

Patient Agreement to Systemic Therapy: Consent Form	
Dabrafenib for melanoma	
Patient identification	<input type="checkbox"/> Male <input type="checkbox"/> Female
	Special requirements:
	Consultant:

Introduction

You need to give your permission before you receive any type of medical treatment or examination. Certain treatments require the permission to be recorded in writing because there are particular risks and considerations. This document is to record that an explanation has been given by an appropriate clinician and that you agree to the treatment, having assessed for yourself the processes, intended benefits and potential risks involved.

Statement of Health Professional

I have discussed the following aspects of the treatment.

The processes involved

- Dabrafenib is taken by mouth as capsules, twice a day on an empty stomach, with approximately 12 hours between doses. You should take it every day. You will need to attend the clinic every 28 days to receive a new supply. Each 28 day period is called one cycle. The standard dose is 150mg twice a day but your own dose may be different.
- I have discussed the system of clinic appointments and blood tests, and how we will assess whether the drug is working.

The intended benefits

- Dabrafenib is designed to work against melanomas with a particular characteristic, a mutation in the BRAF gene. We have evidence that your melanoma shows the BRAF mutation.
- In around 84% of people taking this treatment, the melanoma is likely to stop growing or regress
- When it works, the typical length of time it works for is around 11 months
- These figures are from a large clinical trial of many patients, and your individual experience may be very different. For example, dabrafenib may not work well for you, or it may work for considerably longer than the average.

Common side effects

- Skin rashes, thickening of the skin, inflammation of the hands and feet, skin tumours (including squamous cell carcinomas)
- Fatigue
- Joint pain

Less common side effects

- Fever and chills
- Hair thinning

Rare and significant side effects

- Other cancers caused by the treatment itself
- Headaches, bowel disturbance, sickness, eye and heart effects
- Additional rare and previously unknown side effects
- There are possible effects on fertility based on non-human studies

Precautions

- Certain drugs interact strongly with dabrafenib and should be avoided. These include rifampicin, phenytoin, carbamazepine and St John's wort.
- Some other drugs should be used with caution alongside dabrafenib. These include ketoconazole, clarithromycin, ritonavir and itraconazole.
- Dabrafenib affects multiple other drugs and may decrease their effect. The list includes warfarin, oral contraceptives, antiepileptics, steroids, sedatives, antibiotics. I have checked through your other medications and addressed these potential interactions with you.
- Women of childbearing potential should use effective methods of contraception during therapy and for four weeks after stopping. Men should use barrier contraception to avoid exposing partners to the small quantities of drug that may be present in semen.

Other considerations

- I have discussed the alternatives to this treatment and the associated risks
- I have discussed with you any special risks that might apply to you as an individual
- Additional information is attached to this form. You have agreed to read this and we will give you an opportunity to answer any further questions or concerns before you start treatment.

Clinician Signature	
Sign
Print name
Date
Job title

Statement of Patient

- I have carefully read this form, which describes the benefits and risks of the proposed treatment.
- I have the right to change my mind at any time, including after I have signed this form
- I agree to undergo drug therapy. I understand the treatment and am aware of the potential side effects arising from the treatment.
- I understand that you cannot give me a guarantee that a particular person will perform or manage the treatment. The person will, however, have appropriate training and experience.

Patient Signature

Sign

Print name

Date

Job title

Statement of witness if required

- The patient is unable to sign but has indicated his or her consent.

Witness Signature

Sign

Print name

Date

Job title

Statement of interpreter if required

- 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.

Interpreter Signature

Sign

Print name

Date

Job title

Confirmation of consent

- Completed by the chemotherapy nurse at first treatment attendance
- 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.

Healthcare Practitioner Signature	
Sign
Print name
Date
Job title

Record

- Hardcopy accepted by patient
- Hardcopy for notes
- Scanned

Reason for Update: N/A	Checked and approved by Consultant: Dr M Ajaz
Version: 1	Date: 7.12.15