



EUROPEAN MEDICINES AGENCY
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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Octenidine dihydrochloride for the prevention of late-onset sepsis in premature infants of less than or equal to 32 weeks of gestational age

On 27 July 2010, orphan designation (EU/3/10/755) was granted by the European Commission to Schülke & Mayr GmbH, Germany, for octenidine dihydrochloride for the prevention of late-onset sepsis in premature infants of less than or equal to 32 weeks of gestational age.

What is late-onset sepsis?

Late-onset sepsis is a severe bacterial infection of the blood that occurs in newborn babies at least three days after birth. Premature babies born eight weeks or more too early (32 weeks of gestational age or less) have a higher risk of late-onset sepsis than other babies. This is because their immune system, skin and moist body surfaces are not yet fully developed, and because they need invasive procedures such as mechanical ventilation (using a machine to help them to breathe) or administration of medicines or feeding by injection, which can put them at risk of infections in neonatal intensive care units.

Late-onset sepsis is a life-threatening condition that is one of the causes of high mortality in premature babies born at 32 weeks of gestational age or less.

What is the estimated number of patients at risk of developing the condition?

At the time of designation, the number of premature babies born at 32 weeks of gestational age or less was estimated to be approximately 1.5 people in 10,000 in the European Union (EU)*. This is equivalent to a total of around 76,000 babies, 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).

*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 27), Norway, Iceland and Liechtenstein. This represents a population of 506,500,000 (Eurostat 2010).



What methods of prevention are available?

At the time of designation, no satisfactory methods were authorised in the EU for the prevention of late-onset sepsis in these babies. Common infection-control measures such as hand-washing were used to keep the infection rate as low as possible in neonatal intensive care units. In some cases, antibiotics and skin antiseptics were also used to prevent infection.

How is this medicine expected to work?

Octenidine dihydrochloride is an antiseptic that has been available in the EU since 1997 in two medicines, which also contain alcohol, for disinfecting the skin and moist body surfaces in children and adults. Octenidine dihydrochloride works by blocking the growth of bacteria, fungi and other organisms that can cause infection.

This medicine is an aqueous solution of octenidine dihydrochloride. The absence of alcohol is expected to make it suitable for use on the sensitive skin of premature babies.

What is the stage of development of this medicine?

The effects of octenidine dihydrochloride have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials with octenidine dihydrochloride in premature babies born at 32 weeks of gestational age or less had been started.

At the time of submission, octenidine dihydrochloride as single agent was not authorised anywhere in the EU for the prevention of late-onset sepsis in premature infants 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 8 April 2010 recommending the granting of this designation.

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:

Schülke & Mayr GmbH
Robert-Koch Strasse 2
22851 Norderstedt
Germany
Telephone: +49 40 521 00 666
Telefax: +49 40 521 00 660
E-mail: mail@schuelke-mayr.com

Patient associations' contact points

None available.

Translations of the active ingredient and indication in all official EU languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Octenidine dihydrochloride	Prevention of late-onset sepsis in premature infants of less than or equal to 32 weeks of gestational age
Bulgarian	Октенидин дихидрохлорид	Превенция на сепсис с късно начало, при недоносени новородени на гестационна възраст, по-малка или равна на 32 седмици
Czech	Octenidin dihydrochloridy	Prevence pozdní sepse u kojenců narozených v 32. týdnu těhotenství či dříve
Danish	Octenidin dihydrochlorid	Forebyggelse af sent indsettende sepsis hos præmature spædbørn født før eller i 32. gestationsuge
Dutch	Octenidine dihydrochloride	Preventie van laattijdig optredende sepsis in premature zuigelingen met een zwangerschapsleeftijd van minder of gelijk aan 32 weken.
Estonian	Octenidine dihidrokloriid	32. või väiksema rasedusnädalaga enneaegsete imikute hilise algusega sepsise ennetamine
Finnish	Oktenidiini dihydrokloridi	Keskosten, joiden sikiöikä ("gestational age") on enintään 32 viikkoa, viivästyneen ("late onset") sepsiksen ehkäisy
French	Octenidine dihydrochlorures	Prévention de sepsis de survenue retardée chez les nouveau-nés prématurés de 32 semaines ou moins d'âge gestationnel
German	Octenidine	Prävention einer late onset Sepsis bei Frühgeborenen mit einem Gestationsalter von weniger oder gleich 32 Wochen
Greek	Διοξροχλωρίδιο οκτενιδίνης	Πρόληψη της νοσοκομειακής σήψης βραδείας εκδήλωσης σε πρόωρα βρέφη με κυητική ηλικία ≤ 32 εβδομάδες στη γέννηση
Hungarian	Octenidine dihidroklorid	Későn jelentkező szepszis megelőzése ≤ 32 hetes gesztációs idejű koraszülötteknél
Italian	Octenidina dicloridrato	Prevenzione della sepsi nei neonati prematuri di ≤ 32 settimane d'età gestazionale
Latvian	Oktenidīna dihidrohlorīds	Sepses ar vēlu sākumu profilaksei jaundzimušiem ar gestācijas vecumu mazāku vai vienādu ar 32 nedēļām
Lithuanian	Oktenidino dihidrochloridas	Vėlyvos pradžios neišnešiotų naujagimių 32 savaitių ar mažesnės gestacijos sepsio prevencija
Maltese	Octenidine dihydrochloride	Prevenzjoni ta' sepsis li jibda tard fi trabi prematuri li jkollhom età inqas minn jew sa 32 ġimgħa ta' tqala
Polish	Oktenidyny dwuchlorowodorek	Zapobieganie opóźnionej posocznicy u wcześniaków urodzonych przed lub w 32 tygodniu ciąży
Portuguese	Octenidina di-hidrocloro	Prevenção de sépsis de início tardio em prematuros com 32, ou menos, semanas de idade gestacional

¹ At the time of designation

Language	Active ingredient	Indication
Romanian	Octenidină diclorhidrat	Prevenirea unei septicemii late onset la bebelușii născuți prematur cu vârsta gestațională mai mică sau egală cu 32 săptămâni
Slovak	Oktenidín dihydrochlorid	Prevenia sepsy s neskorým začiatkom u predčasne narodených detí s gestačným vekom 32 týždňov alebo menej
Slovenian	Oktenidinijev dihidroklorid	Preprečevanje poznega nastanka sepse pri novorojenčkih gestacijske starosti 32 tednov ali manj
Spanish	Octenidine dihidrocloruro	Prevención de la sepsis de inicio tardío en neonatos prematuros con edad gestacional igual o menor a 32 semanas
Swedish	Octenidine dihydroklorid	Profylax av sen debut ('late-onset') sepsis hos prematurt nyfödda barn under eller lika 32 veckors gestationsålder
Norwegian	Oktenidindihydroklorid	Forebygging av sen sepsis hos premature spedbarn med gestasjonsalder ≤ 32 uker
Icelandic	Octenidín díhýdróklóríð	Forvörn gegn spítala-sýklasótt hjá fyrirburum eftir ≤ 32 vikna meðgöngu við fæðingu