



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 August 2011
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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Methyl O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]-N2-[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]-L- α -asparaginy]-4-aminobutanoyl-N6-[5-[(3aS,4S,6aR)-hexahydro-2-oxo-1H-thieno[3,4-d]imidazol-4-yl]-1-oxopentyl]-L-lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di-O-methyl-6-O-sulfo- α -D-glucopyranosyl-(1 $\rightarrow$ 4)-O-2,3-di-O-methyl- β -D-glucopyranuronosyl-(1 $\rightarrow$ 4)-O-2,3,6-tri-O-sulfo- α -D-glucopyranosyl-(1 $\rightarrow$ 4)-O-2,3-di-O-methyl- α -L-idopyranuronosyl-(1 $\rightarrow$ 4)-3-O-methyl- α -D-glucopyranoside 2,6-bis(hydrogen sulfate) octasodium salt for the prevention of ischaemia/reperfusion injury associated with solid organ transplantation

On 5 August 2011, orphan designation (EU/3/11/884) was granted by the European Commission to Endotis Pharma, France, for Methyl O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]-N2-[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]-L- α -asparaginy]-4-aminobutanoyl-N6-[5-[(3aS,4S,6aR)-hexahydro-2-oxo-1H-thieno[3,4-d]imidazol-4-yl]-1-oxopentyl]-L-lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di-O-methyl-6-O-sulfo- α -D-glucopyranosyl-(1 $\rightarrow$ 4)-O-2,3-di-O-methyl- β -D-glucopyranuronosyl-(1 $\rightarrow$ 4)-O-2,3,6-tri-O-sulfo- α -D-glucopyranosyl-(1 $\rightarrow$ 4)-O-2,3-di-O-methyl- α -L-idopyranuronosyl-(1 $\rightarrow$ 4)-3-O-methyl- α -D-glucopyranoside 2,6-bis(hydrogen sulfate) octasodium salt for the prevention of ischaemia/reperfusion injury associated with solid organ transplantation.

What is ischaemia/reperfusion injury associated with solid organ transplantation?

Ischaemia and reperfusion injury are problems that can occur to transplant organs as a result of being preserved during the time between donation and transplant. In the course of a transplant, the organ to be transplanted (the 'graft') needs to survive outside the body with no blood supply for a short while. This decrease in blood supply, if prolonged, can cause damage to the organ because of the lack of oxygen and nutrients, a condition called ischaemia. When the graft is attached to the recipient's blood circulation, the restoration of blood supply to the organ (reperfusion) can cause inflammation and damage to the organ, known as reperfusion injury. These processes increase the risk of the graft not working or being rejected by the recipient.

Because ischaemia/reperfusion injury in solid organ transplantation impairs the functioning of the graft, it is a life-threatening condition for the recipient of the graft.



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

At the time of designation, the number of patients at risk of ischaemia/reperfusion injury associated with solid organ transplantation was estimated to be around 0.6 people in 10,000 per year in the European Union (EU)*. This is equivalent to a total of around 30,000 people per year, which 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 methods of prevention are available?

At the time of designation, there were no treatments authorised for ischaemia/reperfusion injury. Methods used to reduce the effects of ischaemia included storage of the organ in cold conditions in special preservation solutions. Two such solutions were authorised for organ preservation in some countries of the EU at the time of designation.

The sponsor has provided sufficient information to show that this medicine might be of significant benefit for patients at risk of ischaemia/reperfusion injury associated with solid organ transplantation because it works in a different way to existing methods and early studies in experimental models show that it might improve the outcome of patients undergoing an organ transplant, particularly when used in combination with existing methods. This assumption will need to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.

How is this medicine expected to work?

This medicine is an anticoagulant, which prevents coagulation (clotting) of the blood which can occur in the vessels of the transplant organ. It works by blocking certain enzymes involved in the process of blood clotting. Since the formation of blood clots is part of the complex process leading to ischaemia, this medicine is expected to reduce the risk of ischaemia in the graft. As coagulation and inflammation are closely related, this medicine may also reduce the inflammation associated with ischaemia and reperfusion. This is expected to reduce the risk of reperfusion injury following an organ transplant.

What is the stage of development of this medicine?

The effects of this medicinal product have been evaluated in experimental models.

At the time of submission of the application for orphan designation, no clinical trials with this medicinal product in patients at risk of ischaemia/reperfusion injury associated with solid organ transplantation had been started.

