



EMA/COMP/1413/2002 Rev.4  
Committee for Orphan Medicinal Products

## Public summary of opinion on orphan designation

Purified bromelain for the treatment of partial deep dermal and full thickness burns

First publication	6 January 2003
Rev.1: administrative update	8 January 2003
Rev.2: transfer of sponsorship	14 June 2010
Rev.3: sponsor's change of address	9 November 2011
Rev.4: information about Marketing Authorisation and transfer of sponsorship	11 September 2013
<b>Disclaimer</b> Please note that revisions to the Public Summary of Opinion are purely administrative updates. Therefore, the scientific content of the document reflects the outcome of the Committee for Orphan Medicinal Products (COMP) at the time of designation and is not updated after first publication.	

On 30 July 2002, orphan designation (EU/3/02/107) was granted by the European Commission to Professor Keith Judkins, United Kingdom, for purified bromelain for the treatment of partial deep dermal and full thickness burns.

The sponsorship was transferred to TEVA Pharma GmbH, Germany, in June 2010 and subsequently to MediWound Germany GmbH, Germany, in July 2013.

### What are partial deep dermal and full thickness burns?

Burns are classified in three degrees of severity. These depend on how deep the burn is. First degree burns are limited to the thin outermost layer of the skin. This layer is called epidermis. One example is sunburn. Second degree burns affect the thick layer of skin or connective tissue beneath the epidermis. This layer contains blood, lymph vessels, sweat glands, and nerve endings. Second degree burns are divided in two groups. These are called superficial, and deep partial thickness burns. The superficial ones result in blistering and are painful, healing occurs naturally, in one to three weeks.

Deep partial thickness burns have blisters, a pale white or yellow colour and absence of pain sensation. Re-growth of the skin takes between 3 weeks to 2 months. Disabling scars can develop in the long term. Third degree burns involve all skin layers (full thickness). This includes a layer of fat under the



connective tissue. There is usually little pain at the beginning. The skin appears dry, leathery and is no longer elastic. Deep partial, or full thickness burns can be life threatening.

### **What is the estimated number of patients affected by the condition?**

At the time of designation, partial deep dermal and full thickness burns affected approximately 1 in 10,000 people in the European Union (EU). This was equivalent to a total of around 38,000 people\*, and is below the threshold for orphan designation, which is 5 people in 10,000. This is based on the information provided by the sponsor and the knowledge of the Committee for Orphan Medicinal Products (COMP).

### **What treatments are available?**

Most deep partial-thickness and full thickness burns larger than three centimetres in diameter are best treated with early removal of dead tissue. The removal is done by surgery. Healthy skin is taken from other parts of the body to replace the removed tissue. The use of purified bromelain might reduce the need for surgery. Satisfactory argumentation has been submitted by the sponsor to justify the assumption that purified bromelain could be of potential significant benefit for the treatment of burns.

### **How is this medicine expected to work?**

Purified bromelain is extracted from plants. It consists of a mixture of enzymes. Enzymes are proteins that control specific functions and chemical reactions. These enzymes might be useful in dissolving dead tissues at the site of the burn.

### **What is the stage of development of this medicine?**

The effects of purified bromelain have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical evaluation in patients with deep partial-thickness and full thickness burns was not completed.

This medicinal product had not been marketed anywhere worldwide for this condition. Also, it had not been designated as orphan medicinal product for this condition, at the time of submission.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 27 June 2002 recommending the granting of this designation.

Update: Purified bromelain (NexoBrid) has been authorised in the EU since 18 December 2012 for removal of eschar in adults with deep partial- and full-thickness thermal burns.

More information on NexoBrid can be found in the European public assessment report (EPAR) on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports)

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\*Disclaimer: For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union. At the time of designation, this represented a population of 380,600,000 (Eurostat 2002).

Opinions on orphan medicinal product designations are based on the following three criteria:

- the seriousness of the condition;
- the existence of alternative methods of diagnosis, prevention or treatment;
- either the rarity of the condition (affecting not more than 5 in 10,000 people in the European Union) or insufficient returns on investment.

Designated orphan medicinal products are products that are still under investigation and are considered for orphan designation on the basis of potential activity. An orphan designation is not a marketing authorisation. As a consequence, demonstration of quality, safety and efficacy is necessary before a product can be granted a marketing authorisation.

## For more information

Sponsor's contact details:

MediWound Germany GmbH  
Eisenstr. 5  
65428 Ruesselsheim  
Germany  
E-mail: [info@mediwound.com](mailto:info@mediwound.com)

For contact details of patients' organisations whose activities are targeted at rare diseases see:

- [Orphanet](#), a database containing information on rare diseases which includes a directory of patients' organisations registered in Europe.
- [European Organisation for Rare Diseases \(EURORDIS\)](#), a non-governmental alliance of patient organisations and individuals active in the field of rare diseases.

## Translations of the active ingredient and indication in all official EU languages<sup>1</sup>, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Purified bromelain	Treatment of partial deep dermal and full thickness burns
Bulgarian	Пречистен бромелаин	Лечение на частични дълбоки дермални и изгаряния на цялостната дебелина на кожата.
Croatian	Pročišćeni bromelain	Liječenje opekline djelomične debljine kože koje zahvaćaju duboki dermis i opekline cijele debljine kože
Czech	Purifikovaný bromelain	Léčba parciálních hlubokých kožních a v plné šíři popálenin
Danish	Oprensset Bromelain	Behandlingen af partielle, dybe dermale og fuld tykkelse brandsår
Dutch	Gezuiverd Bromelain	Behandeling van diep gedeeltelijke en gehele dikte verbranding
Estonian	Puhastatud bromelain	Osalise sügava ja kogu naha paksust haarava nahapõletuse ravi
Finnish	Puhdistettu Bromelaiini	Osittaisten ja koko ihon syvyisten palovammojen hoito
French	Bromélaïne purifiée	Traitement des brûlures de deuxième degré profond et de troisième degré
German	Gereinigtes Bromelain	Behandlung von teilweise tiefen und vollschichtigen Verbrennungen
Greek	Καθαρή Βρωμελίνη	Θεραπεία βαθέων δερματικών εγκαυμάτων μερικού ή ολικού πάχους
Hungarian	Tisztított bromelain	Részleges mély dermális és transzdermális égési sérülés kezelése
Italian	Bromelain purificato	Trattamento da ustioni a profondità parziale e da ustione a pieno spessore
Latvian	Attīrīts bromelains	Dziļa dermāla un pilna ādas biezuma apdeguma ārstēšana
Lithuanian	Išgrynintas bromelainas	Dalinio ir visų odos sluoksnių nudegimų gydymas
Maltese	Bromelain purifikat	Kura ta' ħarqiet li jkunu parzjalment profondi fil-ġilda u fil-ħxuna kollha tal-ġilda
Polish	Oczyszczona bromelaina	Leczenie częściowych i całkowitych głębokich skórnych oparzeń
Portuguese	Bromelaína purificada	Tratamento de queimaduras profundas de espessura parcial e total
Romanian	Bromelaină purificată	Tratamentul arsurilor dermale profunde parțiale și totale
Slovak	Purifikovaný bromelaín	Liečba kožných popálenín - čiastočných a v celej hrúbke kože
Slovenian	Prečiščen bromelain	Zdravljenje parcialne dermalne in subdermalne kožne opekline
Spanish	Bromelaína purificada	Tratamiento de quemaduras profundas parciales o totales de la piel
Swedish	Renad bromelain	Behandling av djupa brännskador i huden, både partiella och full tjockleksskador

<sup>1</sup> At the time of transfer of sponsorship