



The Cyclodextrin Company



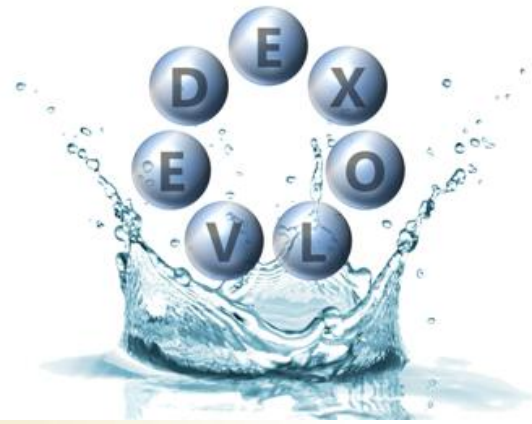
Getting the best out of Cyclodextrins

CYCLOLAB Ltd.

Dexolve™

***Marketed drug products
containing SBECD (Dexolve)***

as of 1st January, 2020



NDC 0781-3416-94

Voriconazole for Injection

200 mg/vial

R_x only

Sterile Single Use Vial
For I.V. Infusion Only

 SANDOZ

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. Reconstitution and Dilution: Reconstitute with 19 mL of Water for Injection to give a clear solution containing 10 mg/mL voriconazole (extractable volume = 20 mL). **Must be further diluted before use.** For appropriate diluents and storage recommendations, refer to prescribing information. Discard unused portion.

FOR INTRAVENOUS ADMINISTRATION

With reconstitution each mL contains 10 mg voriconazole and 160 mg sulfobutyl ether β -cyclodextrin sodium (SBECD).

Finished drug product manufactured by:
Lek Pharmaceuticals d.d., SI-1526, Ljubljana, Slovenia
for Sandoz Inc., Princeton, NJ 08540

Product of India

Rev. 04/2015

NDC 0781-3416-94

Voriconazole for Injection

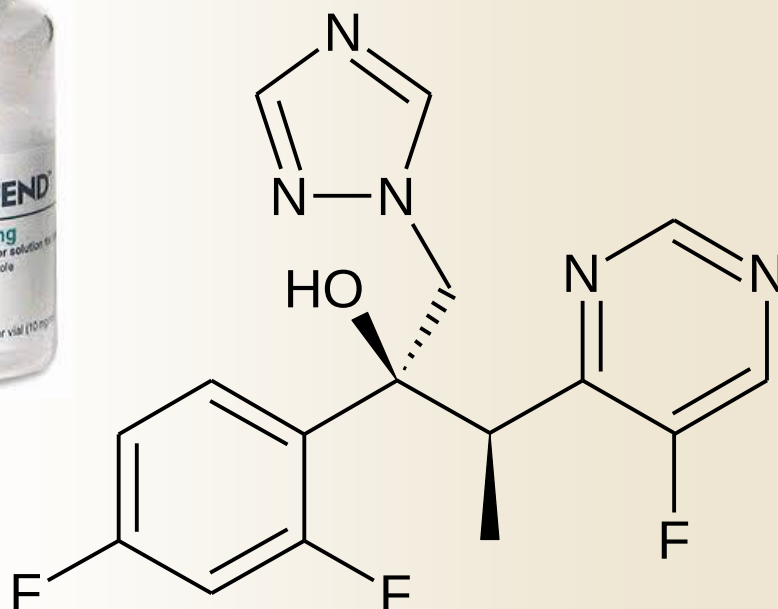
200 mg/vial

Sterile Single Use Vial
For I.V. Infusion Only

R_x only

1 Vial

 SANDOZ



Marketed drug products containing SBECD

Captisol[®] → VFEND[®] (Pfizer)

