



# Midostaurin (Rydapt®)

Akute Myeloische Leukämie (AML) » neu diagnostiziert » Induktion und Konsolidierung

Empfehlungen der Fachgesellschaft zum Einsatz neuer Arzneimittel

## **Herausgeber**

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## **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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# Midostaurin (Rydapt®)

**Dokument:** Fact Sheet

**Spezifizierung:** Akute Myeloische Leukämie (AML) » neu diagnostiziert » Induktion und Konsolidierung

**Stand:** Januar 2021

## 1 Midostaurin, AML, newly diagnosed, induction and consolidation

### Midostaurin, AML, newly diagnosed, induction and consolidation

onkopedia				Facts	Appraisal	EU Approval 2017																											
<b>Parameter</b>	<b>Results<sup>14</sup></b>	<b>HR<sup>15</sup></b>	<b>p value</b>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 12.5%; text-align: center;">5</td> <td style="width: 12.5%; text-align: center;">4</td> <td style="width: 12.5%; text-align: center;">3b</td> <td style="width: 12.5%; text-align: center;">3a</td> <td style="width: 12.5%; text-align: center;">2c</td> <td style="width: 12.5%; text-align: center;">2b</td> <td style="width: 12.5%; text-align: center;">2a</td> <td style="width: 12.5%; text-align: center;">1b</td> <td style="width: 12.5%; text-align: center;">1a</td> </tr> <tr> <td colspan="9">Evidence (LoE)</td> </tr> <tr> <td style="width: 12.5%;"></td> <td style="width: 12.5%;"></td> <td style="width: 12.5%;"></td> <td style="width: 12.5%;"></td> <td style="width: 12.5%;"></td> <td style="width: 12.5%;"></td> <td style="width: 12.5%;"></td> <td style="width: 12.5%; background-color: black;"></td> <td style="width: 12.5%;"></td> </tr> </table>			5	4	3b	3a	2c	2b	2a	1b	1a	Evidence (LoE)																	
5	4	3b	3a	2c	2b	2a	1b	1a																									
Evidence (LoE)																																	
RR <sup>2</sup>	54 vs 59		n.s. <sup>16</sup>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; text-align: center;">1</td> <td style="width: 20%; text-align: center;">2</td> <td style="width: 20%; text-align: center;">3</td> <td style="width: 20%; text-align: center;">4</td> <td style="width: 20%; text-align: center;">5</td> </tr> <tr> <td colspan="5">Clinical benefit (ESMO MCBS)</td> </tr> <tr> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> </tr> </table>			1	2	3	4	5	Clinical benefit (ESMO MCBS)																					
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OS <sup>5</sup>	26 vs 74	0.774	p = 0.009	<div style="display: flex; justify-content: space-around; align-items: center;"> <span style="width: 10px; height: 10px; background-color: blue; margin-right: 5px;"></span> curative                     <span style="width: 10px; height: 10px; background-color: yellow; margin-left: 20px; margin-right: 5px;"></span> non-curative                 </div>																													
EFS <sup>8</sup>	3 vs 8	0.78	p = 0.002	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; text-align: center;">lower</td> <td style="width: 20%; text-align: center;">proven</td> <td style="width: 20%; text-align: center;">not quantifiable</td> <td style="width: 20%; text-align: center;">not minor</td> <td style="width: 20%; text-align: center;">considerable</td> <td style="width: 20%; text-align: center;">major</td> </tr> <tr> <td colspan="6">Additional benefit (G-BA)</td> </tr> <tr> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%; background-color: black;"></td> <td style="width: 20%;"></td> </tr> </table>			lower	proven	not quantifiable	not minor	considerable	major	Additional benefit (G-BA)																				
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Additional benefit (G-BA)																																	
<b>Patients</b>	de novo AML, 18 - 60 years																																
<b>Trial</b>	RATIFY																																
<b>Randomisation</b>	1 : 1																																
<b>N<sup>1</sup></b>	717																																
<b>New Therapy</b>	Chemotherapy + Midostaurin																																
<b>Control</b>	Chemotherapy + Placebo																																
<b>Publication</b>	DOI:10.1056/NEJMoa1614359																																

Legende:

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

<sup>2</sup> RR - remission rate, in %

<sup>5</sup> OS - overall survival in months

<sup>8</sup> EFS - Event-Free Survival

<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

<sup>19</sup> Complete Remission Rate (CR + CRi)