



## Ibrutinib (Imbruvica®)

Chronische Lymphatische Leukämie (CLL) » + Rituximab » Erstlinie,  
≤70 Jahre, IGHV mutiert

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

## **Herausgeber**

DGHO Deutsche Gesellschaft für Hämatologie und  
Medizinische Onkologie e.V.  
Bauhofstr. 12  
10117 Berlin

Geschäftsführender Vorsitzender: Prof. Dr. med. Andreas Hochhaus

Telefon: +49 (0)30 27 87 60 89 - 0

[info@dgho.de](mailto:info@dgho.de)

[www.dgho.de](http://www.dgho.de)

## **Ansprechpartner**

Prof. Dr. med. Bernhard Wörmann  
Medizinischer Leiter

## **Quelle**

[www.onkopedia.com](http://www.onkopedia.com)

Die Empfehlungen der DGHO für die Diagnostik und Therapie hämatologischer und onkologischer Erkrankungen entbinden die verantwortliche Ärztin / den verantwortlichen Arzt nicht davon, notwendige Diagnostik, Indikationen, Kontraindikationen und Dosierungen im Einzelfall zu überprüfen! Die DGHO übernimmt für Empfehlungen keine Gewähr.

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# Ibrutinib (Imbruvica®)

**Dokument:** Fact Sheet

**Spezifizierung:** Chronische Lymphatische Leukämie (CLL) » + Rituximab » Erstlinie, ≤70 Jahre, IGHV mutiert

**Stand:** Oktober 2020

## 1 Ibrutinib + Rituximab, CLL, first line, ≤70 years, IGHV mutated

Ibrutinib + Rituximab, CLL, first line, ≤70 years, IGHV mutated																																			
		<b>Facts</b>	<b>Appraisal</b>																																
		EU Approval 2019																																	
Parameter	Results <sup>14</sup>	HR <sup>15</sup>	p value																																
PFS <sup>3</sup>		0.44 (0.14 - 1.36)	n.s. <sup>16</sup>																																
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;"></td> <td style="text-align: center;"> <table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 12.5%;">5</td> <td style="width: 12.5%;">4</td> <td style="width: 12.5%;">3b</td> <td style="width: 12.5%;">3a</td> <td style="width: 12.5%;">2c</td> <td style="width: 12.5%;">2b</td> <td style="width: 12.5%;">2a</td> <td style="width: 12.5%; background-color: black;">1b</td> <td style="width: 12.5%;">1a</td> </tr> </table> </td> </tr> <tr> <td colspan="4" style="border: none;">Evidence (LoE)</td> </tr> <tr> <td colspan="4" style="border: none;">Clinical benefit (ESMO MCBS)</td> </tr> <tr> <td colspan="4" style="border: none;"> <table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 20%;">1</td> <td style="width: 20%;">2</td> <td style="width: 20%;">3</td> <td style="width: 20%;">4</td> <td style="width: 20%;">5</td> </tr> </table> </td> </tr> <tr> <td colspan="4" style="border: none;"> <div style="display: flex; justify-content: space-between; align-items: center;"> <span style="color: blue;">■</span> curative                             <span style="color: yellow;">■</span> non-curative                         </div> </td> </tr> </table>					<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 12.5%;">5</td> <td style="width: 12.5%;">4</td> <td style="width: 12.5%;">3b</td> <td style="width: 12.5%;">3a</td> <td style="width: 12.5%;">2c</td> <td style="width: 12.5%;">2b</td> <td style="width: 12.5%;">2a</td> <td style="width: 12.5%; background-color: black;">1b</td> <td style="width: 12.5%;">1a</td> </tr> </table>	5	4	3b	3a	2c	2b	2a	1b	1a	Evidence (LoE)				Clinical benefit (ESMO MCBS)				<table border="1" style="width: 100%; height: 20px;"> <tr> <td style="width: 20%;">1</td> <td style="width: 20%;">2</td> <td style="width: 20%;">3</td> <td style="width: 20%;">4</td> <td style="width: 20%;">5</td> </tr> </table>				1	2	3	4	5	<div style="display: flex; justify-content: space-between; align-items: center;"> <span style="color: blue;">■</span> curative                             <span style="color: yellow;">■</span> non-curative                         </div>			
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Patients	≤70 years, no del17p/TP53mut, IGHV mutated																																		
Trial	E1912, phase 3																																		
Randomisation	2 : 1																																		
N <sup>1</sup>	114																																		
New Therapy	Ibrutinib + Rituximab																																		
Control	Fludarabine / Cyclophosphamide / Rituximab (FCR)																																		
Publication	DOI:10.1056/NEJMoa1817073																																		

Legende:

<sup>1</sup> N - number of patients

<sup>3</sup> PFS - progression-free survival in months

<sup>14</sup> results for control, results for new therapy

<sup>15</sup> hazard ratio for new therapy

<sup>16</sup> n. s. not significant