At the time of submission, this medicinal product was not authorised anywhere in the EU for the prevention of ischaemia/reperfusion injury associated with solid organ transplantation 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 5 May 2011 recommending the granting of this designation.

*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 506,300,000 (Eurostat 2011).

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:

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Telefax: +33 1 48 46 98 29
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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 languages¹, Norwegian and Icelandic

Language	Active ingredient	Indication
English	Methyl <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]- <i>N</i> ² -[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]- <i>L</i> -α-asparaginy]-4-aminobutanoyl- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahydro-2-oxo-1 <i>H</i> -thieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentyl]- <i>L</i> -lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di- <i>O</i> -methyl-6- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-β- <i>D</i> -glucopyranuronosyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-α- <i>L</i> -idopyranuronosyl-(1→4)-3- <i>O</i> -methyl-α- <i>D</i> -glucopyranoside 2,6-bis(hydrogen sulfate) octasodium salt	Prevention of ischaemia/reperfusion injury associated with solid organ transplantation
Bulgarian	Метил <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(аминоиминометил)фенил]метил]-2-оксо-2-(1-пиперидинил)етил]- <i>N</i> ² -[(4-метокси-2,3,6-триметилфенил)сулфонил]- <i>L</i> -α-аспарагинил-4-аминобутаноил- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-хексахидро-2-оксо-1 <i>H</i> -тиено[3,4- <i>d</i>]имидазол-4-ил]-1-оксопентил]- <i>L</i> -лизил]амино]етокси]етокси]етокси]етил]-2,3-ди- <i>O</i> -метил-6- <i>O</i> -сулфо-α- <i>D</i> -глюкопиранозил-(1→4)- <i>O</i> -2,3-ди- <i>O</i> -метил-β- <i>D</i> -глюкопирануринозил-(1→4)- <i>O</i> -2,3,6-три- <i>O</i> -сулфо-α- <i>D</i> -глюкопиранозил-(1→4)- <i>O</i> -2,3-ди- <i>O</i> -метил-α- <i>L</i> -идопирануринозил-(1→4)-3- <i>O</i> -метил-α- <i>D</i> -глюкопиранозид 2,6-бис(хидрогенсулфат)октанатриева сол	Превенция на исхемия/реперфузия увреда, свързана с трансплантация на плътни органи.
Czech	Oktasodná sůl methyl <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminomethyl)fenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]- <i>N</i> ² -[(4-methoxy-2,3,6-trimethylfenyl)sulfonyl]- <i>L</i> -α-asparaginy]-4-aminobutanoyl- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahydro-2-oxo-1 <i>H</i> -thieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentyl]- <i>L</i> -lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di- <i>O</i> -methyl-6- <i>O</i> -sulfo-α- <i>D</i> -glukopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-β- <i>D</i> -glukopyranuronosyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glukopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-α- <i>L</i> -idopyranuronosyl-(1→4)-3- <i>O</i> -methyl-2,6-di- <i>O</i> -sulfo-α- <i>D</i> -glukopyranosidu	Prevence ischemie/reperfuzního poškození u transplantace solidních orgánů

