



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Orphan Medicinal Products

## Public summary of opinion on orphan designation

### Sodium hypochlorite for the treatment of partial deep dermal and full thickness burns

On 14 July 2016, orphan designation (EU/3/16/1709) was granted by the European Commission to Hypo-Stream Ltd, United Kingdom, for sodium hypochlorite for the treatment of partial deep dermal and full thickness burns.

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

Partial deep dermal and full thickness burns are deep burns to the skin. In the case of full thickness burns, injury can also extend to layers of fat beneath the skin.

These types of burns are debilitating in the long term because of the scarring, disfigurement and disability that can follow. They are also life threatening because they can lead to serious infection.

#### **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 1.5 in 10,000 people in the European Union (EU). This was equivalent to a total of around 77,000 people<sup>\*</sup>, and is below the ceiling 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?**

At the time of the orphan designation, some products were authorised in the EU for wound care in patients with deep burns (e.g. povidone-iodine) and for removing dead tissue (e.g. NexoBrid).

The sponsor has provided sufficient information to show that this medicine might be of significant benefit for patients with partial deep dermal and full thickness burns, with early studies showing improved survival in patients with widespread burns. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

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<sup>\*</sup>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 (EU 28), Norway, Iceland and Liechtenstein. This represents a population of 513,700,000 (Eurostat 2016).



## How is this medicine expected to work?

When applied to the burn wound, sodium hypochlorite causes a reduction in the amount of proteins known as cytokines, which are involved in inflammation. The lower levels of cytokines and the subsequent reduction in inflammation are then expected to help in wound healing.

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

The effects of sodium hypochlorite have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials with sodium hypochlorite in patients with partial deep dermal and full thickness burns were ongoing.

At the time of submission, a sodium hypochlorite solution was authorised in Italy for disinfection and cleaning of damaged skin (wounds, sores, burns, etc.) and the disinfecting of external genitalia.

At the time of submission, sodium hypochlorite was not authorised anywhere in the EU for partial deep dermal and full thickness burns or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000 of 16 December 1999, the COMP adopted a positive opinion on 16 June 2016 recommending the granting of this designation.

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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 EU) 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:

Contact details of the current sponsor for this orphan designation can be found on EMA website, on the medicine's [rare disease designations page](#).

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	Sodium hypochlorite	Treatment of partial deep dermal and full thickness burns
Bulgarian	Натриев хипохлорит	Лечение на частични дълбоки дермални и изгаряния на цялостната дебелина на кожата.
Croatian	Natrijev hipoklorit	Liječenje opekline djelomične debljine kože koje zahvaćaju duboki dermis i opekline cijele debljine kože
Czech	Chlornan sodný	Léčba parciálních hlubokých kožních a v plně šíři popálenin
Danish	Natriumhypoklorit	Behandlingen af partielle, dybe dermale og fuld tykkelse brandsår
Dutch	Natriumhypochloriet	Behandeling van partiële diepe en gehele dikte verbranding
Estonian	Naatriumhüpoklorit	Osalise sügava ja kogu naha paksust haarava nahapõletuse ravi
Finnish	Natriumhypokloriitti	Osittaisten ja koko ihon syvyisten palovammojen hoito
French	Hypochlorite de sodium	Traitement des brûlures de deuxième degré profond et de troisième degré
German	Natrium hypochlorite	Behandlung von teilweise tiefen und vollschichtigen Verbrennungen
Greek	υποχλωριώδες νάτριο	Θεραπεία βαθέων δερματικών εγκαυμάτων μερικού ή ολικού πάχους
Hungarian	Nátrium-hipoklorit	Részleges mély dermális és transzdermális égési sérülés kezelése
Italian	Ipoclorito di sodio	Trattamento da ustioni a profondità parziale e da ustione a pieno spessore
Latvian	Nātrija hipohlorīts	Dalēja dziļa dermāla un pilna ādas biezuma apdeguma ārstēšana
Lithuanian	Natrio hipochloritas	Dalinio ir visų odos sluoksnių nudegimų gydymas
Maltese	Sodium hypochlorite	Kura ta' ħarqiet li jkun parzjalment profondi fil-ġilda u fil-ħxuna kollha tal-ġilda
Polish	Podchloryn sodu	Leczenie częściowych i całkowitych głębokich skórnych oparzeń
Portuguese	Hipoclorito de sódio	Tratamento de queimaduras profundas de espessura parcial e total
Romanian	Hipoclorit de sodiu	Tratamentul arsurilor dermale profunde parțiale și totale
Slovak	Chlornan sodný	Liečba kožných popálenín-čiastočných a v celej hrúbke kože
Slovenian	Natrijev hipoklorit	Zdravljenje parcialne dermalne in subdermalne kožne opekline
Spanish	Hipoclorito de sodio	Tratamiento de quemaduras profundas parciales o totales de la piel
Swedish	Natriumhypoklorit	Behandling av djupa brännskador i huden, både partiella och full tjockleksskador
Norwegian	Natriumhypokloritt	Behandling av dype brannskader i huden, både dermale og subdermale skader

<sup>1</sup> At the time of designation

Language	Active ingredient	Indication
Icelandic	Natríumhýpóklórít	Meðhöndlun á djúpum fullþykktar húðbruna