

ACUTE MYELOID  
LEUKAEMIA  
On consolidation  
chemotherapy

CHRONIC  
LYMPHOCYTIC  
LEUKAEMIA

ACUTE MYELOID  
LEUKAEMIA  
Preparing for  
allogeneic HSCT



These are not real patient cases and are for illustrative purposes only.  
Before prescribing CRESEMBA® and VFEND® please refer to the full Summary of Product Characteristics (SmPC).  
Please refer to your local authorities concerning reimbursement status. Medicinal product subject to medical prescription.  
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PP-CRB-GLB-0902  
Date of preparation: March 2022.



# CHARLES

CRESEMBA® is indicated in adults for the treatment of:<sup>1</sup>

- Invasive aspergillosis
- Mucormycosis in patients for whom amphotericin B is inappropriate

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# CHARLES

## BACKGROUND

- Male, 65 years of age
- Diagnosed with AML
- Currently on consolidation chemotherapy
- Moderate renal dysfunction (eGFR=52 mL/min/1.73 m<sup>2</sup>)

## CLINICAL DEVELOPMENTS

- Receives antiviral therapy and corticosteroids
- Respiratory symptoms continue to worsen
- Chest CT shows nodules with halo sign
- BAL PCR positive for influenza B and *Aspergillus fumigatus*

## DIAGNOSIS

- Probable invasive aspergillosis post influenza in previously healthy patient with liver function abnormalities

## CONSIDERATIONS



Requires an effective antifungal agent to quickly control the fungal infection



Renal impairment can limit the utility of IV voriconazole<sup>2</sup>



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## CRESEMBA® can be used in patients with renal impairment<sup>1,3</sup>

In patients with renal impairment and invasive aspergillosis, CRESEMBA® offers survival rates comparable with voriconazole, combined with potential cost savings from early hospital discharge.<sup>4,5</sup>

Treatment outcomes with CRESEMBA® appear to be unaffected by kidney function, with no evidence of loss of efficacy or drug safety concerns in patients with renal impairment.<sup>3,4</sup>

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The IV formulation of CRESEMBA® does not contain cyclodextrin and can be administered to patients with renal impairment, including those with ESRD, without dose adjustments.<sup>1</sup>

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Compared with voriconazole, CRESEMBA® may help shorten hospital stay in patients with moderate-to-severe renal impairment,<sup>a</sup> with a 10-day reduction in length of stay observed in the SECURE trial (9 vs 19 days,  $p=0.0032$ ).<sup>4</sup>



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<sup>a</sup>Baseline eGFR <60 mL/min/1.73 m<sup>2</sup>.  
ESRD, end-stage renal disease.



# STEVE

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# STEVE

## BACKGROUND

- Male, 66 years of age
- Diagnosed with CLL a year ago
- Currently receiving ibrutinib treatment

## CLINICAL DEVELOPMENTS

- Hospitalised with fever, cough and confusion
- Several pulmonary nodules on chest CT
- Brain abscesses on MRI
- Positive galactomannan test
- BAL culture positive for *Aspergillus* spp.

## DIAGNOSIS

- Probable invasive aspergillosis, with pulmonary and cerebral involvement, in patient with CLL receiving ibrutinib

## CONSIDERATIONS



Needs an effective antifungal treatment to control the infection as soon as possible



Would benefit from an antifungal that can be given in combination with ibrutinib, to continue treating the underlying condition



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## **CRESEMBA® (isavuconazole) may be used in combination with ibrutinib<sup>6–8</sup>**

Ibrutinib has been shown to induce long-lasting remissions in patients with CLL, while being well tolerated.<sup>7,9</sup>

However, evidence suggests ibrutinib use may be associated with the development of invasive fungal infections, in particular invasive aspergillosis.<sup>7,10,11</sup>

As a metabolic substrate of CYP3A4, ibrutinib should not be coadministered with antifungals that are strong CYP3A4 inhibitors.<sup>6</sup>

CRESEMBA® may be considered for coadministration even with high-dose ibrutinib, meaning it may be considered to treat invasive fungal infections in patients receiving this BTK inhibitor.<sup>7,8</sup>