¹ At the time of designation

Language	Active ingredient	Indication
Danish	Methyl <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidiny]ethyl]- <i>N</i> ² -[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]- <i>L</i> -α-asparaginy]l-4-aminobutanoyl- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahydro-2-oxo-1 <i>H</i> -thieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentyl]- <i>L</i> -lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di- <i>O</i> -methyl-6- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-β- <i>D</i> -glucopyranuronosyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-α- <i>L</i> -idopyranuronosyl-(1→4)-3- <i>O</i> -methyl-α- <i>D</i> -glucopyranosid 2,6-bis(hydrogensulfat) octanatriumsalt	Prævention af den iskæmi/reperfusionsskade associeret med transplantation af solide organer
Dutch	Methyl <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminomethyl)fenyl]methyl]-2-oxo-2-(1-piperidiny]ethyl]- <i>N</i> ² -[(4-methoxy-2,3,6-trimethylfenyl)sulfonyl]- <i>L</i> -α-asparaginy]l-4-aminobutanoyl- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahydro-2-oxo-1 <i>H</i> -thieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentyl]- <i>L</i> -lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di- <i>O</i> -methyl-6- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-β- <i>D</i> -glucopyranuronosyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-α- <i>L</i> -idopyranuronosyl-(1→4)-3- <i>O</i> -methyl-α- <i>D</i> -glucopyranoside 2,6-bis(waterstofsulfaat) octanatriumzout	Preventie van ischemie- / reperfusieletsel geassocieerd aan soliede orgaantransplantatie
Estonian	Metüül <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometüül)fenüül]metüül]-2-okso-2-(1-piperidinüül)etüül]- <i>N</i> ² -[(4-metoksü-2,3,6-trimetüülfenüül)sulfonüül]- <i>L</i> -α-asparaginüül-4-aminobutanoüül- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-heksahüdro-2-okso-1 <i>H</i> -tieno[3,4- <i>d</i>]imidasool-4-yl]-1-okso-pentüül]- <i>L</i> -lüsüül]amino]etoksü]etoksü]etoksü]etüül]-2,3-di- <i>O</i> -metüül-6- <i>O</i> -sulfo-α- <i>D</i> -glükopüranosüül-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metüül-β- <i>D</i> -glükopüranuronosüül-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glükopüranosüül-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metüül-α- <i>L</i> -idopüranuronosüül-(1→4)-3- <i>O</i> -metüül-α- <i>D</i> -glükopüranosiid 2,6-bis(vesiniksulfaat) okta-naatriumsool	Soliidorganite siirdamisega seotud isheemia/reperfusioonvi gastuse ennetamine
Finnish	Metyyli <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometyyli)fenyyli]metyyli]-2-okso-2-(1-piperidinyyli)etyyli]- <i>N</i> ² -[(4-metoksi-2,3,6-trimetyylifenyyli)sulfonyyli]- <i>L</i> -α-asparaginyyli-4-aminobutanoyyli- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-heksahydro-2-okso-1 <i>H</i> -tieno[3,4- <i>d</i>]imidatsoli-4-yyli]-1-okso-pentyyli]- <i>L</i> -lyssyyli]amino]etoksi]etoksi]etoksi]etyyli]-2,3-di- <i>O</i> -metyyli-6- <i>O</i> -sulfo-α- <i>D</i> -glukopyranosyyli-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metyyli-β- <i>D</i> -glukopyranuronosyyli-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glukopyranosyyli-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metyyli-α- <i>L</i> -idopyranuronosyyli-(1→4)-3- <i>O</i> -metyyli-α- <i>D</i> -glukopyranosidi 2,6-bis(vetyysulfaatti) oktanatriumsuola	Iskemia- /reperfuusiovaurio esto elinsiirtoleikkauksessa

