Product Information as approved by the CHMP on 18 February 2010, pending endorsement by the European Commission

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ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

REGRANEX 0.01% gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 100 µg of becaplermin*.
* Recombinant human Platelet Derived Growth Factor-BB (rhPDGF-BB) produced in *Saccharomyces cerevisiae* by recombinant DNA technology.

Excipients:
Each gram contains E218 (methyl parahydroxybenzoate) 1.56 mg and E216 (propyl parahydroxybenzoate) 0.17 mg, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel.

REGRANEX is a clear colourless to straw-coloured gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

REGRANEX is indicated, in association with other good wound care measures, to promote granulation and thereby the healing of full-thickness, neuropathic, chronic, diabetic ulcers less than or equal to 5 cm^2.

4.2 Posology and method of administration

Treatment with REGRANEX should be initiated and monitored by physicians (specialists or non-specialists) who are experienced in the management of diabetic wounds.

REGRANEX should always be used in conjunction with good wound care consisting of initial debridement (to remove all the necrotic and/or infected tissue), additional debridement as necessary and a non-weight-bearing regimen to alleviate pressure on the ulcer.

REGRANEX should be applied as a continuous thin layer to the entire ulcerated area(s) once daily using a clean application aid. The site(s) of application should then be covered by a moist saline gauze dressing that maintains a moist wound-healing environment. REGRANEX should not be used in conjunction with occlusive dressings.

- A tube of REGRANEX should be used on a single patient only.
- Care should be taken during use to avoid microbial contamination and spoilage.
- Hands should be washed thoroughly before applying REGRANEX.
- The tip of the tube should not come into contact with the wound or any other surface.
- The use of a clean application aid is recommended and contact with other parts of the body should be avoided.
- Before each application, the ulcer should be gently rinsed with saline or water to remove residual gel.
- The tube should be closed tightly after each use.

REGRANEX should not be used for more than 20 weeks.

If during treatment with REGRANEX no meaningful healing progress is evident after the first ten weeks of continuous therapy, treatment should be re-evaluated, and factors known to compromise healing (such as osteomyelitis, ischaemia, infection) should be re-assessed. Therapy should be continued to the maximum of 20 weeks as long as healing progress is seen on periodic evaluations.

Special population
Paediatric population
Safety and effectiveness in children and adolescents below the age of 18 years have not been established.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients.
- **Any k~~K~~nown malignancies** ~~neoplasm(s) at or near the site(s) of application~~ **(See section 4.4).**
- In patients with clinically infected ulcers. (See section 4.4).

4.4 Special warnings and precautions for use

~~Since becaplermin is a growth factor, REGRANEX should be used with caution in patients with known malignancies.~~ **Malignancies distant from the site of application have occurred in becaplermin users in both clinical trial and in post-marketing use**~~.~~ In view of these data ~~the benefits and risks of becaplermin treatment must be carefully evaluated on a case-by-case basis before prescribing.~~ **and since becaplermin is a growth factor, Regranex treatment is contraindicated in patients with any known malignancies.**

Prior to the use of REGRANEX, related underlying conditions such as osteomyelitis and peripheral arteriopathy should be excluded or treated if present. Osteomyelitis should be assessed by X-ray examination. Peripheral arteriopathy should be excluded by assessment of the pedal pulses or other techniques. Ulcers with a suspicious appearance should be biopsied to exclude malignancy.

Wound infection should be treated prior to the use of REGRANEX. If a wound becomes infected during REGRANEX therapy, the product should be discontinued until the infection has cleared.

REGRANEX should not be used in patients with ulcers that are not of primarily neuropathic origin, such as those due to arteriopathy or other factors.

REGRANEX should not be used in ulcers of baseline surface area > 5 cm^2, or for more than 20 weeks in any individual. There are insufficient data to support safe use of the product for more than 20 weeks (see 5.1 Pharmacodynamic properties). Efficacy has not been demonstrated for ulcers of baseline surface area > 5 cm^2.

REGRANEX contains E218 (methyl parahydroxybenzoate) and E216 (propyl parahydroxybenzoate). These may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed. Consequently, it is recommended that REGRANEX should not be applied to the ulcer site in conjunction with other topical medications.

4.6 Pregnancy and lactation

Pregnancy

There are no adequate data from the use of becaplermin in pregnant women.

