

**ANNEX III**

**AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE SUMMARY  
OF PRODUCTS CHARACTERISTICS, LABELLING AND PACKAGE LEAFLET**

## **SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)**

The following wording should be included in the SmPC of the marketing authorisations to be varied, as relevant:

### **Section 4.2**

- {(Invented) Name} is contraindicated in children less than 30 months (see section 4.3).
- “The duration of treatment is limited to 3 days.”

### **Section 4.3**

- “Hypersensitivity to the active substances or to any of the excipients”
- “Children less than 30 months”
- “Children with a history of epilepsy or febrile convulsion”
- “Recent history of anorectal lesion”

### **Section 4.4**

- “This product contains terpenic derivatives which, at excessive dose, may cause neurological disorders as convulsions in infants and children.”
- “Do not prolong the treatment over 3 days due to the risks related to terpenic derivatives storage (because of their lipophilic properties, the rate of metabolism and elimination is unknown) in tissues and brain, in particular neuropsychological disorders; and the risk of rectal burning.”
- “Do not administer at a dose higher than recommended due to an increased risk of adverse drug reactions and disorders related to overdosage (see section 4.9).”
- “As this product is inflammable, do not go near a flame.”

### **Section 4.5**

- “Do not use concomitantly with other products (medicinal or cosmetic) containing terpenic derivatives whatever the route of administration (oral, rectal, cutaneous, or pulmonary).”

### **Section 4.6**

#### **Pregnancy**

There are no or limited amount of data from the use of {Active substance} in pregnant women.

{(Invented) Name} is not recommended during pregnancy <and in women of childbearing potential not using contraception.>

#### **Lactation**

There is insufficient information on the excretion of {Active substance} in human milk.

{(Invented) Name} should not be used during breast-feeding.

### **Section 4.8**

- “Due to the presence of <name(s) of terpenic derivative(s)> and in case of non-adherence to the recommended doses, there is a risk of convulsions in children and infants”

### **Section 4.9**

- “Repeated and prolonged use may cause rectal burning.”

- “In case of accidental oral intake or administration error in infants and children, there is a risk of neurological disorders.”
- “If required, appropriate symptomatic treatment should be given in specialized care unit”.

### Section 5.1

- “Terpenic derivatives may lower the epileptogenous threshold.”

## **LABELLING**

The following wording should be included in the labelling of the marketing authorisations to be varied, as relevant:

### Section 15

- “Do not use in children less than 30 months”

## **PACKAGE LEAFLET**

The following wording should be included in the package leaflet of the marketing authorisations to be varied, as relevant:

### Section 1

- Removal of posology related to children less than 30 months.
- “The duration of treatment is limited to 3 days.”

### Section 2

#### **“Do not use {(Invented) Name} suppositories:**

- In children less than 30 months
- In children with a history of epilepsy or febrile convulsion”
- In children with a recent history of anorectal lesion

#### **“Take special care with {(Invented) Name} suppositories:**

- This product contains <name(s) of terpenic derivative(s)> which, at excessive dose, may lead to neurological disorders as convulsion, in infants and children.
- Do not prolong the treatment over 3 days due to the possible risks related to the accumulation of terpenic derivatives (for example camphor, cineole, niaouli, wild thyme, terpineol, terpine, citral, menthol and essential oils of pine needle, eucalyptus and turpentine) in the body including the brain, in particular neuropsychological disorders; and the risk of rectal burning.”
- “Do not administer at doses higher than recommended due to an increased risk of adverse drug reactions and overdose related disorders.”
- “As this product is inflammable, do not go near a flame.”

#### **“Pregnancy and breast-feeding:**

- Do not use during pregnancy or breast-feeding”

#### **“Use with other medicines**

- Do not use {(Invented) Name} while also taking other products (medicinal or cosmetic) containing terpenic derivatives (for example camphor, cineole, niaouli, wild thyme, terpineol,

terpine, citral, menthol and essential oils of pine needle, eucalyptus and turpentine) whatever the administration route (oral, rectal, cutaneous or pulmonary).”

**Section 3**

- “Due to the presence of <name(s) of terpenic derivative(s)> and in case of patients not complying with the recommended doses there is a risk of convulsions in children and infants”