Language	Active ingredient	Indication
French	Sel octasodique du méthyl O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(aminoiminométhyl)phényl]méthyl]-2-oxo-2-(pipéridin-1-yl)éthyl]-N ² -[(4-méthoxy-2,3,6-triméthylphényl)sulfonyl]-L-α-asparaginy]-4-aminobutanoyl-N ⁶ -[5-[(3aS,4S,6aR)-hexahydro-2-oxo-1H-thiéno[3,4-d]imidazol-4-yl]-1-oxopentyl]-L-lysyl]amino]éthoxy]éthoxy]éthoxy]éthyl]-2,3-di-O-méthyl-6-O-sulfo-α-D-glucopyranosyl-(1→4)-O-2,3-di-O-méthyl-β-D-glucopyranuronosyl-(1→4)-O-2,3,6-tri-O-sulfo-α-D-glucopyranosyl-(1→4)-O-2,3-di-O-méthyl-α-L-idopyranuronosyl-(1→4)-3-O-méthyl-2,6-di-O-sulfo-α-D-glucopyranoside	Prévention des lésions d'ischémie-reperfusion associées aux transplantations d'organes solides
German	Methyl O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidinyl)ethyl]-N ² -[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]-L-α-asparaginy]-4-aminobutanoyl-N ⁶ -[5-[(3aS,4S,6aR)-hexahydro-2-oxo-1H-thieno[3,4-d]imidazol-4-yl]-1-oxopentyl]-L-lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di-O-methyl-6-O-sulfo-α-D-glucopyranosyl-(1→4)-O-2,3-di-O-methyl-β-D-glucopyranuronosyl-(1→4)-O-2,3,6-tri-O-sulfo-α-D-glucopyranosyl-(1→4)-O-2,3-di-O-methyl-α-L-idopyranuronosyl-(1→4)-3-O-methyl-α-D-glucopyranosid 2,6-bis(hydrogen sulfat) octanatrium Salz	Prävention von Ischämie-/Reperfusionssyndromen bei Transplantation solider Organe
Greek	Μεθυλο O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(αμινοϊμινομεθυλο)φαινυλο]μεθυλο]-2-οξο-2-(1-πιπεριδινυλο)αιθυλο]-N ² -[(4-μεθοξυ-2,3,6-τριμεθυλοφαινυλο)σουλφονυλ]-L-α-ασπαραγινυλο-4-αμινοβουτανοϋλο-N ⁶ -[5-[(3aS,4S,6aR)-εξαϋδρο-2-οξο-1H-θιενο[3,4-d]ιμιδαζολο-4-υλ]-1-οξοπεντυλ]-L-λυσυλο]αμινο]εθοξυ]εθοξυ]εθοξυ]αιθυλο]-2,3-δι-O-μεθυλο-6-O-σουλφο-α-D-γλυκοκυρανοσυλο-(1→4)-O-2,3-δι-O-μεθυλο-β-D-γλυκοκυρανοουρονοσυλο-(1→4)-O-2,3,6-τρι-O-σουλφο-α-D-γλυκοκυρανοσυλο-(1→4)-O-2,3-δι-O-μεθυλο-α-L-ιδοκυρανοουρονοσυλο-(1→4)-3-O-μεθυλο-α-D-γλυκοκυρανοζίδιο 2,6-δισ(θειϊκό άλας υδρογόνου) άλας οκτανατρίου	Πρόληψη της ισχαιμίας/τραυματισμού λόγω επαναιμάτωσης που συσχετίζεται με τη μεταμόσχευση συμπαγών οργάνων
Hungarian	Metil O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(amino-imino-metil)fenil]metil]-2-oxo-2-(1-piperidinil)etil]-N ² -[(4-metoxi-2,3,6-trimetil-fenil)sulfonyl]-L-α-aszparaginil-4-amino-butanoil-N ⁶ -[5-[(3aS,4S,6aR)-hexahidro-2-oxo-1H-tieno[3,4-d]imidazol-4-il]-1-oxopentil]-L-lizil]amino]etoxi]etoxi]etoxi]etil]-2,3-di-O-metil-6-O-szulfo-α-D-glükopiranozil-(1→4)-O-2,3-di-O-metil-β-D-glükopiranuronozil-(1→4)-O-2,3,6-tri-O-szulfo-α-D-glükopiranozil-(1→4)-O-2,3-di-O-metil-α-L-idopiranuronozil-(1→4)-3-O-metil-α-D-glükopiranozid 2,6-bisz(hidrogén-szulfát) oktanátrium só	Szervátültetéssel összefüggő ischémia/reperfúziós károsodás megelőzése

