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Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

Ovine anti-colchicine polyclonal antibody fragments for the treatment of colchicine poisoning

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Disclaimer 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 17 December 2010, orphan designation (EU/3/10/825) was granted by the European Commission to Laboratoires SERB, France, for ovine anti-colchicine polyclonal antibody fragments for the treatment of colchicine poisoning.

What is colchicine poisoning?

Colchicine is a natural product that was originally extracted from plants. It is used mainly to treat gout (high levels of uric acid in the blood causing symptoms especially painful inflammation in the joints). Colchicine is toxic at doses that are very close to the dose used for treatment and this can lead to poisoning.

Colchicine poisoning can be intentional (mainly by suicide attempts) or happen by mistake, through a single overdose or excessive use of colchicine-containing medicines over time, particularly in patients with kidney or liver problems as they are less able to eliminate it from the body.

Colchicine poisoning is potentially life threatening as it can rapidly lead to severe complications including cardiogenic shock (inadequate circulation of blood due to the heart's failure to function properly), respiratory failure and multiple organ failure.

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

At the time of designation, colchicine poisoning affected less than 0.01 people in 10,000 per year in the European Union (EU). This is equivalent to a total of fewer than 500 people per year[*], which was considered to be below the ceiling for orphan designation. 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 designation, there were no satisfactory methods of treatment authorised in the EU for colchicine poisoning. Depending on the stage and severity of the poisoning, the condition was treated with procedures intended to stop the body absorbing the poisonous substance from the gut and to treat the resulting complications. These include emergency procedures such as gastric lavage (stomach pumping), oxygen supplementation, fluid replacement and emergency life support treatment.

How is this medicine expected to work?

Ovine anti-colchicine polyclonal antibody fragments are expected to be used as an antidote to colchicine. They are made from antibodies produced from sheep. An antibody is a protein that helps the body to fight infections and other diseases by attaching to and helping to destroy antigens.

The antibody fragments are expected to work by attaching to colchicine in the human body. This prevents colchicine from attaching to the protein that it normally attaches to inside the cells, redistributing it away from the cells. This prevents damage to the organs and body tissues and allows the colchicine to be eliminated through the urine.

What is the stage of development of this medicine?

The effects of anti-colchicine polyclonal antibody fragments derived from goats, but not from sheep, have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials with ovine anti-colchicine polyclonal antibody fragments were planned but had not been started.

At the time of submission, ovine anti-colchicine polyclonal antibody fragments were not authorised anywhere in the EU for colchicine poisoning 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 7 October 2010 recommending the granting of this designation.

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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 (EU 27), Norway, Iceland and Liechtenstein.
At the time of designation, this represented a population of 506,300,000 (Eurostat 2010).

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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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[1], Norwegian and Icelandic

Language	Active ingredient	Indication
English	Ovine anti-colchicine polyclonal antibody fragments	Treatment of colchicine poisoning
Bulgarian	Овчи анти-колхицин поликлонални антителни фрагменти	Лечение на отравяне с колхицин
Czech	Fragmenty ovčí polyklonální protilátky proti kolchicinu	Léčba otravy kolchicinem
Danish	Fragmenter af ovint polyklonalt anticolchicin-antistof	Behandling af colchicin-forgiftning
Dutch	Anti-colchicine polyklonale antistoffragmenten bij schapen	Behandeling van colchicinevergiftiging
Estonian	Lamba kolhitsiinivastase polüklonaalse antikeha fragmendid	Kolhitsiinimürgistuse ravi
Finnish	Lampaan polyklonaaliset kolkisiinivasta-ainefragmentit	Kolkisiinimyrkytyksen hoito
French	Fragments d'anticorps polyclonaux anti-colchicine d'origine ovine	Traitement de l'intoxication à la colchicine
German	Polyklonale Colchicin-Antikörperfragmente vom Schaf	Behandlung einer Colchicinvergiftung
Greek	Τμήματα πολυκλωνικού αντισώματος προβάτου κατά της κολχικίνης	Θεραπεία της δηλητηρίασης από κολχικίνη
Hungarian	Birka kolhicin ellenes poliklonális ellenanyag fragmentumok	Kolhicin mérgezés kezelése
Italian	Frammenti anticorpali policlonali anti-colchicina di origine ovina	Trattamento dell'avvelenamento da colchicina
Latvian	Aitu anti-kolhicīna poliklonālo antivielu fragmenti	Saindēšanās ar kolhicīnu ārstēšana
Lithuanian	Aitu anti-kolhicīna poliklonālo antivielu fragmenti	Apsinuodijimo kolchicinu gydymas
Maltese	Frammenti ta' antikorpi poliklonali anti-colchicine li ġejjin min-nagħaġ	Kura ta' avvelenament miċ-colchicine
Polish	Fragmenty owczych przeciwciał poliklonalnych anty-kolchicynowych	Leczenie zatrucia kolchicyną
Portuguese	Fragmentos de anticorpo policlonal ovino anti-colchicina.	Tratamento da intoxicação por colchicina
Romanian	Fragmente de anticorpi policlonali anti-colchicină de origine ovină	Tratamentul intoxicaţiei cu colchicină
Slovak	Fragmenty ovčej polyklonálnej protilátky proti kolchicínu	Liečba otravy kolchicínom
Slovenian	Fragmenti ovčjih poliklonskih protiteles proti kolhicinu	Zdravljenje zastrupitve s kolhicinom

[1] At the time of designation

Spanish	Fragmentos de anticuerpo policlonal anticolchicina de origen ovino	Tratamiento de la intoxicación por colchicina
Swedish	Fragment av polyklonala anti-kolkicinantikroppar från får	Behandling av kolkicinförgiftning
Norwegian	Anti-kolkisin-polyklonale antistoffragmenter fra sau	Behandling av kolkisinforgiftning
Icelandic	Fjölklóna mótefnabrot úr sauðfé gegn kolcicíni	Meðferð við kolcicín eitrun