EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 September 2015
EMA/COMP/508488/2015
Committee for Orphan Medicinal Products

Public summary of opinion on orphan designation

2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)- 2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl -(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidilyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidine, sodium salt for the treatment of diffuse large B-cell lymphoma

withdrawn

On 10 August 2015, orphan designation (EU/3/15/1542) was granted by the European Commission to PhaRA bvba, Belgium, for 2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)- 2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl -(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidilyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidine, sodium salt medicine for treatment of diffuse large B-cell lymphoma.

What is diffuse large B-cell lymphoma?

Diffuse large B-cell lymphoma is a type of blood cancer and the most common form of a group of blood cancers known as non-Hodgkin lymphomas.

Diffuse large B-cell lymphoma affects a type of white blood cell called B lymphocytes, or B cells. In patients with this cancer, the B cells multiply too quickly and live for too long, so there are too many of them in the lymph nodes. The first sign of the disease is usually a lump in the neck, under the arm or

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in the groin area, which is caused by an enlarged lymph node. Patients with diffuse large B-cell lymphoma may also have fever, tiredness, night sweats or weight loss that have no obvious cause.

Although some people with diffuse large B-cell lymphoma can be cured, it remains a serious and life-threatening disease, particularly when the disease is diagnosed late or has come back after initial treatment.

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

At the time of designation, diffuse large B-cell lymphoma affected approximately 2.3 in 10,000 people in the European Union (EU). This was equivalent to a total of around 118,000 people*, 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 designation, several medicines were authorised for the treatment of diffuse large B-cell lymphoma in the EU. The main treatment was chemotherapy (medicines to treat cancer) usually in combination with other medicines called monoclonal antibodies and sometimes in combination with radiotherapy (treatment with radiation). Autologous haematopoietic (blood) stem-cell transplantation was also used in patients at risk of the disease coming back after treatment. This is a complex procedure where patients receive their own stem cells to help restore the bone marrow.

The sponsor has provided sufficient information to show that medicine might be of significant benefit for patients with diffuse large B-cell lymphoma because early studies in patients suggest that patients whose disease has returned or is not responding to alternative treatments respond to the treatment. 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 made of a small piece of DNA that interferes with the *BCL2* gene, a gene known to promote cancer cell survival. It does so by targeting and attaching to specific parts of the gene that regulate it. Once attached, it is expected to block the gene's activity resulting in the death of cancer cells.

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 diffuse large B-cell lymphoma were ongoing.

At the time of submission, the medicine was not authorised anywhere in the EU for diffuse large B-cell lymphoma 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 July 2015 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 28), Norway, Iceland and Liechtenstein. This represents a population of 512,900,000 (Eurostat 2015).

withdrawn

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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Anneessensstraat 3-5 B9
2018 Antwerp
Belgium
Tel. +32 3 29 39 084
Fax +32 3 34 50 605
E-mail: RA@phara-consulting.be

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.

withdrawn

Translations of the active ingredient and indication in all official EU languages[1], Norwegian and Icelandic

Language	Active ingredient	Indication
English	2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxythymidylyl-(3’,5’-phosphoryl)- 2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidilyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxythymidylyl-(3’,5’-phosphoryl)-2’-deoxyadenosyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyadenosyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyadenosyl-(3’,5’-phosphoryl)-2’-deoxycytidine, sodium salt	Treatment of diffuse large B-cell lymphoma
Bulgarian	2’-деоксигуанозилил-(3’,5’-фосфорил)-2’-деокситимидилил-(3’,5’-фосфорил)- 2’-деоксигуанозилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксигуанозилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деокситимидилил-(3’,5’-фосфорил)-2’-деоксиаденозил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксигуанозилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксигуанозилил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксиаденозил-(3’,5’-фосфорил)-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксигуанозилил-2’-деоксицитидилил-(3’,5’-фосфорил)-2’-деоксиаденозил-(3’,5’-фосфорил)-2’-деоксицитидин, натриева сол	Лечение на дифузен B-едроклетъчен лимфом