Consequently, REGRANEX should not be used during pregnancy.

Breastfeeding

It is not known whether becaplermin is excreted in human milk. Therefore, REGRANEX should not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The safety of REGRANEX Gel was evaluated in 1883 adult patients who participated in 17 clinical trials of REGRANEX and placebo and/or standard therapy (saline dressing). These 1883 patients had at least one topical administration of REGRANEX and provided safety data. Based on pooled safety data from these clinical trials, the most commonly reported (≥5% incidence) adverse drug reactions (ADRs) were (with % incidence) infected skin ulcer (12.3), cellulitis (10.3), and osteomyelitis (7.2). Including the above-mentioned ADRs, the following table displays ADRs that have been reported with the use of REGRANEX from either clinical trial or postmarketing experiences.

The displayed frequency categories use the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1000); very rare (<1/10,000); not known (cannot be estimated from the available clinical trial data).

Adverse Drug Reactions Reported in Clinical Trials and Postmarketing Experience

System Organ Class	Adverse Drug Reactions			
	Frequency Category			
	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)**
Infections and Infestations	Infected skin ulcer,Cellulitis	Osteomyelitis		
Nervous System Disorders			Burning sensation[1]	
Skin and Subcutaneous Tissue Disorders		Rash, Erythema[2]		Dermatitis bullous, Excessive granulation tissue
General Disorders and Administration Site Conditions		Pain		Oedema

1. The bundled term burning sensation consists of the preferred terms burning sensation, skin burning sensation, and application site irritation, all of which referred specifically to burning at the application site.
2. Refers to erythema at the application site.

4.9 Overdose

There are limited data on the effects of becaplermin overdose. Since there was no consistent increase in plasma platelet-derived growth factor-BB concentrations above pre-treatment concentrations, following 14 consecutive daily topical applications to ulcers, no untoward systemic events are expected.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Preparation for treatment of wounds and ulcers, ATC code: D 03 AX06

REGRANEX contains becaplermin, a recombinant human Platelet Derived Growth Factor-BB (rhPDGF-BB). Becaplermin is produced by insertion of the gene for the B chain of human platelet derived growth factor into the yeast, *Saccharomyces cerevisiae*. The biological activity of becaplermin includes promoting the chemotactic recruitment and proliferation of cells involved in wound repair. Thus it helps the growth of normal tissue for healing. In animal wound models, the predominant effect of becaplermin is to enhance the formation of granulation tissue. From data combined from 4 clinical trials conducted over a 20 week treatment phase for ulcers of baseline surface area less than or equal to 5 cm^2, 47% of ulcers treated with becaplermin 100 µg/g gel completely healed, compared to 35% which were treated with placebo gel alone. Subjects recruited into these studies were diabetic adults aged 19 years or over who were suffering from at least one stage III or IV diabetic ulcer of at least 8 weeks duration.

5.2 Pharmacokinetic properties

Absorption

Clinical absorption studies were conducted in patients with a mean diabetic ulcer area of 10.5 cm^2 (range 2.3 - 43.5 cm^2). Following 14 consecutive daily topical applications of REGRANEX, there was no consistent increase in plasma platelet-derived growth factor-BB concentrations above pre-treatment concentrations.

5.3 Preclinical safety data

Becaplermin was not mutagenic in a battery of *in vitro* and *in vivo* tests. Since there was no consistent increase in plasma platelet-derived growth factor-BB concentrations above pre-treatment concentrations, following 14 consecutive daily topical applications to ulcers in man, carcinogenesis and reproductive toxicity studies have not been conducted with REGRANEX. In the process of healing the wound, becaplermin induces cell proliferation. ~~However, skin tumours have not been reported in the clinical trials at the site of application or in close proximity.~~

In a preclinical study designed to determine the effects of PDGF on exposed bone, rats injected at the metatarsals with 3 or 10 µg/site (concentration of 30 or 100 µg/ml/site) of becaplermin every other day for 13 days displayed histological changes indicative of accelerated bone remodelling consisting of periosteal hyperplasia and subperiosteal bone resorption and exostosis. The soft tissue adjacent to the injection site had fibroplasia with accompanying mononuclear cell infiltration reflective of the ability of PDGF to stimulate connective tissue growth.

