

### **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, Extraneal and Nutrineal, 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 product manufactured at Alliston, Canada only).**  
The product, once removed from its overpouch, should be used immediately

#### **EXTRANEAL**

##### 6.3 Shelf Life

2 years.  
**12 months (for medicinal product manufactured at Alliston, Canada 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 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)
- 2.0L 6 units per box Twin bag Sy II (luer connector)
- 2.0L 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)
- 2.5L 5 units per box Single bag Sy II (luer connector)
- 2.5L 5 units per box Single bag Sy III (spike connector)
- 2.5L 5 units per box Twin bag Sy II (luer connector)
- 2.5L 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

#### **NUTRINEAL**

##### 6.3 Shelf Life

2 years.  
**12 months (for medicinal product manufactured at Alliston, Canada only)**

## 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

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

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