Dexolve[®] → Sandoz generic

antifungal

intravenous

200 mg voriconazole / vial

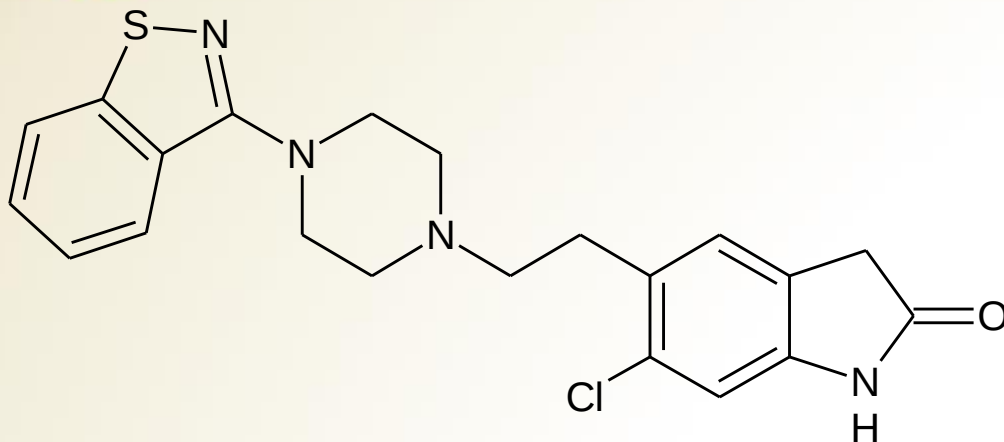
3200 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 2.6$

EXPECTED PATENT EXPIRY: 2019 (US6632803)



Marketed drug products containing SBECD



GEODON® IM

antipsychotic (Anti-schizophrenic)

intramuscular

20 mg ziprasidone (mesylate) / vial

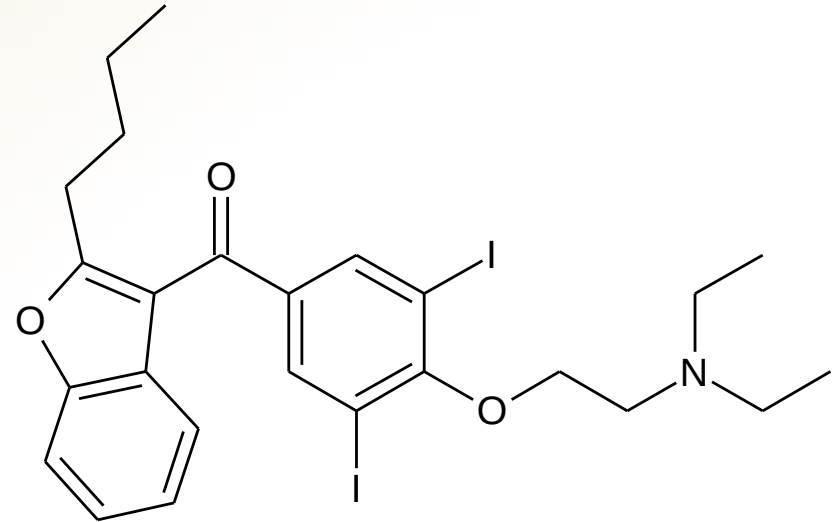
294 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 2.8$



EXPECTED PATENT EXPIRY: 2021 (US6399777)

Marketed drug products containing SBECD



NEXTERONE®

antiarrhythmic

infusion

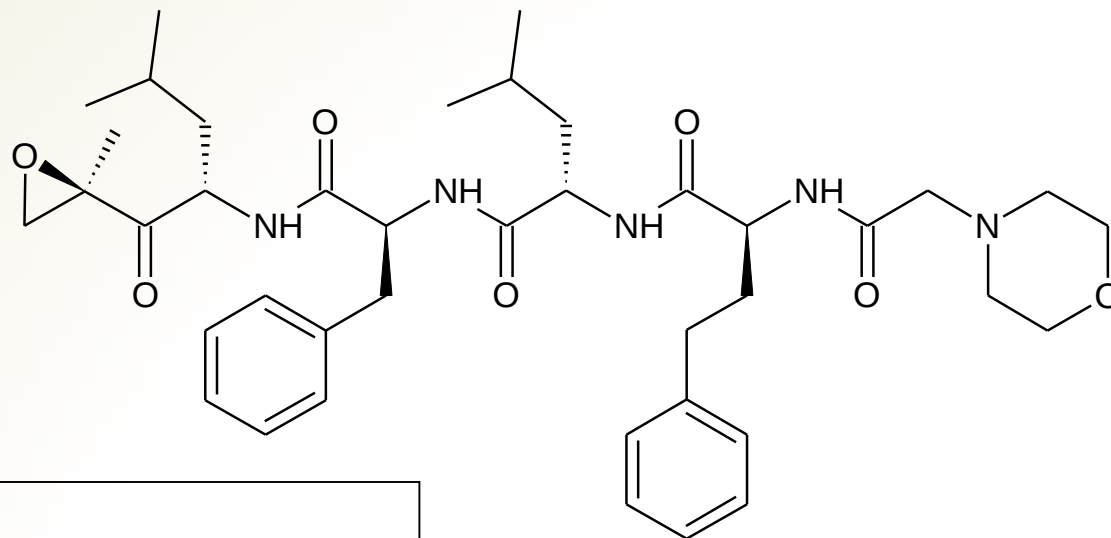
150 / 360 mg amiodarone.HCl / inf. bag

1500 / 3600 mg SBECD / inf. bag

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 3$

EXPECTED PATENT EXPIRY: 2022 (US6869939)

