

OFF-LABEL USE OF RITUXIMAB

PATIENT CONSENT FORM

In order for medicines to be marketed in Australia, they must be sponsored by a pharmaceutical company and undergo and pass testing by the Australian Therapeutic Goods Administration (TGA) for safe and effective use in specific medical conditions. However, for a variety of reasons, pharmaceutical companies may not sponsor the medicine for all potential medical conditions for which a medicine may be useful. This has occurred with rituximab, which is only approved for use (that is, registered) for certain medical conditions, which are listed in its Product Information. When a medicine is used outside the approved conditions for use, it is said to be an off-label use.

Before using a medicine off-label, it is recommended that patient consent is obtained after the potential benefits and harms of the medicine have been explained to the patient and/or their carer.

Rituximab is not registered for use in Australia for the treatment of

_____ (medical condition)

PATIENT CONSENT

By signing this form

I _____, confirm:
(Name of patient or parent/guardian)

- that the effectiveness or safety of rituximab in treating my medical condition is not fully known;
- that I have received adequate explanation regarding the off-label use of rituximab for my medical condition including the potential side effects, in order for me to make an informed decision; and,
- with this knowledge, I agree to treatment with off-label rituximab, knowing that I have the right to change my mind at any time.

Signature of patient (or name and signature of parent/guardian):

_____ Date: ___/___/___

Name and signature of witness: _____ Date: ___/___/___

DOCTOR'S STATEMENT

I have provided to the patient or their parent/ guardian*:

- an explanation of the off label use of rituximab and its potential benefits and harms; and,
- an Off Label Rituximab Patient Information Sheet.

*Tick box if interpreter used for NESB patient

Doctor's name: _____

Signature of doctor: _____ Date: ___/___/___

Completed signed form should be kept in the patient's medical records.