ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Vaniqa 11.5% cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 115 mg of eflornithine (as hydrochloride monohydrate).

Excipients with known effect:
Each gram of cream contains 47.2 mg of cetostearyl alcohol, 14.2 mg of stearyl alcohol, 0.8 mg of methyl parahydroxybenzoate and 0.32 mg of propyl parahydroxybenzoate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

White to off white cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of facial hirsutism in women.

4.2 Posology and method of administration

Posology
Vaniqa cream should be applied to the affected area twice daily, at least eight hours apart. Efficacy has only been demonstrated for affected areas of the face and under the chin. Application should be limited to these areas. Maximal applied doses used safely in clinical trials were up to 30 grams per month.
Improvement in the condition may be noticed within eight weeks of starting treatment.
Continued treatment may result in further improvement and is necessary to maintain beneficial effects.
The condition may return to pre-treatment levels within eight weeks following discontinuation of treatment.
Use should be discontinued if no beneficial effects are noticed within four months of commencing therapy.
Patients may need to continue to use a hair removal method (e.g. shaving or plucking) in conjunction with Vaniqa. In that case, the cream should be applied no sooner than five minutes after shaving or use of other hair removal methods, as increased stinging or burning may otherwise occur.

Special population
Elderly: (> 65 years) no dosage adjustment is necessary.

Paediatric population:

The safety and efficacy of Vaniqa in children aged 0 to 18 years has not been established. There is no data available to support use in this age group.

Hepatic/renal impairment: the safety and efficacy of Vaniqa in women with hepatic or renal impairment have not been established. As the safety of Vaniqa has not been studied in patients with

severe renal impairment, caution should be used when prescribing Vaniqa for these patients. No data are available.

Method of administration
A thin layer of the cream should be applied to clean and dry affected areas. The cream should be rubbed in thoroughly. The medicinal product should be applied such that no visual residual product remains on the treated areas after rub-in. Hands should be washed after applying this medicinal product. For maximal efficacy, the treated area should not be cleansed within four hours of application. Cosmetics (including sunscreens) can be applied over the treated areas, but no sooner than five minutes after application.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Excessive hair growth can result from serious underlying disorders (e.g. polycystic ovary syndrome, androgen secreting neoplasm) or certain active substances (e.g. cyclosporin, glucocorticoids, minoxidil, phenobarbitone, phenytoin, combined oestrogen-androgen hormone replacement therapy). These factors should be considered in the overall medical treatment of patients who might be prescribed Vaniqa.
Vaniqa is for cutaneous use only. Contact with eyes or mucous membranes (e.g. nose or mouth) should be avoided. Transient stinging or burning may occur when the cream is applied to abraded or broken skin.
If skin irritation or intolerance develops, the frequency of application should be reduced temporarily to once a day. If irritation continues, treatment should be discontinued and the physician consulted.
This medicinal product contains cetostearyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) as well as methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
Throughout clinical trials data from a limited number of exposed pregnancies (22) indicate that there is no clinical evidence that treatment with Vaniqa adversely affects mothers or foetuses. Among the 22 pregnancies that occurred during the trials, only 19 pregnancies occurred while the patient was using Vaniqa. Of these 19 pregnancies, there were 9 healthy infants, 5 elective abortions, 4 spontaneous abortions and 1 birth defect (Down's Syndrome to a 35 year old). To date, no other relevant epidemiological data are available. Animal studies have shown reproductive toxicity (see section 5.3). The potential risk to humans is unknown. Therefore, women who are pregnant or planning pregnancy should use an alternative means to manage facial hair.

Breast-feeding
It is not known whether eflornithine/metabolites are excreted in human milk. Women should not use Vaniqa whilst breastfeeding.

Fertility
There are no data available.

4.7 Effects on ability to drive and use machines

Vaniqa has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The mostly skin related adverse reactions reported were primarily mild in intensity and resolved without discontinuation of Vaniqa or initiation of medical treatment. The most frequently reported adverse reaction was acne, which was generally mild. In the vehicle-controlled trials (n= 596), acne was observed in 41% of patients at baseline; 7% of patients treated with Vaniqa and 8% treated with vehicle experienced a worsening of their condition. Of those with no acne at baseline, similar percentages (14%) reported acne following treatment with Vaniqa or vehicle.
The following listing notes the frequency of adverse skin reactions seen in clinical trials, according to MedDRA convention. MedDRA conventions for frequency are very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), or not known (cannot be estimated from the available data) including isolated reports. Note that over 1350 patients were treated with Vaniqa in these trials for 6 months to one year, while only slightly more than 200 patients were treated with vehicle for 6 months. Most events were reported at similar rates between Vaniqa and vehicle. The skin effects of burning, stinging, tingling, rash and erythema were reported at higher levels in Vaniqa treated patients compared to vehicle, as indicated by the asterisk (*).