Language	Active ingredient	Indication
Italian	Sale octasodico di metil <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometil)fenil]metil]-2-oxo-2-(1-piperidinil)etil]- <i>N</i> ² -[(4-metossi-2,3,6-trimetilfenil)sulfonyl]- <i>L</i> -α-asparaginil-4-aminobutanoil- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-esaidro-2-oxo-1 <i>H</i> -tieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentil]- <i>L</i> -lisil]amino]etossi]etossi]etossi]etil]-2,3-di- <i>O</i> -metil-6- <i>O</i> -sulfo-α- <i>D</i> -glucopiranosil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-β- <i>D</i> -glucopiranuronosil-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopiranosil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-α- <i>L</i> -idopiranuronosil-(1→4)-3- <i>O</i> -metil-α- <i>D</i> -glucopiranoside 2,6-di(idrogeno solfato)	Prevenzione del danno da ischemia/riperfusione associato al trapianto di organi solidi
Latvian	Metil <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometil)fenil]metil]-2-okso-2-(1-piperidinil)etil]- <i>N</i> ² -[(4-metoksi-2,3,6-trimetilfenil)sulfonyl]- <i>L</i> -α-asparaginil-4-aminobutanoil- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-heksahidro-2-okso-1 <i>H</i> -tieno[3,4- <i>d</i>]imidazol-4-il]-1-oksopentil]- <i>L</i> -lisil]amino]etoksi]etoksi]etoksi]etil]-2,3-di- <i>O</i> -metil-6- <i>O</i> -sulfo-α- <i>D</i> -glikopiranozil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-β- <i>D</i> -glikopiranuronozil-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glikopiranozil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-α- <i>L</i> -idopiranuronozil-(1→4)-3- <i>O</i> -metil-α- <i>D</i> -glikopiranozīda 2,6-bis(hidrogēnsulfāta) oktanātrija sāls	Išēmisko/reperfūzijas bojājumu profilakse saistībā ar orgānu transplantāciju
Lithuanian	Metil <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometil)fenil]metil]-2-okso-2-(1-piperidinil)etil]- <i>N</i> ² -[(4-metoksi-2,3,6-trimetilfenil)sulfonyl]- <i>L</i> -α-asparaginil-4-aminobutanoil- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-heksahidro-2-okso-1 <i>H</i> -tieno[3,4- <i>d</i>]imidazol-4-il]-1-oksopentil]- <i>L</i> -lizil]amino]etoksi]etoksi]etoksi]etil]-2,3-di- <i>O</i> -metil-6- <i>O</i> -sulfo-α- <i>D</i> -gliukopiranozil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-β- <i>D</i> -gliukopiranuronozil-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -gliukopiranozil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-α- <i>L</i> -idopiranuronozil-(1→4)-3- <i>O</i> -metil-α- <i>D</i> -gliukopiranozido 2,6-bis(hidrogensulfato) oktanatrio druska	Išemijos / reperfuzijos pažeidimo prevencija, susijusi su parenchiminių organų transplantacija
Maltese	Melħ octasodium ta' methyl <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminomethyl)phenyl]methyl]-2-oxo-2-(1-piperidiny]ethyl]- <i>N</i> ² -[(4-methoxy-2,3,6-trimethylphenyl)sulfonyl]- <i>L</i> -α-asparaginy]l-4-aminobutanoyl- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahydro-2-oxo-1 <i>H</i> -thieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentyl]- <i>L</i> -lysyl]amino]ethoxy]ethoxy]ethoxy]ethyl]-2,3-di- <i>O</i> -methyl-6- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-β- <i>D</i> -glucopyranuronosyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopyranosyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -methyl-α- <i>L</i> -idopyranuronosyl-(1→4)-3- <i>O</i> -methyl-α- <i>D</i> -glucopyranoside 2,6-bis(hydrogen sulfate)	Prevenzjoni tad-dannu minn iskemija/riperfusjoni assoċjat mat-trapjant ta' organi solidi