Marketed drug products containing SBECD



KYPROLIS®

anticancer (Multiple Myeloma)

intravenous

60 mg carfilzomib / vial

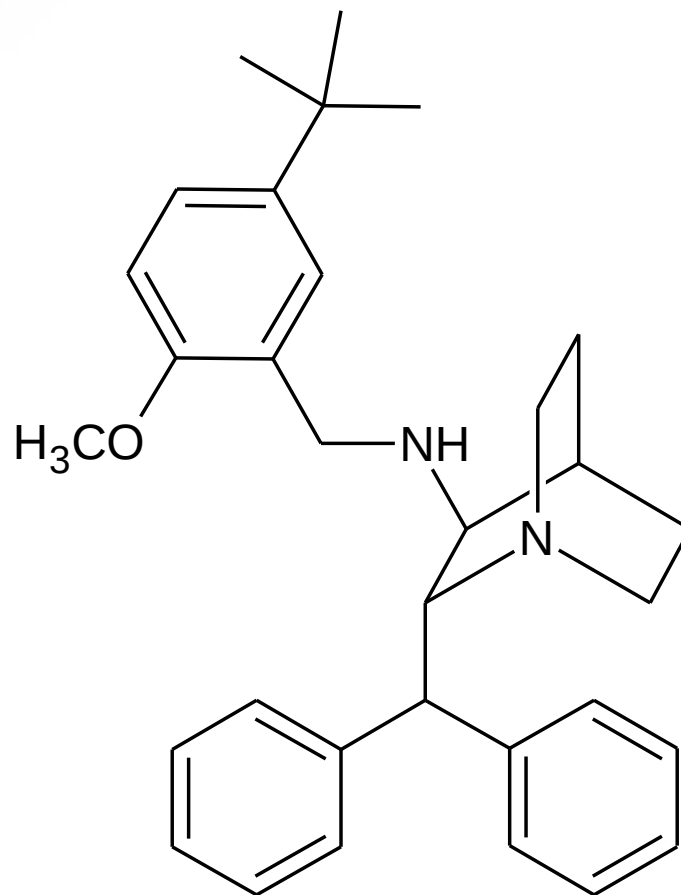
3000 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 16.6$

EXPECTED PATENT EXPIRY: 2025 (US7737112)



Marketed drug products containing SBECD



Cerenia™

canine and feline Anti-Nausea
subcutaneous injection

200 mg Maropitant (citrate) / vial

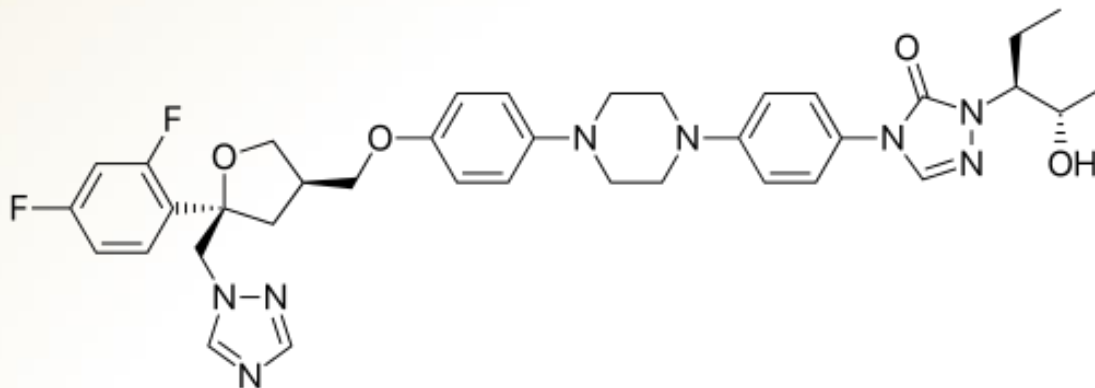
1260 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 1.4$