Frequency of adverse skin reactions seen in Vaniqa clinical trials, (according to MedDRA frequency convention).

Skin and subcutaneous tissue disorders

Very common (≥1/10)	Acne
Common (≥1/100 to <1/10)	Pseudofolliculitis barbae, alopecia, stinging skin*, burning skin*, dry skin, pruritus, erythema*, tingling skin*, irritated skin, rash*, folliculitis
Uncommon (≥1/1,000 to <1/100)	Ingrown hair, oedema face, dermatitis, oedema mouth, papular rash, bleeding skin, herpes simplex, eczema, cheilitis, furunculosis, contact dermatitis, abnormal hair texture and abnormal hair growth, hypopigmentation, flushing skin, lip numbness, skin soreness
Rare (≥1/10,000 to <1/1,000)	Rosacea, seborrheic dermatitis, skin neoplasm, maculopapular rash, skin cysts, vesiculobullous rash, skin disorder, hirsutism, skin tightness

Paediatric population
The adverse reactions observed in adolescents are similar to the ones observed in adults.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Given the minimal cutaneous penetration of eflornithine (see section 5.2), overdose is highly unlikely. However, should very high dose cutaneous administration or accidental oral ingestion occur, attention should be paid to the effects seen with therapeutic doses of intravenous eflornithine (400 mg/kg/day or approximately 24 g/day) used in the treatment of *Trypanosoma brucei gambiense* infection (African sleeping sickness): hair loss, facial swelling, seizures, hearing impairment, gastrointestinal

disturbance, loss of appetite, headache, weakness, dizziness, anaemia, thrombocytopenia and leucopenia.
If symptoms of overdose occur the use of the medicinal product should be stopped.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other dermatological preparations, ATC code: D11AX16.

Mechanism of action
Eflornithine irreversibly inhibits ornithine decarboxylase, an enzyme involved in the production of the hair shaft by the hair follicle. Vaniqa has been shown to reduce the rate of hair growth.

Clinical efficacy and safety
The safety and efficacy of Vaniqa was evaluated in two double-blind, randomised, vehicle-controlled clinical trials involving 596 women of skin types I-VI (395 on Vaniqa, 201 on vehicle) treated for up to 24 weeks. Physicians assessed the change from baseline on a 4-point scale, 48 hours after women had shaved the treated areas of the affected areas of the face and under the chin, considering parameters such as hair length and density, and darkening of the skin associated with the presence of terminal hair. Improvement was seen as early as 8 weeks after initiation of treatment.

The combined results of these two trials are presented below:

Outcome*	Vaniqa 11.5% cream	Vehicle
Clear / almost clear	6%	0%
Marked improvement	29%	9%
Improved	35%	33%
No improvement / worse	30%	58%

* At end of therapy (Week 24). For patients who discontinued therapy during the trial last observations were carried forward to Week 24.

Statistically significant ($p \leq 0.001$) improvement for Vaniqa versus vehicle was seen in each of these studies for women with marked improvement and clear/almost clear responses. These improvements resulted in a corresponding reduction in the darkening appearance of the facial skin associated with the presence of terminal hair. Subgroup analysis revealed a difference in treatment success where 27% of non-white women and 39% of white women showed a marked or better improvement. Subgroup analysis also showed that 29% of obese women (BMI ≥ 30) and 43% of normal weight women (BMI < 30) showed a marked or better improvement. About 12% of women in the clinical trials were postmenopausal. Significant improvement ($p < 0.001$) versus vehicle was seen in postmenopausal women.
Patient self-assessments demonstrated a significantly reduced psychological discomfort with the condition, as measured by responses to 6 questions on a visual analogue scale. Vaniqa significantly reduced how bothered patients felt by their facial hair and by the time spent removing, treating, or concealing facial hair. Patient comfort in various social and work settings was also improved. Patient self-assessments were found to correlate with physician observations of efficacy. These patient-observable differences were seen 8 weeks after initiating treatment.
The condition returned to pre-treatment levels within eight weeks after discontinuation of treatment.