Preclinical absorption studies through full-thickness wounds were conducted in rats with a wound area of 1.4 - 1.6 cm^2. Systemic absorption of a single dose and multiple applications for 5 consecutive days of becaplermin to those wounds was insignificant.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

carmellose sodium (E466)
sodium chloride
sodium acetate
glacial acetic acid (E260)
methyl parahydroxybenzoate (methylparaben) (E218)
propyl parahydroxybenzoate (propylparaben) (E216)
metacresol
lysine hydrochloride
water for injections

6.2 Incompatibilities

There are no known incompatibilities.

6.3 Shelf life

1 year.

Use within 6 weeks after first opening.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Close tightly after each use.

6.5 Nature and contents of container

15 g of gel in a multidose tube (laminated polyethylene-lined). Pack size of 1.

6.6 Special precautions for disposal

After treatment is completed, any unused gel should be discarded in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

JANSSEN-CILAG INTERNATIONAL NV
Turnhoutseweg, 30
B-2340 Beerse
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/99/101/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 March 1999
Date of latest renewal: 19 March 2009

10. DATE OF REVISION OF THE TEXT

February 2010.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER (S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) of the biological active substance(s)

Novartis Vaccines and Diagnostics, Inc., 4560 Horton Street, Emeryville, CA 94608, USA.

Name and address of the manufacturer(s) responsible for batch release

Janssen-Pharmaceutica N.V., Turnhoutseweg 30, B-2340 Beerse, Belgium.

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

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

~~Not applicable.~~
Risk Management Plan

The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version 1.0 of the Risk Management Plan (RMP) presented in Module 1.8.2 of the Marketing Authorisation and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted

- **When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities**
- **Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached**
- **At the request of the EMEA**

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

OUTER BOX/TUBE

1. NAME OF THE MEDICINAL PRODUCT

REGRANEX 0.01% gel
becaplermin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram of gel contains 100 μg of becaplermin

3. LIST OF EXCIPIENTS

Contains carmellose sodium (E466), sodium chloride, sodium acetate, glacial acetic acid (E260), methyl parahydroxybenzoate (methylparaben) (E218), propyl parahydroxybenzoate (propylparaben) (E216), metacresol, lysine hydrochloride and water for injections.

See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Gel in a multidose tube (15 gram).

Pack size of 1.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

For cutaneous use only.
Read the package leaflet before use.

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

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
Use within 6 weeks after first opening.
Date opened:

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).
Do not freeze.
Close tightly after each use.

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

After treatment is completed, any unused gel should be discarded in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
JANSSEN-CILAG INTERNATIONAL NV
Turnhoutseweg, 30
B-2340 Beerse
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/99/101/001

13. BATCH NUMBER

Batch.

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE (CARTON ONLY)

REGRANEX

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

REGRANEX 0.01% Gel.
Becaplermin

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. WHAT REGRANEX IS AND WHAT IT IS USED FOR

The name of your medicine is REGRANEX. It contains a substance called becaplermin. Becaplermin is a human recombinant Platelet Derived Growth Factor (rhPDGF).
REGRANEX is used to help the growth of normal tissue in order to heal skin ulcers. It is used with other good wound care measures to help with the healing of the ulcers.

Good wound care measures include:
- Your doctor or healthcare professional removing dead skin/debris from the wound whenever necessary
- Keeping weight off your feet, perhaps by wearing special orthopaedic shoes or by other methods
- Your doctor or healthcare professional treating any infection of the wound - treatment with REGRANEX should be stopped if the wound becomes infected
- Continuing to visit your doctor or healthcare professional and following your treatment plan

REGRANEX is used for skin ulcers that:
- Are not more than 5 square centimetres (see diagram opposite) and have a good blood supply
- Are due to complications of diabetes.

Insert diagram of size (circle measuring 2.524 cm in diameter)

By using REGRANEX, it is more likely that your skin ulcers will heal quickly and completely.

2. BEFORE YOU USE REGRANEX

Do not use REGRANEX:
- If you are allergic (hypersensitive) to becaplermin or to any of the other ingredients of REGRANEX (listed in section 6 below)
- If you have **or have had cancer** ~~a skin tumour at or near the area where you apply REGRANEX~~
- If your ulcer is infected
- If your ulcer is larger than 5 square centimetres (see diagram above)
- If you are under 18 years of age.