[1] At the time of designation

Language	Active ingredient	Indication
Croatian	Natrijeva sol 2'-deoksigvanozilil-(3',5'-fosforil)-2'-deoksitimidilil-(3',5'-fosforil)-2'-deoksigvanozilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksigvanozilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksitimidilil-(3',5'-fosforil)-2'-deoksiadenozil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksigvanozilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksigvanozilil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksiadenozil-(3',5'-fosforil)-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksigvanozilil-2'-deoksicitidilil-(3',5'-fosforil)-2'-deoksiadenozil-(3',5'-fosforil)-2'-deoksicitidina	Liječenje difuznog limfoma velikih B-stanica
Czech	2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxythymidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl -(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidilyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxythymidylyl-(3',5'-fosforyl)-2'-deoxyadenosyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyadenosyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyadenosyl-(3',5'-fosforyl)-2'-deoxycytidin, sodná sůl	Léčba velkobuněčného difuzního B-lymfomu
Danish	2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)- 2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidilyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxythymidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyguanosylyl-2'-deoxycytidylyl-(3',5'-phosphoryl)-2'-deoxyadenosyl-(3',5'-phosphoryl)-2'-deoxycytidin, natriumsalt	Behandling af diffust storcellet B-celle lymfom

Language	Active ingredient	Indication
Dutch	2’-desoxyguanosylyl-(3’,5’-fosforyl)-2’-desoxythymidylyl-(3’,5’-fosforyl)-2’-desoxyguanosylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxyguanosylyl-(3’,5’-fosforyl)-2’-desoxycytidilyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxythymidylyl-(3’,5’-fosforyl)-2’-desoxyadenosyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxyguanosylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxyguanosylyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxyadenosyl-(3’,5’-fosforyl)-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxyguanosylyl-2’-desoxycytidylyl-(3’,5’-fosforyl)-2’-desoxyadenosyl-(3’,5’-fosforyl)-2’-desoxycytidine, natriumzout	Behandeling van diffuus grootcellig B-cel-lymfoom
Estonian	2’-deoksüguanosülüül-(3’,5’-fosforüül)-2’-deoksütümidülüül-(3’,5’-fosforüül)-2’-deoksüguanosülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksüguanosülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksütümidülüül-(3’,5’-fosforüül)-2’-deoksüadenosüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksüguanosülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksüguanosülüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksüadenosüül-(3’,5’-fosforüül)-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksüguanosülüül-2’-deoksütsütidülüül-(3’,5’-fosforüül)-2’-deoksüadenosüül-(3’,5’-fosforüül)-2’-deoksütsütidiin, naatriumisool	Diffuusse suure B-rakulise lümfoomi ravi

Language	Active ingredient	Indication
Finnish	2’-deoksiguanosylyyli-(3’,5’-fosforyyli)-2’-deoksitymidylyyli-(3’,5’-fosforyyli)-2’-deoksiguanosylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’- deoksiguanosylyyli -(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksitymidylyyli-(3’,5’-fosforyyli)-2’-deoksiadenosyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksiguanosylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksiguanosylyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksiadenosyyli-(3’,5’-fosforyyli)-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksiguanosylyyli-2’-deoksisytidylyyli-(3’,5’-fosforyyli)-2’-deoksiadenosyyli-(3’,5’-fosforyyli)-2’-deoksisytidiini, natriumsuola	Diffuusin suurisoluisen B-solulymfooman hoito
French	2’-désoxyguanosylyl-(3’,5’-phosphoryl)-2’-désoxythymidylyl-(3’,5’-phosphoryl)-2’-désoxyguanosylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxyguanosylyl-(3’,5’-phosphoryl)-2’-désoxycytidilyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxythymidylyl-(3’,5’-phosphoryl)-2’-désoxyadénosyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxyguanosylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxyguanosylyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxyadénosyl-(3’,5’-phosphoryl)-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxyguanosylyl-2’-désoxycytidylyl-(3’,5’-phosphoryl)-2’-désoxyadénosyl-(3’,5’-phosphoryl)-2’-désoxycytidine, sel de sodium	Traitement du lymphome diffus à grandes cellules B

Language	Active ingredient	Indication
German	2’-desoxyguanosylyl-(3’,5’-phosphoryl)-2’-desoxythymidylyl-(3’,5’-phosphoryl)-2’-desoxyguanosylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxyguanosylyl-(3’,5’-phosphoryl)-2’-desoxycytidilyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxythymidylyl-(3’,5’-phosphoryl)-2’-desoxyadenosyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxyguanosylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxyguanosylyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxyadenosyl-(3’,5’-phosphoryl)-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxyguanosylyl-2’-desoxycytidylyl-(3’,5’-phosphoryl)-2’-desoxyadenosyl-(3’,5’-phosphoryl)-2’-desoxycytidin, Natriumsalz	Behandlung des diffusen großzelligen B-Zell-Lymphoms
Greek	2’-δεοξυγουανοσυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυθυμιδυλύλ-(3’,5’-φωσφορύλ)- 2’-δεοξυγουανοσυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυγουανοσυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’- δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’- δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυθυμιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυαδενοσύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυγουανοσυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυγουανοσυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυαδενοσύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυγουανοσυλύλ-2’-δεοξυκυτιδυλύλ-(3’,5’-φωσφορύλ)-2’-δεοξυαδενοσύλ-(3’,5’-φωσφορύλ)-2’-δεοξυκυτιδίνη, άλας νατρίου	Θεραπεία του διάχυτου μεγαλοκυτταρικού λεμφώματος Β-κυττάρου (DLBCL)