5.2 Pharmacokinetic properties

Steady state cutaneous penetration of eflornithine in women from Vaniqa on facial skin of shaving women was 0.8%.
The steady state plasma half-life of eflornithine was approximately 8 hours. Steady state was reached within four days. The steady state peak and trough plasma concentrations of eflornithine were

approximately 10 ng/ml and 5 ng/ml, respectively. The steady state 12-hour area under the plasma concentration versus time curve was 92.5 ng.hr/ml.
Eflornithine is not known to be metabolised and is eliminated primarily in the urine.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity, genotoxicity and carcinogenic potential, including one photocarcinogenicity study in mice. In a dermal fertility study in rats, no adverse effects on fertility were observed at up to 180 times the human dose. In dermal teratology studies, no teratogenic effects were observed in rats and rabbits at doses up to 180 and 36 times the human dose, respectively. Higher doses resulted in maternal and foetal toxicity without evidence of teratogenicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol;
Macrogol cetostearyl ether;
Dimeticone;
Glyceryl stearate;
Macrogol stearate;
Methyl parahydroxybenzoate (E218);
Liquid paraffin;
Phenoxyethanol;
Propyl parahydroxybenzoate (E216);
Purified water;
Stearyl alcohol;
Sodium hydroxide (E524) (to adjust pH)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Shelf-life after first opening: 6 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene tube with a polypropylene screw cap containing 15 g, 30 g or 60 g of cream. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Almirall, S.A.
Ronda General Mitre, 151,
08022 Barcelona,
Spain.

8. MARKETING AUTHORISATION NUMBERS

EU/1/01/173/001-003

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 March 2001
Date of latest renewal: 07 March 2011

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Almirall Hermal GmbH
Scholtzstrasse 3
D-21465 Reinbek
Germany

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**
  The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON TEXT

1. NAME OF THE MEDICINAL PRODUCT

Vaniqa 11.5% cream
eflornithine

2. STATEMENT OF ACTIVE SUBSTANCE

Each gram of cream contains 115 mg eflornithine (as hydrochloride monohydrate).

3. LIST OF EXCIPIENTS

Also contains: cetostearyl alcohol; macrogol cetostearyl ether; dimeticone; glyceryl stearate; macrogol stearate; methyl parahydroxybenzoate (E218); liquid paraffin; phenoxyethanol; propyl parahydroxybenzoate (E216); purified water; stearyl alcohol and sodium hydroxide (to adjust pH).

4. PHARMACEUTICAL FORM AND CONTENTS

Cream
15 g
30 g
60 g

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Cutaneous use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

Discard the tube 6 months after opening.

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Almirall, S.A.
Ronda General Mitre, 151
08022 Barcelona
Spain.

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/01/173/001
EU/1/01/173/002
EU/1/01/173/003

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

vaniqa

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC
SN
NN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

TUBES

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Vaniqa 11.5% cream
eflornithine

2. METHOD OF ADMINISTRATION

Read the package leaflet before use.
Cutaneous use.

3. EXPIRY DATE

EXP

Discard the tube 6 months after opening.

4. BATCH NUMBER

Batch

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

15 g
30 g
60 g

6. OTHER

Almirall, S.A.

Keep out of the sight and reach of children.

Do not store above 25°C.

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Vaniqa 11.5% cream
eflornithine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vaniqa is and what it is used for
Vaniqa contains the active substance eflornithine. Eflornithine slows down the growth of hair through its effect on a specific enzyme (a protein in the body involved in the production of hair).

Vaniqa is used to reduce the growth of excessive hair (Hirsutism) on the face of women older than 18 years of age.

2. What you need to know before you use Vaniqa

Do not use Vaniqa

- if you are allergic to eflornithine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Vaniqa.

- tell your doctor of any other medical problems you may be experiencing (especially related to your kidneys or liver).
- if you are unsure whether or not to use this medicine, contact your doctor or pharmacist for advice.

Excessive growth of hair may be a result of underlying diseases. Talk to your doctor if you suffer from polycystic ovary syndrome (PCOS) or specific hormone producing tumours, or if you take medicines that can induce hair growth, e.g. cyclosporine (following organ transplants), glucocorticoids (e.g. against rheumatic or allergic diseases), minoxidil (against high blood pressure), phenobarbitone (against seizures), phenytoin (against seizures) or hormone replacement therapy with male hormone like effects.

Children and adolescents

Vaniqa is not recommended for use in anyone younger than 18 years of age.

Other medicines and Vaniqa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Talk to your doctor if you need to use other medicines on the areas of skin where you are using the cream.

Pregnancy and breast-feeding

Do not use Vaniqa if you are pregnant or breast-feeding. You should use an alternative method to manage your facial hair if you are pregnant or trying to become pregnant.