Do not use this medicine if any of the above apply to you. If you are unsure, talk to your doctor or pharmacist before using REGRANEX.

Take special care with REGRANEX
Check with your doctor or pharmacist before using this medicine if:
- You have any severe or persistently worsening types of cancer
- You have infections of the bone which may be seen as fever, severe pain around the bone that is affected, swelling and redness of the joints
- You have diseases of the arteries.

Taking other medicines
Do not apply any medicines to your ulcer while using REGRANEX, except for salt solution (saline) or water to clean the ulcer.

Please tell your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Pregnancy and breast-feeding
- Do not use this medicine if you are pregnant, think you might be pregnant or planning to become pregnant
- Do not use this medicine if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Important information about possible allergies to some of the ingredients
REGRANEX contains E218 (methyl parahydroxybenzoate) and E216 (propyl parahydroxybenzoate). These may cause allergic reactions (possibly delayed).

3. HOW TO USE REGRANEX

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one application once a day for a maximum of 20 weeks.

Before using REGRANEX
- Wash your hands thoroughly. Do this before you apply REGRANEX
- Your ulcer should be cleaned with salt solution or water. This is important to ensure the ulcer heals as quickly and completely as possible, and to remove any REGRANEX gel from the previous application.

Applying REGRANEX
- Apply REGRANEX gel once a day using a clean cotton swab or wooden spatula. Apply a thin layer of REGRANEX gel to the entire wound area. You can obtain wooden spatulas from your pharmacist
- Cover the ulcer with a moist saline (salt) gauze dressing. The dressing should be changed at least once a day to keep the wound moist.

Further information
- Only apply REGRANEX to the wound area. Avoid contact with any other area of the body
- Do not touch the wound with the tip of the tube
- Do not use air- or water-tight (occlusive) dressings on the wound. If you are unsure, check with your doctor or pharmacist

- Do not apply pressure or walk on the ulcer during treatment. Follow your doctor's advice to relieve pressure from your ulcer.

Your doctor will monitor the progress of your treatment.

Contact your doctor immediately if you notice signs of infection of the ulcer (redness, swelling, fever, pain, or odour). You should stop using it until the infection has cleared.

When to stop using REGRANEX
REGRANEX should **not be used continuously for more than 20 weeks**.

If there is **no sign of healing after the first ten weeks** of treatment, **contact your doctor**. Your doctor will decide whether you should continue to use REGRANEX.

If your ulcer heals and then returns, do not use REGRANEX again without first checking with your doctor.

If you use too much REGRANEX

If you apply too much REGRANEX, it is unlikely to do you any harm. Always try to follow the instructions for use exactly.

If you forget to use REGRANEX
- Apply the next dose as soon as possible. If it is almost time for the next application, forget about the missed dose and continue as normal
- Do not apply a double amount to make up for a missed dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, REGRANEX can have side effects, although not everybody gets them.

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).

Stop using REGRANEX and tell your doctor straight away if you notice or suspect the following:
- Excessive growth of new tissue at the wound (rare)
- Infected skin ulcer (very common)

Other side effects

Common

- Infections of the bone which may be seen as fever, severe pain, swelling and redness around the bone that is affected
- Redness and pain of skin

Uncommon

- Burning sensation at the application site

Rare

- Blisters and swelling under the skin

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE REGRANEX

Keep out of the reach and sight of children.

Do not use REGRANEX after the expiry date, which is stated on the tube and the outer carton after EXP. The expiry date refers to the last date of that month.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Close the tube tightly after each use.

Use within 6 weeks after opening the seal of the tube. Please record the date of opening on the tube label.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What REGRANEX contains

The active substance in REGRANEX is becaplermin. Each gram of Regranex contains 100 micrograms of becaplermin.

The other ingredients are: carmellose sodium (E466), sodium chloride, sodium acetate, glacial acetic acid (E260), methyl parahydroxybenzoate (methylparaben) (E218), propyl parahydroxybenzoate (propylparaben) (E216), metacresol, lysine hydrochloride and water for injections.

What REGRANEX looks like and contents of the pack

Regranex is presented as a gel and is filled in multi-dose tubes containing 15 grams.

Regranex is a clear colourless to straw-coloured gel.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last approved in mm/yyyy

Detailed information on this medicine is available on the European Medicines Agency (EMEA) website: http://www.emea.europa.eu