



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 May 2020
EMADOC-628903358-1825

Public summary of opinion on orphan designation

Nicardipine for the treatment of non-traumatic subarachnoid haemorrhage

On 9 January 2020, orphan designation EU/3/19/2240 was granted by the European Commission to BIT Pharma GmbH, Austria, for nicardipine for the treatment of non-traumatic subarachnoid haemorrhage.

What is non-traumatic subarachnoid haemorrhage?

Non-traumatic subarachnoid haemorrhage is bleeding into the subarachnoid space (the space between two membranes that surround the brain). The bleeding is not due to an injury to the head but is usually caused by the bursting of a weakened blood-vessel wall in the brain (a cerebral aneurysm). It is a form of stroke, and the bleeding increases pressure on the brain and damages surrounding brain tissue. In addition, blood vessels near the site of the aneurysm go into spasm (vasospasm) reducing the supply of oxygen and essential nutrients to brain cells from the blood. Patients may develop seizures (fits) and other complications including heart problems.

Non-traumatic subarachnoid haemorrhage is life threatening and debilitating because of brain damage, impairment of brain functions and heart problems.

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

At the time of designation, non-traumatic subarachnoid haemorrhage affected approximately 1 in 10,000 people per year in the European Union (EU). This was equivalent to a total of around 52,000 people per year*, and is 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?

Treatment of subarachnoid haemorrhage involves surgery or a procedure using a catheter to close or block off the bleeding blood vessel. At the time of designation, nimodipine, a medicine that relaxes blood vessels and lowers blood pressure, was authorised in the EU for the prevention and treatment of complications due to vasospasm following subarachnoid haemorrhage.

*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 (European Union (EU 28), Norway, Iceland and Liechtenstein). This represents a population of 518,400,000 (Eurostat 2019).



The sponsor has provided sufficient information to show that the medicine might be of significant benefit for patients with non-traumatic subarachnoid haemorrhage because early results suggest it may reduce the risk of vasospasm better than nimodipine. 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?

Nicardipine is a medicine known as a calcium-channel blocker that has been used in the EU for many years to treat angina (chest pains caused by reduced blood flow to the heart) and high blood pressure. Like the related substance nimodipine it relaxes and widens blood vessels, reducing blood pressure and improving the flow of blood. In this medicine it has been incorporated into an implant that steadily releases nicardipine. When this is implanted in the brain during surgery to repair the bleeding blood vessel, it supplies nicardipine just to the area where it is needed, relaxing the surrounding blood vessels and preventing them from going into vasospasm.

What is the stage of development of this medicine?

The effects of the medicine have been evaluated in experimental models.

At the time of submission of the application for orphan designation, clinical trials with the medicine in patients with non-traumatic subarachnoid haemorrhage were ongoing.

At the time of submission, the medicine was not authorised anywhere in the EU for the treatment of non-traumatic subarachnoid haemorrhage or designated as an orphan medicinal product elsewhere for this condition.

In accordance with Regulation (EC) No 141/2000, the COMP adopted a positive opinion on 5 December 2019, 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:

Contact details of the current sponsor for this orphan designation can be found on [EMA website](#).

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	Nicardipine	Treatment of non-traumatic subarachnoid haemorrhage
Bulgarian	Никардипин	Лечение на нетравматичен субарахноидален кръвоизлив
Croatian	Nikardipin	Liječenje netraumatskog subarahnoidalnog krvarenja
Czech	Nikardipin	Léčbě ne traumatického subarahnoidálního krvácení
Danish	Nicardipin	Behandling af ikke traumatisk subaraknoidalblødning
Dutch	Nicardipine	Behandeling van niet-traumatische subarachnoïdale bloeding
Estonian	Nikardipiin	Mittetraumaatilise subarahnoidaalse hemorraagia ravi
Finnish	Nikardipiini	Lukinkalvonalaisen ei-traumaattisen verenvuodon hoito
French	Nicardipine	Traitement de l'hémorragie sous-arachnoïdienne non-traumatique
German	Nicardipin	Behandlung von nicht traumatischer Subarahnoidalblutungen
Greek	Νικαρδινίνη	θεραπεία της μη-τραυματικής υπαραχνοειδούς αιμορραγίας
Hungarian	Nikardipin	Nem traumás szubarachnoid vérzés kezelése
Italian	Nicardipina	Trattamento dell'emorragia subaracnoidea non traumatica
Latvian	Nikardipīns	Netraumatiska subarahnoidāla asinsizplūduma ārstēšana
Lithuanian	Nikardipinas	Netrauminio subarahnoidinio kraujavimo gydymas
Maltese	Nikardipina	Kura ta' emorraġija subaraknojde mhux trawmatika
Polish	Nikardypina	Leczenie nie urazowego krwotoku podpajęczynówkowego
Portuguese	Nicardipina	Tratamento de hemorragia subaracnóidea não traumática
Romanian	Nicardipină	Tratamentul hemoragiei subarahnoidiene non-traumatice
Slovak	Nikardipín	Liečba netraumatického subarahnoidálneho krvácania
Slovenian	Nikardipin	Zdravljenje netravmatske subarahnoidne krvavitve
Spanish	Nicardipina	Tratamiento de la hemorragia subaracnoidea no traumática
Swedish	Nikardipin	Behandling av icke-traumatisk subaraknoidalblødning
Norwegian	Nikardipin	Behandling av ikke-traumatisk subaraknoidalblødning
Icelandic	Nikardipín	Meðferð við innanskúmsblæðingu án áverka

¹ At the time of designation