Driving and using machines

Vaniqa is not expected to have any effect on your ability to drive or use machines.

Vaniqa contains cetostearyl alcohol and stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis). **Vaniqa also contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)** which may cause allergic reactions (possibly delayed).

3. How to use Vaniqa

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Use twice a day, at least 8 hours apart.
- If you experience irritation (e.g. stinging burning), reduce the use of Vaniqa to once daily until the irritation has gone. If it persists contact your doctor.
- If you have just shaved or used any other hair removal method, wait at least **5 minutes** before using Vaniqa. It may sting or burn if you put this cream on cut or irritated skin.
- Clean and dry the areas of the skin where you will be using the cream.
- Apply a thin layer of cream and rub it in thoroughly until no visual residual product remains on the treated areas.
- If possible, **do not** wash these areas of skin for 4 hours after applying the cream
- Wash your hands after applying the cream.
- Wait at least **5 minutes** before using make-up or sunscreen on the same areas.
- When using on the face**, avoid** contact with your eyes or the inside of your nose or mouth. If you should accidentally get Vaniqa into your eyes, mouth or nose, rinse well with water**.**

Vaniqa is **not** a depilatory cream, so you may need to continue with your hair removal method, for example by shaving or plucking.

It may take 8 weeks before you see results. It is important to continue using the cream. If you do not see any improvement after using it for 4 months contact your doctor. If you stop using it your original hair growth may return within 8 weeks.

If you use more Vaniqa than you should

If you put too much cream on your skin, it is unlikely to harm you.

If you or anyone else accidentally swallows Vaniqa, contact your doctor **immediately.**

If you forget to use Vaniqa

Apply straight away, but wait at least 8 hours before using it again.

If you stop using Vaniqa

To maintain the reduction of hair growth keep using Vaniqa continuously as indicated.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects are usually limited to the skin and mild in intensity. In such cases they normally resolve without discontinuation of Vaniqa.

The frequency of possible side effects listed below is defined using the following convention:

very common	(affects more than 1 user in 10)
common	(affects 1 to 10 users in 100)
uncommon	(affects 1 to 10 users in 1,000)
rare	(affects 1 to 10 users in 10,000)
very rare	(affects less than 1 user in 10,000)
not known	(frequency cannot be estimated from the available data).

Very common (affects more than 1 user in 10)
- acne

Common (affects 1 to 10 users in 100)
- dry skin
- hair loss
- inflammation around the hair shaft
- itching
- rash
- redness
- skin irritation and bumps caused by shaving
- skin irritation
- stinging, tingling or burning feeling on the skin

Uncommon (may affect up to 1 users in 100 people)
- bumpy rash (papular rash)
- cold sores
- redness and irritation at the site where the cream is applied
- eczema
- inflammed, dry, cracked or numb lips
- ingrowing hairs
- pale areas on the skin

- skin bleeding
- skin boils
- skin flushing
- skin inflammation
- sore skin
- swelling of the mouth or face
- unusual hair texture or hair growth

Rare (may affect up to 1 users in 1,000 people)
- abnormal skin growth (skin neoplasm)
- excessive hair growth
- flushing, facial redness and pimples possibly with pus
- other skin disorders
- red, scaly and itchy skin inflammation (seborrhoeic dermatitis)
- red, bumpy or blistering rash
- skin cysts
- skin tightness

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Vaniqa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and on the bottom of the tube after EXP. The expiry date refers to the last day of that month.

Discard the opened tube with any remaining cream after 6 months.

Make sure the cap of the tube is tightly closed after each use.

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vaniqa contains

The active substance is eflornithine.
Each gram of cream contains 115 mg of eflornithine (as hydrochloride monohydrate).

The other ingredients are:
cetostearyl alcohol; macrogol cetostearyl ether; dimeticone; glyceryl stearate; macrogol stearate; methyl parahydroxybenzoate (E218); liquid paraffin; phenoxyethanol; propyl parahydroxybenzoate (E216); purified water and stearyl alcohol. Tiny amounts of sodium hydroxide (E524) are sometimes added to keep acidity levels (pH levels) normal.

What Vaniqa looks like and the contents of the pack

Vaniqa is a cream which is white to off white in colour. It is supplied in tubes of 15 g, 30 g and 60 g but not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Almirall, S.A.
Ronda General Mitre, 151
08022 Barcelona
Spain.
Tel: + 34 93 291 30 00

Manufacturer

Almirall Hermal GmbH
Scholtzstrasse 3
D-21465 Reinbek
Germany

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