Language	Active ingredient	Indication
Polish	Sól ośmiosodowa metylo <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometylo) fenylo]metylo]-2-okso-2-(1-piperydynylo)etylo]- <i>N</i> ² -[(4-metoksy-2,3,6-trimetylfenylo) sulfonylo]- <i>L</i> -α-asparaginylo-4-aminobutanoil- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-heksahydro-2-okso-1 <i>H</i> -tieno[3,4- <i>d</i>]imidazolo-4-yl]-1-okso-pentylo]- <i>L</i> -lizylo]amino]etoksy]etoksy]etoksy]etylo]-2,3-di- <i>O</i> -metyl-6- <i>O</i> -sulfo-α- <i>D</i> -glukopiranozyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metyl-β- <i>D</i> -glukopiranuronozyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glukopiranozyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metyl-α- <i>L</i> -idopiranuronozyl-(1→4)-3- <i>O</i> -metyl-α- <i>D</i> -glukopiranozyd 2,6-bis(kwaśnego siarczanu)	Zapobieganie uszkodzeniu narządu spowodowanego niedokrwieniem/reperfuzją związanym z przeszczepem narządów litych
Portuguese	Sal octassódico de Metil <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometil)fenil]metil]-2-oxo-2-(1-piperidinil)etil]- <i>N</i> ² -[(4-metoxi-2,3,6-trimetilfenil)sulfonil]- <i>L</i> -α-asparaginil-4-aminobutanoil- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahidro-2-oxo-1 <i>H</i> -tieno[3,4- <i>d</i>]imidazol-4-il]-1-oxopentil]- <i>L</i> -lisil]amino]etoxi]etoxi]etoxi]etil]-2,3-di- <i>O</i> -metil-6- <i>O</i> -sulfo-α- <i>D</i> -glucopiranosil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-β- <i>D</i> -glucopiranuronosil-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopiranosil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-α- <i>L</i> -idopiranuronosil-(1→4)-3- <i>O</i> -metil-α- <i>D</i> -glucopiranosido 2,6-bis(hidrogenossulfato)	Prevenção da lesão de isquémia/reperfusão associada ao transplante de órgãos sólidos
Romanian	Sare octasodică de metil <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometil)fenil]metil]-2-oxo-2-(1-piperidinil)etil]- <i>N</i> ² -[(4-metoxi-2,3,6-trimetilfenil)sulfonil]- <i>L</i> -α-asparaginil-4-aminobutanoil- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahidro-2-oxo-1 <i>H</i> -tieno[3,4- <i>d</i>]imidazol-4-il]-1-oxopentil]- <i>L</i> -lisil]amino]etoxi]etoxi]etoxi]etil]-2,3-di- <i>O</i> -metil-6- <i>O</i> -sulfo-α- <i>D</i> -glucopiranozil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-β- <i>D</i> -glucopiranuronozil-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glucopiranozil-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metil-α- <i>L</i> -idopiranuronozil-(1→4)-3- <i>O</i> -metil-α- <i>D</i> -glucopiranozid 2,6-di(hidrogen sulfat)	Prevenirea leziunilor de ischemie /reperfuzie asociate cu transplantul de organe solide
Slovak	Oktasodná soľ metyl <i>O</i> -4- <i>O</i> -[2-[2-[2-[2-[<i>N</i> -[(1 <i>R</i>)-1-[[4-(aminoiminometyl)fenyl]metyl]-2-oxo-2-(1-piperidinyl)etyl]- <i>N</i> ² -[(4-metoxi-2,3,6-trimetylfenyl)sulfonyl]- <i>L</i> -α-asparaginylo-4-aminobutanoyl- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahydro-2-oxo-1 <i>H</i> -thieno[3,4- <i>d</i>]imidazol-4-yl]-1-oxopentyl]- <i>L</i> -lysyl]amino]etoxyl]etoxyl]etoxyl]etyl]-2,3-di- <i>O</i> -metyl-6- <i>O</i> -sulfo-α- <i>D</i> -glukopyranozyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metyl-β- <i>D</i> -glukopyranuronozyl-(1→4)- <i>O</i> -2,3,6-tri- <i>O</i> -sulfo-α- <i>D</i> -glukopyranozyl-(1→4)- <i>O</i> -2,3-di- <i>O</i> -metyl-α- <i>L</i> -idopyranuronozyl-(1→4)-3- <i>O</i> -metyl-α- <i>D</i> -glukopyranozid 2,6-bis(hydrogénsíranu)	Prevenia ischemicko-reperfúzneho poškodenia súvisiaceho s postupom pri transplantácii solídneho orgánu