EXPECTED PATENT EXPIRY: 2026 (US8183230)



Marketed drug products containing SBECD



NOXAFIL®

antifungal

intravenous

300 mg posaconazole / vial

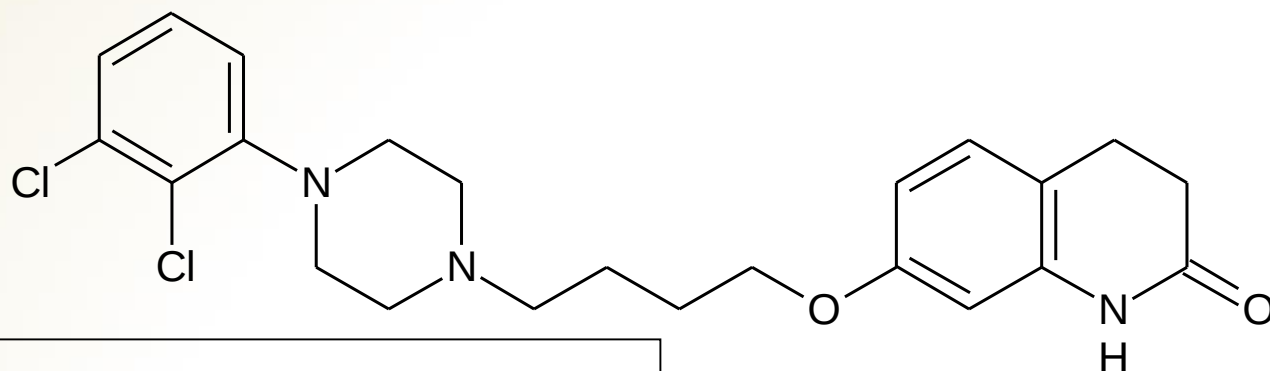
6680 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 7.2$

EXPECTED PATENT EXPIRY: 2032 (US9023790)



Marketed drug products containing SBECD



ABILIFY® IM

antipsychotic (anti-schizophrenic)

intramuscular

9.75 mg aripiprazole / vial

195 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 4.1$

EXPECTED PATENT EXPIRY: 2033 (US8999952)

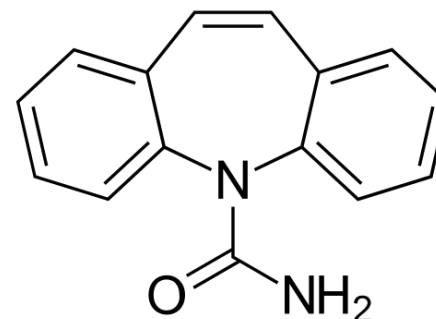


Marketed drug products containing SBECD



CarnexivTM
(carbamazepine) injection

Continuity counts.



CARNEXIV[®]

antiepilepsy

intravenous

200 mg carbamazepine / vial

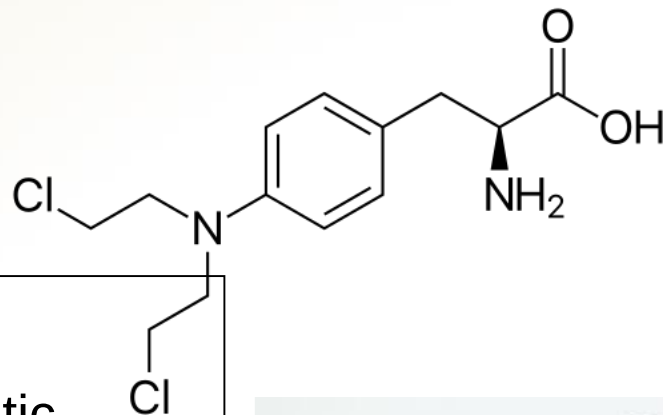
5000 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 2.7$

EXPECTED PATENT EXPIRY: 2033 (US9770407)



Marketed drug products containing SBECD



EVOMELA®

conditioning treatment prior to hematopoietic progenitor (stem) cell transplantation

intravenous

50 mg melphalan / vial

2700 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 7.6$



EXPECTED PATENT EXPIRY: no patent granted so far, orphan drug exclusivity until 2023, US Patent Appl: 14/108,169 (patent term: 2030 - expected)



