	luer/spike
2.5L	5	Twin bag (CAPD)	luer/spike
2.5L	4	Single bag (APD)	luer / spike
2.5L	4	Twin bag (CAPD)	luer / spike /lineo

The Lineo connector contains iodine.
Not all configurations may be marketed.