

Patient Agreement to Systemic Therapy: Consent Form	
Kadcyla (Trastuzumab emtansine)	
Patient's details / addressograph:	<input type="checkbox"/> Male <span style="margin-left: 200px;"><input type="checkbox"/> Female</span>
	Special requirements (e.g. other language/other communication method)
	<b>Consultant:</b>

**Name of proposed course of treatment:****Kadcyla**

IV infusion on day 1

Repeated every 3 weeks until disease progression

Macmillan leaflet given 

**Statement of health professional** (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

- I have discussed what the treatment is likely to involve (including inpatient / outpatient treatment, timing of the treatment, follow-up appointments) and location.

**The intended benefits**

- Curative – to give you the best possible chance of being cured
- Palliative – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival
- Adjuvant – therapy given after surgery to reduce the risk of recurrence of cancer
- Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer

**Significant, unavoidable or frequently occurring risks:**

**Early, administration-related side effects:** flu-like symptoms which include a headache, high temperature and chills, feeling sick or being sick. You may notice these while the drug is given or within 1-3 hours and they are usually most noticeable with the first dose, and are less noticeable with following doses.

**Other common side effects include:** bruising or bleeding (due to low platelets), anaemia (low number of red blood cells), diarrhoea or constipation, feeling sick (nausea) and being sick (vomiting), tiredness, rash, pain in the joints or muscles, numbness or tingling in the hands and feet. Kadcyla may also cause changes in the way your liver works (this usually returns to normal after treatment).

**Less common but potentially life threatening side-effects:** reduced resistance to infection which can lead to a potentially fatal blood infection, allergic reaction, effects on the lungs (report any new breathlessness, wheezing or cough)

**Other less common side-effects include:** effects on the heart (in order to check your heart function you will have regular tests - usually an echocardiogram, or a MUGA)

Kadcyla may damage the development of a foetus, leading to the many risks associated with an abnormal pregnancy. Therefore, I have discussed the issues of protected sex. This is an issue for both men and women. The patient has been advised not to become pregnant / not to get a partner pregnant during the period of treatment, and for 7 months after treatment has completed.

Any other risks:

.....  
 .....

<b>Clinician Signature</b>	
Signed.....	Date .....
Full Name (print) ..... / .....	Job Title.....
(Forename)	(Surname)

**Statement of patient**

<b>Patient Signature</b>
Please read this form carefully, which describes the benefits and risks of the proposed treatment. You have the right to change your mind at any time, including after you have signed this form.
I agree to undergo chemotherapy. I understand the treatment and am aware of the potential side-effects arising from this treatment.
<b>I understand</b> that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate training and experience.
Signed..... Name.....
Date.....
<b>A witness should sign below if the patient is unable to sign but has indicated his or her consent.</b>
Signature ..... Date .....
Name (PRINT) .....

**Statement of interpreter** (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ..... Name (PRINT) ..... Date.....

**Confirmation of consent** (to be completed by the chemotherapy nurse when the patient attends for the first cycle)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the treatment to go ahead.

Signed ..... Name (PRINT) ..... Date.....

**Copy accepted by patient: yes/no** (please ring)

**Copy to be retained in patient's notes**

Reason for Update: N/A	Checked and approved by Consultant: Dr A Neal
Version: 1	Date: 16.11.15