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## **CRESEMBA® combines the efficacy of voriconazole with improved safety and tolerability<sup>5</sup>**

In the pivotal SECURE Phase 3 trial, CRESEMBA® achieved survival rates comparable with voriconazole, the standard of care for invasive aspergillosis.<sup>5</sup>

While the overall frequency of TEAEs was similar between treatment groups, drug-related AEs and treatment discontinuations were less common with CRESEMBA®.<sup>5</sup>

AEs typically observed with voriconazole (skin, eye and hepatobiliary disorders) were also significantly reduced with CRESEMBA®.<sup>5</sup>



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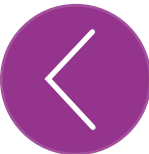


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Drug-related AEs and treatment discontinuations in the SECURE trial<sup>5,a</sup>

	CRESEMBA® (n=257)	Voriconazole (n=259)	p-value
Drug-related AEs	42%	60%	<0.001
TEAEs leading to discontinuation	14%	23%	NS
Drug-related AEs leading to discontinuation	8%	14%	NS
Skin and subcutaneous tissue disorders	33%	42%	0.037
Eye disorders	15%	27%	0.002
Hepatobiliary disorders	9%	16%	0.016



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<sup>a</sup>The overall incidence of AEs was similar between groups (96% vs 98%).<sup>5</sup>  
AE, adverse event; BTK, Bruton's tyrosine kinase; NS, not significant; TEAE, treatment-emergent adverse event.



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# MARK

## BACKGROUND

- Male, 70 years of age
- Diagnosed with AML
- Preparing for potentially life-saving allogeneic HSCT
- Receiving immunosuppressants

## CLINICAL DEVELOPMENTS

- Develops pneumonia
- Galactomannan antigen test: 4.5 (BAL)
- Three nodular non-excavated
- lesions on chest CT consistent with *Aspergillus* spp. infection
- Panfungal PCR weakly positive (lung biopsy)
- Culture positive for *Aspergillus* spp.
- HSCT postponed due to known interactions between proposed antifungal therapy and immunosuppressants, which is devastating for the patient and his family (HSCT was a lifeline)

## DIAGNOSIS

- Proven invasive aspergillosis in patient waiting for HSCT

## CONSIDERATIONS



Needs rapid and effective invasive aspergillosis treatment



HSCT delay needs to be minimised/avoided



Requires an antifungal able to minimise the risk of interactions with other concomitant medications (including immunosuppressants)



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<sup>a</sup>For further details and a full list of drug interactions, please consult the Summary of Product Characteristics.<sup>1</sup>  
AML, acute myeloid leukaemia; BAL, bronchoalveolar lavage; CT, computerised tomography;  
HSCT, haematopoietic stem-cell transplant; PCR, polymerase chain reaction.



## **With CRESEMBA® (isavuconazole), you can manage the invasive mould infection while focusing on the underlying condition<sup>12</sup>**

CRESEMBA® combines standard-of-care efficacy in invasive aspergillosis with improved tolerability vs voriconazole.<sup>5</sup>

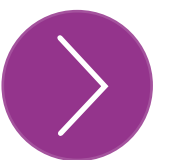
CRESEMBA® also has a lower potential for drug interactions<sup>1,13</sup> and can be used with several medications, including the immunosuppressants ciclosporin, sirolimus and tacrolimus.<sup>1</sup>



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## Recommendations for the coadministration of CRESEMBA® with some common concomitant agents<sup>1,a</sup>

Concomitant medication	Recommendation <sup>1</sup>
Proton pump inhibitors	No dose adjustment for either CRESEMBA® or the concomitant medication
Statins	
Warfarin	
Methadone	
Methotrexate	
Repaglinide	
Ciclosporin, tacrolimus and sirolimus	No CRESEMBA® dose adjustment Monitoring of concomitant medication and dose adjustment if required

CRESEMBA® is contraindicated for coadministration with ketoconazole, high-dose ritonavir, and strong CYP3A4/5 inducers such as rifampicin, rifabutin, carbamazepine, long-acting barbiturates, phenytoin and St. John's wort, or with moderate CYP3A4/5 inducers such as efavirenz, nafcillin and etravirine.<sup>1</sup>



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References





## References

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