Language	Active ingredient	Indication
Hungarian	2’-dezoxiguanoszilil-(3’,5’-foszforil)-2’-dezoxitimidilil-(3’,5’-foszforil)-2’-dezoxiguanoszilil-(3’,5’-phosphoril)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxiguanoszilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxitimidilil-(3’,5’-foszforil)-2’-dezoxiadenozil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxiguanoszilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxiguanoszilil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxiadenozil-(3’,5’-foszforil)-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxiguanoszilil-2’-dezoxicitidilil-(3’,5’-foszforil)-2’-dezoxiadenozil-(3’,5’-foszforil)-2’-dezoxicitidin, nátrium só	Diffúz nagy B-sejtes lymphoma kezelése
Italian	2’-deossiguanosilil-(3’,5’-fosforil)-2’-deossitimidilil-(3’,5’-fosforil)-2’-deossiguanosilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossiguanosilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossitimidilil-(3’,5’-fosforil)-2’-deossiadenosil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossiguanosilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossiguanosilil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossiadenosil-(3’,5’-fosforil)-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossiguanosilil-2’-deossicitidilil-(3’,5’-fosforil)-2’-deossiadenosil-(3’,5’-fosforil)-2’-deossicitidina, sale sodico	Terapia del Linfoma non-Hodgkin diffuso a grandi cellule di tipo B (DLBCL)
Latvian	2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksitimidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’ -deoksicitidilil-(3’,5’-fosforil)-2’-deoksitimidilil-(3’,5’-fosforil)-2’-deoksiadenosil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiadenosil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiadenosil-(3’,5’-fosforil)-2’-deoksicitidīna nātrija sāls	Difūzas lielo B šūnu limfomas ārstēšana

Language	Active ingredient	Indication
Lithuanian	2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksitimidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksitimidilil-(3’,5’-fosforil)-2’-deoksiadenosil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiadenosil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiguanosilil-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiadenosil-(3’,5’-fosforil)-2’-deoksicitidinas, natrio druska	Difuzinės stambiųjų B ląstelių limfomos gydymas
Maltese	2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxythymidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidilyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxythymidylyl-(3’,5’-phosphoryl)-2’-deoxyadenosyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyadenosyl-(3’,5’-phosphoryl)-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyguanosylyl-2’-deoxycytidylyl-(3’,5’-phosphoryl)-2’-deoxyadenosyl-(3’,5’-phosphoryl)-2’-deoxycytidine, sodium salt	Kura tal-limfoma taċ-ċelluli tat-tip B kbar mxerrda

Language	Active ingredient	Indication
Polish	Sól sodowa 2'-deoksyguanosylylo-(3',5'-fosforylo)-2'-deoksytymidylylo-(3',5'-fosforylo)-2'-deoksyguanosylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksyguanosylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksytymidylylo-(3',5'-fosforylo)-2'-deoksyadenozylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksyguanosylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksyguanosylylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksyadenozylo-(3',5'-fosforylo)-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksyguanosylylo-2'-deoksycytydylylo-(3',5'-fosforylo)-2'-deoksyadenozylo-(3',5'-fosforylo)-2'-deoksycytydyny	Leczenie rozlanego chłoniaka z dużych limfocytów B
Portuguese	Sal de sódio 2'-deoxiguanosilil-(3',5'-fosforil)-2'-deoxitimidilil-(3',5'-fosforil)-2'-deoxiguanosilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanosilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxitimidilil-(3',5'-fosforil)-2'-deoxiadenosil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanosilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanosilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiadenosil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanosilil-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiadenosil-(3',5'-fosforil)-2'-deoxicitidina	Tratamento do linfoma difuso de grandes células B
Romanian	Sare sodică de 2′-deoxiguanozilil-(3',5'-fosforil)-2'-deoxitimidilil-(3',5'-fosforil)-2'-deoxiguanozilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanozilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxitimidilil-(3',5'-fosforil)-2'-deoxiadenozil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanozilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanozilil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiadenozil-(3',5'-fosforil)-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiguanozilil-2'-deoxicitidilil-(3',5'-fosforil)-2'-deoxiadenozil-(3',5'-fosforil)-2'-deoxicitidină,	Tratamentul limfomului difuz cu celule B mari