Marketed drug products containing SBECD



BaxdelaTM

(delafloxacin) 450 mg tablets
300 mg vial for injection

BAXDELA[®]

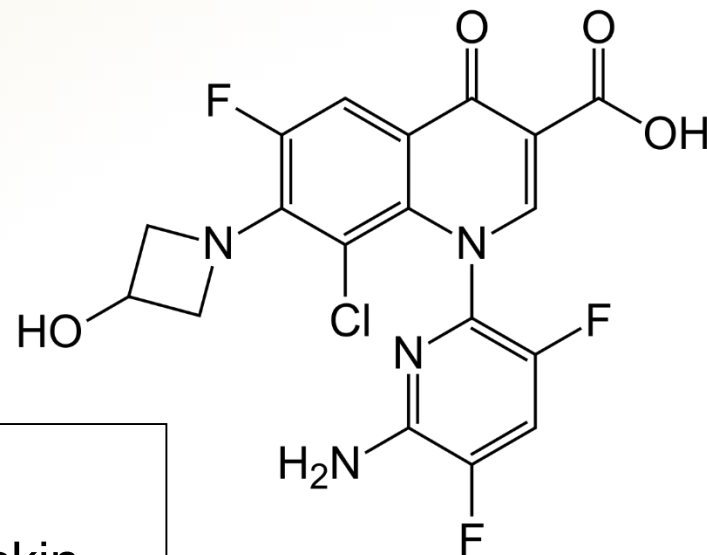
for the treatment of acute bacterial skin and skin
structure infections

intravenous

300 mg delafloxacin / vial

2400 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 1.6$



**EXPECTED PATENT EXPIRY: US Patent Appl: 15/042,886 (patent term:
2029 - expected) – status: final rejection (27-11-2018, USPTO)**

Marketed drug products containing SBECD

ZULRESSO®

for the treatment of
postpartum depression

Intravenous infusion

25 mg brexanolone / vial

1250 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 7.4$

PHARMACEUTICAL NEWS



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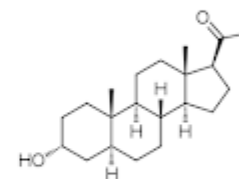
ZULRESSO (BREXANOLONE) IS THE FIRST DRUG APPROVED BY THE FDA SPECIFICALLY FOR POSTPARTUM DEPRESSION (PPD)



Zulresso

What is Zulresso?

Zulresso (brexanolone) is a gamma-aminobutyric acid A (GABAA) receptor positive allosteric modulator indicated for the treatment of postpartum depression (PPD).



Brexanolone

1-(3-Hydroxy-10,13-dimethyl-2,3,4,5,6,7,8,9,11,12,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-17-yl)ethanone

EXPECTED PATENT EXPIRY: 2036 (US10246482)



Marketed drug products containing SBECD

Levosimendan

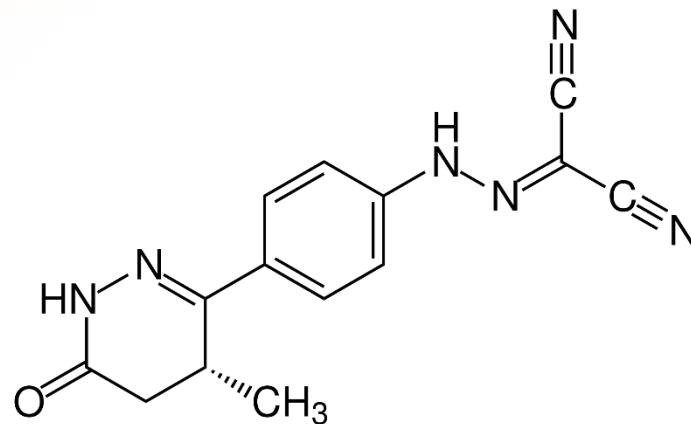
Intravenous infusion

management of acutely
decompensated congestive
heart failure

12.5 mg levosimendan / vial

875 mg SBECD / vial*

$n_{\text{Drug}} : n_{\text{SBECD}} = 1 : 9.1$



*Calculated data from Example 2 of WO2017077032 but exactly consistent with 60.5 mg Na-content noted in the package insert of the product