Language	Active ingredient	Indication
Slovenian	Metil O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(aminoiminometil)fenil]metil]-2-okso-2-(1-piperidinil)etil]-N ² -[(4-metoksi-2,3,6-trimetilfenil)sulfonyl]-L-α-asparaginil-4-aminobutanoil-N ⁶ -[5-[(3aS,4S,6aR)-heksahidro-2-okso-1H-tieno[3,4-d]imidazol-4-il]-1-oksopentil]-L-lizil]amino]etoksi]etoksi]etoksi]etil]-2,3-di-O-metil-6-O-sulfo-α-D-glukopiranozil-(1→4)-O-2,3-di-O-metil-β-D-glukopiranuronozil-(1→4)-O-2,3,6-tri-O-sulfo-α-D-glukopiranozil-(1→4)-O-2,3-di-O-metil-α-L-idopiranuronozil-(1→4)-3-O-metil-α-D-glukopiranozid 2,6-bis(hidrogensulfat) oktanatrijeva sol	Preprečevanje ishemične/reperfuzijske poškodbe, povezane s presaditvijo parenhimskih organov
Spanish	Sal octasódica del metil O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(aminoiminometil)fenil]metil]-2-oxo-2-(1-piperidinil)etil]-N ² -[(4-metoxi-2,3,6-trimetilfenil)sulfonyl]-L-α-asparaginil-4-aminobutanoil-N ⁶ -[5-[(3aS,4S,6aR)-hexahidro-2-oxo-1H-tieno[3,4-d]imidazol-4-il]-1-oxopentil]-L-lisil]amino]etoxi]etoxi]etoxi]etil]-2,3-di-O-metil-6-O-sulfo-α-D-glucopiranosil-(1→4)-O-2,3-di-O-metil-β-D-glucopiranuronosil-(1→4)-O-2,3,6-tri-O-sulfo-α-D-glucopiranosil-(1→4)-O-2,3-di-O-metil-α-L-idopiranuronosil-(1→4)-3-O-metil-α-D-glucopiranosido 2,6-bis(sulfato de hidrógeno)	Prevención del daño por isquemia/reperfusión asociado al transplante de órganos sólidos
Swedish	Metyl O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(aminoiminometyl)fenyl]metyl]-2-oxo-2-(1-piperidinyl)etyl]-N ² -[(4-metoxi-2,3,6-trimetylphenyl)sulfonyl]-L-α-asparaginy-4-aminobutanoyl-N ⁶ -[5-[(3aS,4S,6aR)-hexahydro-2-oxo-1H-tieno[3,4-d]imidazol-4-yl]-1-oxopentyl]-L-lysyl]amino]etoxi]etoxi]etoxi]etyl]-2,3-di-O-metyl-6-O-sulfo-α-D-glukopyranosyl-(1→4)-O-2,3-di-O-metyl-β-D-glukopyranuronosyl-(1→4)-O-2,3,6-tri-O-sulfo-α-D-glukopyranosyl-(1→4)-O-2,3-di-O-metyl-α-L-idopyranuronosyl-(1→4)-3-O-methyl-α-D-glukopyranosid 2,6-bis(vätesulfat) oktanatriumsalt	Förebyggande av ischemia/reperfusionsskada i samband med organtransplantation
Norwegian	Metyl O-4-O-[2-[2-[2-[2-[N-[(1R)-1-[[4-(aminoiminometyl)fenyl]metyl]-2-okso-2-(1-piperidinyl)etyl]-N ² -[(4-metoksy-2,3,6-trimetylphenyl)sulfonyl]-L-α-asparaginy-4-aminobutanoyl-N ⁶ -[5-[(3aS,4S,6aR)-heksahydro-2-okso-1H-tieno[3,4-d]imidazol-4-yl]-1-oksopentyl]-L-lysyl]amino]etoksy]etoksy]etoksy]etyl]-2,3-di-O-metyl-6-O-sulfo-α-D-glukopyranosyl-(1→4)-O-2,3-di-O-metyl-β-D-glukopyranuronosyl-(1→4)-O-2,3,6-tri-O-sulfo-α-D-glukopyranosyl-(1→4)-O-2,3-di-O-metyl-α-L-idopyranuronosyl-(1→4)-3-O-metyl-α-D-glukopyranosid 2,6-bis(hydrogensulfat) oktanatriumsalt	Forebygging av iskemi/reperfusjonsskade forbundet med solid organ-transplantasjon

Language	Active ingredient	Indication
Icelandic	Metýl O-4-O-[2-[2-[2-[N-[(1 <i>R</i>)-1-[[4-(amínóímínómetýl)fenýl]metýl]-2-oxó-2-(1-píperídínýl)etýl]- <i>N</i> ² -[(4-metoxý-2,3,6-trímetýlfenýl)súlfónýl]-L-α-asparagínýl-4-amínóbútanóýl]- <i>N</i> ⁶ -[5-[(3 <i>aS</i> ,4 <i>S</i> ,6 <i>aR</i>)-hexahýdró-2-oxó-1 <i>H</i> -tíenó[3,4- <i>d</i>]ímídazól-4-ýl]-1-oxópentýl]-L-lýsýl]amínó]etoxý]etoxý]etoxý]etýl]-2,3-dí-O-metýl-6-O-súlfó-α-D-glúkópýranósýl-(1→4)-O-2,3-dí-O-metýl-β-D-glúkópýranúrónósýl-(1→4)-O-2,3,6-trí-O-súlfó-α-D-glúkópýranósýl-(1→4)-O-2,3-dí-O-metýl-α-L-ídópýranúrónósýl-(1→4)-3-O-metýl-α-D-glúkópýranósíð 2,6-bis(hýdrógensúlfat) oktanatríumsalt	Forvörn gegn blóðþurrðar/endurblóðv æðingar skaða í tengslum við líffæraígræðslu.