Language	Active ingredient	Indication
Slovak	2’-deoxyguanozylyl-(3’,5’-fosforyl)-2’-deoxytymidylyl-(3’,5’-fosforyl)-2’-deoxyguanozylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxyguanozylyl-(3’,5’-fosforyl)-2’-deoxycytidilyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxytymidylyl-(3’,5’-fosforyl)-2’-deoxyadenozyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxyguanozylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxyguanozylyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxyadenozyl-(3’,5’-fosforyl)-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxyguanozylyl-2’-deoxycytidylyl-(3’,5’-fosforyl)-2’-deoxyadenozyl-(3’,5’-fosforyl)-2’-deoxycytidín, sodná soľ	Liečba difúzneho veľkobunkového lymfómu z buniek B
Slovenian	2’-deoksigvanosilil-(3’,5’-fosforil)-2’-deoksitimidilil-(3’,5’-fosforil)-2’- deoksigvanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksigvanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksitimidilil-(3’,5’-fosforil)-2’-deoksiadenozil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksigvanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksigvanosilil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiadenozil-(3’,5’-fosforil)-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksigvanosilil-2’-deoksicitidilil-(3’,5’-fosforil)-2’-deoksiadenozil-(3’,5’-fosforil)-2’-deoksicitidin, natrijeva sol	Zdravljenje razširjenega limfoma velikih B celic

Language	Active ingredient	Indication
Spanish	2'-desoxiguanosilil-(3',5'-fosforil)-2'-desoxitimidilil-(3',5'-fosforil)-2'-desoxiguanosilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxiguanosilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxitimidilil-(3',5'-fosforil)-2'-desoxiadenosil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxiguanosilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxiguanosilil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxiadenosil-(3',5'-fosforil)-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxiguanosilil-2'-desoxicitidilil-(3',5'-fosforil)-2'-desoxiadenosil-(3',5'-fosforil)-2'-desoxicitidina, sal de sodio	Tratamiento del linfoma difuso de células B grandes
Swedish	2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxytymidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidilyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxytymidylyl-(3',5'-fosforyl)-2'-deoxyadenosyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyadenosyl-(3',5'-fosforyl)-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyguanosylyl-2'-deoxycytidylyl-(3',5'-fosforyl)-2'-deoxyadenosyl-(3',5'-fosforyl)-2'-deoxycytidin, natriumsalt	Behandling av diffusa storcelliga B-cells lymfom

Language	Active ingredient	Indication
Norwegian	2’-deoksyguanosylyl-(3’,5’-fosforyl)-2’-deoksytymidylyl-(3’,5’-fosforyl)-2’-deoksyguanosylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksyguanosylyl-(3’,5’-fosforyl)-2’-deoksycytidilyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksytymidylyl-(3’,5’-fosforyl)-2’-deoksyadenosyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksyguanosylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksyguanosylyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksyadenosyl-(3’,5’-fosforyl)-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksyguanosylyl-2’-deoksycytidylyl-(3’,5’-fosforyl)-2’-deoksyadenosyl-(3’,5’-fosforyl)-2’-deoksycytidin, natriumsalt	Behandling av diffust storcellet B-celle lymfom
Icelandic	2’-deoxýgúanósýlýl-(3’,5’-fosfórýl)-2’-deoxýtýmidýlýl-(3’,5’-fosfórýl)-2’-deoxýgúanósýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýgúanósýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýtýmidýlýl-(3’,5’-fosfórýl)-2’-deoxýadenósýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýgúanósýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýgúanósýlýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýadenósýl-(3’,5’-fosfórýl)-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýgúanósýlýl-2’-deoxýsýtidýlýl-(3’,5’-fosfórýl)-2’-deoxýadenósýl-(3’,5’-fosfórýl)-2’-deoxýsýtidín, natríumsalt	Til meðferðar á dreifðu stórfrumu B frumu eitlakrabbameini