

## APPENDIX I

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME

PROGESTOGEL 1 PER CENT, gel for local application

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PROGESTERONE .....	1.0 g
Octyl dodecanol .....	1.0 g
Carbomer (980) .....	0.5 g
Macrogolglycerol hydroxystearate .....	4.0 g
Trolamine .....	0.5 g
96 per cent ethanol expressed as anhydrous ethanol .....	47.7 g
Purified water .....	q.s.f. 100.0 g

Bottle with dispensing pump; one squeeze of the bottle corresponds to 1.25g of gel, i.e. 0.0125 g of progesterone.

One ruler delivers 2.5 g of gel i.e. 0.025 g of progesterone

#### 3. PHARMACEUTICAL FORM

Gel for local application

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Benign breast diseases :

- . mastodynia
- . complementary treatment of benign mastopathy in case of progesterone insufficiencies

##### 4.2 Posology and method of administration

On average, one ruler i.e. to 2.5 g of gel should be applied over each breast. In general the treatment had rather be administrated continuously, every day of the month, including during menstrual periods.

After personal toilet, spread the product all over the two breasts until it has penetrated. After applying hands should be washed.

##### 4.3 Contraindications

##### 4.4 Special warnings and precautions for use

##### 4.5 Interactions with other medication and other forms of interaction

##### 4.6 Pregnancy and lactation

This medicine could be prescribed during pregnancy.

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

4.9 Overdose

## 5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

PROGESTATIVE BY LOCAL ROUTE  
(G : Genito-urinary system and sex hormones)

5.2 Pharmacokinetic properties

- Around 10 % of the dose administrated penetrates the skin
- Local metabolism (skin, breast : gland and adipose tissue)
- There is little or no general diffusion of progesterone

5.3 Preclinical safety data

## 6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

6.2 Shelf life

Two years

6.3 Special precautions for storage

Do not store above 25°C

6.4 Nature and contents of container

Aluminium tube varnished on the inside containing (epoxyphenolic varnish)  
75 g in bottles (PE/polypropylene) with a dispensing pump (60 doses).

6.5 Instructions for use/handling

## 7. PRESENTATION AND ADMINISTRATIVE IDENTIFICATION NUMBER

313 141.2 : aluminium tube of 80 g (varnished aluminium)  
3697 664-3 : 75 g in bottles (PE/polypropylene) with dispensing pump (60 doses).

## 8. CONDITIONS OF PRESCRIPTION AND DISPENSING

9. HOLDER OF THE MARKETING AUTHORIZATION

Laboratories BESINS INTERNATIONAL  
3, rue du Bourg l'Abbé  
75003 PARIS  
France

10. DATE OF APPROVAL/REVISION