

orBec® Access Form

I would like to obtain orBec® for the following patient:

Patient Identification: _____

Patient Gender: M / F (circle one) Patient weight: _____

Please send orBec® for the above patient

Declaration: Prior to prescribing this medication, I can confirm the patient meets the following inclusion criteria:

Inclusion criteria:

1. The patient has received an allogeneic hematopoietic cell transplant.
2. The patient has symptoms consistent with gastrointestinal GVHD with endoscopic evidence of GVHD without another plausible explanation for symptoms.
3. The patient has a confirmed absence of gastrointestinal infection within 7 days prior to the first dose of orBec®.
4. The patient has demonstrated an ability to swallow 2 tablets of the size and configuration of orBec®.
5. The patient will be receiving anti-candidal prophylaxis with an effective drug prior to the first dose of orBec®.
6. If female and of childbearing potential, the patient is willing to use adequate contraception for the duration of the study.
7. The patient has the ability to read, understand, and sign (or have a legal representative sign) appropriate patient informed consent or assent form.
8. The patient is 18 years of age or older.
9. The patient does not have skin GVHD, other than a slowly evolving rash that involves ≥50% of the body surface.
10. The patient does not have liver GVHD by liver histology or clinical criteria or evidence of liver dysfunction with a total serum bilirubin >3 mg/dL plus conjugated (direct) serum bilirubin >1.0 mg/dL.
11. The patient has not had >1000 mL diarrhoea on any 1 day within the 3 days prior to the first dose of orBec®.
12. The patient has not used any prescription corticosteroids (parenteral or oral) within 30 days prior to the first dose of orBec®. **NOTE:** Use of corticosteroids such as dexamethasone as anti-emetics during conditioning therapy, or use of single doses of corticosteroid in conjunction with infusion of blood products or medications to lessen side effects of these infusions, or short-term (less than 2 days) stress coverage, does not exclude patients. If the patient's attending physician believe that immediate initiation of high dose corticosteroid treatment for presumptive GVHD is clinically indicated, up to two doses of prednisone or equivalent, each dose equal to 0.5 mg/kg, or a total of 1 mg/kg/day, may be given prior to treatment initiation).
13. The patient does not have persistent vomiting of oral intake that precludes ingestion of orBec® tablets.
14. The patient does not have multi-organ failure, sepsis syndrome, or other condition with high mortality (*i.e.*, life expectancy less than 3 months).
15. The patient does not have infection of the mouth or oesophagus with a fungal organism.
16. If the patient is female, she is not pregnant or lactating.
17. The patient does not have known HIV seropositivity.
18. Overt gastrointestinal bleeding has not been observed.

I confirm the patient meets all Inclusion criteria stated above

Physician signature:	
Physician Name:	
Address:	Hospital / Department:
City:	Country:
Phone:	Fax:
License Number:	Email:
MD Specialty:	