

Technical Data Sheet CB035

Balancing Day cream / Balancing Dagcrème / Crème de jour équilibrante

Information to the pharmacist:

While HeW Pharma BV is the original manufacturer of this product, the pharmacist remains the end responsible person for the quality of each individual unit. Under Belgian law, any act of refilling of a bulk product or addition of any ingredient to a bulk product is considered manufacturing. You are required by law to correctly label and notify the resulting end product (either refilled bulk product as such or processed bulk product).

Notification of your end product can be performed at the Cosmetic Products Notification Portal (CPNP) via the following steps:

- Create an EU Login in account following the step on the following web site: [CPNP - How to create an EU Login account? \(europa.eu\)](http://europa.eu/CPNP-How-to-create-an-EU-Login-account/)
- Make an account via the following web site <https://webgate.ec.europa.eu/cpnp/public/ecascreate.cfm> and log in.
- Follow the tutorial: http://ec.europa.eu/growth/sectors/cosmetics/cpnp_en

Information to add in the CPNP

Product Name: Balancing Day cream / Balancing Dagcrème / Crème de jour équilibrante

Product imported in the Community: no

Member state of first placing on the market: Belgium

CMR substances of category 1A or 1B present: Not present.

Nano materials present: Not present.

Category of cosmetic product: Level 1: Skin products. Level 2: Skin care products. Level 3: Face care products other than face mask.

Physical form: Cream/paste

Formulation name: Skin Care Cream, Lotion, Gel

PREDEFINED FRAME FORMULATION (to be used for CPNP): 1.1 -2013.

<https://webgate.ec.europa.eu/cnnp/resources/ff/FF-2013-EN-TRA-00.pdf>

Glycols and glycol ethers present: Not present.

Hydrocarbon solvents present: Not present.

Alcohols other than ethanol and isopropanol present: Not present.

Vitamine A or its derivatives: Not present.

Xanthines present: Not present.

Total levels of essential oils, camphor, menthol or eucalyptus present: Not present.

Toxicity information: None.

Label needs to be added

Note that the following information is mandatory on the label:

- Name of the product
- Function of the product
- List of ingredients with INCI name
- Nominal content
- Name & address of the responsible person
- Mode of use when applicable
- Only supported claims can be added on the label
- Batch number
- Expiry date (not mandatory if shelf life is > 30 months)
- Period after opening

INCI :

Aqua, Coco-Caprylate/Caprata, Propanediol, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Caprylic/Capric Triglyceride, Simmondsia Chinensis (Jojoba) Seed Oil, Gaultheria Procumbens (Wintergreen) Leaf Extract, Althaea Officinalis Root Extract, Opuntia Ficus-Indica Fruit Extract, Kaolin, Carbomer, Cetearyl Alcohol, Sodium Hydroxide, Sodium Levulinate, Sodium Anisate, Sclerotium Gum, Parfum, Tetrasodium Glutamate Diacetate, Linalool

Suggested application: Apply daily on cleansed skin. For external use only.

Use and dosage: Apply daily on cleansed skin.

Supported claims: This specific skin care is carefully designed for imperfect skin with blemishes or acne-prone skin. This using a plant-derived salicylic acid, namely wintergreen. It purifies the skin and creates a perfect complexion. The skin is refined and mattified.

In addition, this skin care contains marshmallow root extract, traditionally known for its soothing and moisturizing properties. Day cream with a gentle application and young fresh fragrance.

Tested and proven:

A scientific user test* showed excellent dermatological tolerance.

90% of users say the cream spreads well.

85% say the skin becomes brighter and cleaner from the first application. The fragrance is young and fresh.

80% confirm that skin texture is visibly refined and after multiple uses, the skin regains its perfect complexion. The overall condition of the skin is improved.

75% note that their skin is purified and shiny skin is reduced.

*After 21 days of application (twice a day) on 20 adolescents.

Compatibility test on packaging:

The product has been tested on polypropylene plastic packaging both at room temperature and at 40 °C. No effects of packaging on the products qualities were observed.

Characteristics

Appearance: White, shiny gelcream

Color: white - offwhite

Odor: Characteristic

Viscosity: 2500-3500 mPa.S-1 measured with an R-3 spindle at 250 rpm, room temperature.

pH value: 5,0-5,5

Preservative: Sodium Levulinate, Sodium Anisate

PAO (Period After Opening): 6M

Shelf life: 31M

Storage conditions: Dark, at Room Temperature

Allergens:

- Linalool (as per Annex III of the Cosmetics Regulation 1223/2009).

Other information:

- Contains 98.2% ingredients of natural origin.
- +/- 1% Physiological variation can appear on the final product due to the naturalness of the raw materials used.
- The color of the cream can become darker over time due to the naturalness of the raw materials used.

NOTE: In our formulations, heavy metal, petrolatum, propylene glycol, isopropyl alcohol, isothiazolinones, parabens, gluten, genetically modified organisms are excluded. Nickel <1 p.p.m. Products can undergo modifications and variations to improve their functionality. In particular, the use of active principles and plant extracts, although obtained with standardized methods, it can change the color and smell of the products for the impossibility of obtaining vegetable crops equal to each other.

Overview:

The cream provides optimal hydration to the skin and with the addition of various natural extracts, it offers a solution to acne problems without having comedogenic effects. A total of 4 natural extracts/oils are used, each with their own unique aspects and functions. Firstly, *Althea officinalis* is added for its wound healing and anti-inflammatory properties. Moreover, the extract possesses antibacterial properties which will offer a reduction in acne. Another natural oil added to the day-cream is derived from *Simmondsia Chinensis*, which increases the enrichment of active ingredients due to its similarity to human sebum but also has some sebum-regulating properties. *Opuntia ficus-indica* is high in vitamin E and therefore also has interesting anti-inflammatory and anti-redness properties. In addition, it also acts as an enrichment of antioxidants, vitamins and fatty acids. Last but not least, *Gaultheria procumbens* is rich in BHA (Beta Hydroxy Acid) and offers a natural solution to the well-known and highly effective salicylic acid in the treatment of acne.

General properties:

This specific skin care is carefully designed for imperfect skin with blemishes or acne-prone skin. For normal to acne-prone skin.

Efficacy, safety and other in vitro and in vivo tests:

All stability, microbial challenge and safety assessments and tests have been performed and documented as required in the Product Information Dossier.

Disclaimer:

HeW Pharma BV does not support nor recommends the use of other claims to this product.

HeW Pharma BV cannot be held responsible for any incorrect information on final labelling or as a result of marketing of the final product.