Marketed drug products containing SBECD

SESQUIENT

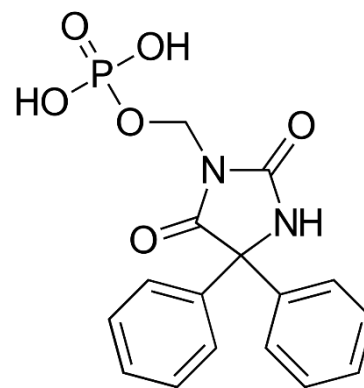
Intravenous anticonvulsant

75 mg fosphenytoin Na / ml

100 mg SBECD / ml

(2 and 10 ml vials are available)

$n_{\text{Drug}} : n_{\text{SBECD}} = 4 : 1^*$



SBECD is used in substoichiometric amount applied for chemical stabilization

EXPECTED PATENT EXPIRY: expired (WO1998056422)



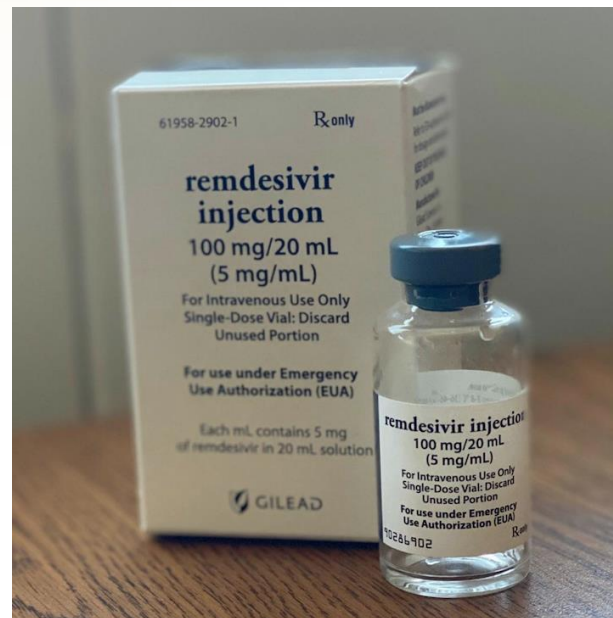
Marketed drug products containing SBECD

VEKLURY® 100 mg **concentrate** for solution for infusion
treatment of coronavirus disease 2019 (COVID-19) in adults and
adolescents (with pneumonia requiring supplemental oxygen)

Intravenous infusion

100 mg remdesivir + 6000 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = \mathbf{1 : 16.7}$

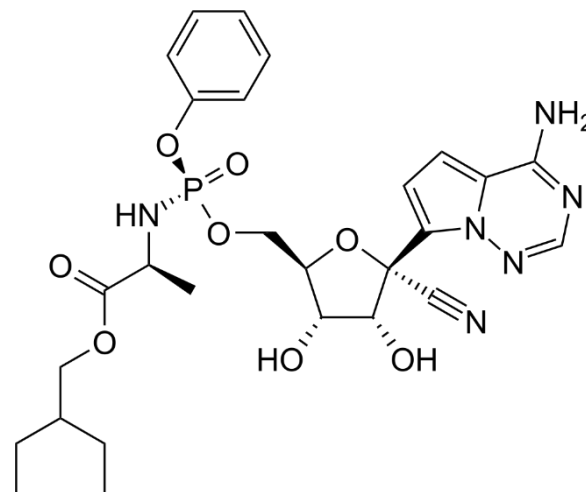


VEKLURY® 100 mg **powder** for concentrate for solution for
infusion

Intravenous infusion

100 mg remdesivir + 3000 mg SBECD / vial

$n_{\text{Drug}} : n_{\text{SBECD}} = \mathbf{1 : 8.3}$



EXPECTED PATENT EXPIRY: 2038 (WO2019014247)



Dexolve™

for Improved Pharmaceutical Formulations

Company contacts – ASK FOR A FREE SAMPLE:

CycloLab Cyclodextrin Research & Development Laboratory Ltd.

Budapest, P.O. Box 435, H-1525 Hungary

Location: Illatos út 7., Budapest, H-1097- Hungary

TEL: (+36) 1-347-60-60 or -70; FAX: (+36) 1-347-60-71

E-mail: dexolve@cyclolab.hu; Homepage: <http://www.cyclolab.hu>

Contact person:

Tamas Sohajda, R&D Director sohajda@cyclolab.hu (+36) 30-315-70-38

Zoltán Kovács, BD specialist kovacs@cyclolab.hu (+36) 30-163-71-77