

Dabrafenib and Trametinib

The possible benefits of treatment vary. This treatment aims to control the cancer and its symptoms. Your doctor will explain to you the treatment and its side effects. Your doctor or nurse will be happy to answer any questions you have about your treatment.

Your treatment

Your doctor or nurse clinician has prescribed for you a targeted therapy called dabrafenib and trametinib. The treatment is suitable for patients with a specific mutation in their cancer. These drugs are taken in combination. You should continue to take the medication without interruption unless advised by your doctor or if you develop a high temperature while taking them. Your doctor will monitor your progress regularly while you are on this medication.

- The medications should be swallowed whole with a full glass of water. It is important to take them on an empty stomach (one hour before food or 2 hours after food).
- The dabrafenib is to be taken twice daily as close to 12 hours apart as possible.
- The trametinib is to be taken once daily with either the morning or evening dose of dabrafenib.
- If you forget to take your medicine you may take it when you remember as long as it is not less than six hours before your next dose of dabrafenib and not less than 12 hours before your next dose of trametinib.
- Do not take double doses. If you vomit after your dose do not repeat the dose.

You will need to have regular blood tests while taking this medication.

Dabrafenib should be stored at room temperature away from heat, light and moisture. Trametinib should be stored in the fridge at 2°C – 8°C. Please keep both medicines out of reach of children.

Grapefruit and grapefruit juice can interact with your medication and should be avoided.

This treatment can have serious or possibly life-threatening side effects. It is very important that you report side effects straight away. Don't delay, if you feel unwell, please ring The Christie Hotline on **0161 446 3658**. The lines are open 24 hours a day.

Please tell your doctor if you have:

- liver or kidney problems
 - diabetes
 - eye problems
- or if you are on other medications.



Possible side effects

The side effects of dabrafenib and trametinib are different from those experienced by patients receiving chemotherapy. Some are more likely to occur than others. We are all different so we may get different side effects with varying severity. Some side effects are serious and potentially life-threatening. It is important to tell your treating doctor or nurse about any side effects so they can be monitored and treated. Most are temporary and can be managed. Below is a list of possible side effects that can occur. This is a guide only and not an exhaustive list.

Common side effects (more than 1 in 10)

• Fever

Fever is a common side effect with dabrafenib and trametinib and usually occurs within the first couple of months of therapy. It can however, occur at any time. Fever is defined as a temperature of more than 38.5°C. You should have a digital thermometer available at home and check your temperature if you feel unwell. Symptoms of fever include shivering, sweats and feeling hot or flushed. If you develop a fever you should contact The Christie Hotline on **0161 446 3658** so the doctor treating you can be informed.

If you develop a fever you should stop taking your dabrafenib and trametinib capsules until advised by your treating doctor. You can take paracetamol to help bring your temperature down to normal. Please see additional information sheet 'Guidance on management of fever'.

• Skin changes

Dabrafenib and trametinib can cause other changes to your skin. These include:

- a rash
- thickening of the palms of the hands and soles of the feet; this may be associated with a tingling sensation
- new lesions that look like warts (papilloma)
- changes in old moles.

Your doctor may refer you to a skin specialist or dermatologist if necessary.

• Hair loss

Your hair may become thinner or the structure of your hair may change.

• Painful and stiff joints

This treatment can be associated with muscle and joint aches and pains. You may need painkillers to help with this. For mild pain you can take paracetamol or ibuprofen. In some cases your doctor may need to prescribe strong painkillers.

• Diarrhoea

Diarrhoea can occur with this treatment. It is not usually severe and can be managed with an anti-diarrhoeal medication when required. It is also important to remain well-hydrated by drinking water. If you are having more than 4 episodes of diarrhoea per day, are becoming dehydrated or have associated abdominal pains you should contact your doctor or The Christie Hotline on **0161 446 3658**.

• Headache

Headache can sometimes occur and can be managed with painkillers. If it is severe you should contact The Christie Hotline as there are other causes of headache that need to be considered.

• Nausea and loss of appetite

If you lose your appetite, try eating small meals. If you are losing weight you might need to see a dietitian or ask your medical team for further advice.

• Feeling tired

Feeling fatigued is a common side effect. You may need to limit your activities to help with this. Do what you feel capable of and take plenty of rest if you need to.

• Cough

You may develop a cough when you have this treatment. It can be eased by drinking warm fluids or your treating doctor may prescribe cough medicines to help.

Uncommon side effects (less than 1 in 10)

• Squamous cell cancers

This treatment may cause a type of skin cancer called squamous cell carcinoma (cuSCC). These cancers are generally not serious and do not usually spread to other parts of the body. During treatment we will monitor your skin for cuSCC. You should also check your skin and if you develop anything of concern, please make sure you inform your treating doctor. Look out for lesions that look like a new wart or a reddish bump that bleeds or does not heal. In some circumstances, these skin cancers need to be removed.

Rare side effects (up to 1 in 100)

• Vision changes

The drugs can rarely cause inflammation of part of the eye called uveitis. Please let The Christie Hotline team know immediately if you develop blurred vision, eye pain, swelling, or redness.

Serious and potentially life-threatening side effects

In a small proportion of patients immunotherapy can result in very severe side effects which may rarely result in death. The team caring for you will discuss the risk of these side effects with you.

If you are taking any other medications:

Dabrafenib can react with other medications. It is important to let your doctor know if you are on any medications for other conditions or if there are any changes to your medication.

Common types of medications which might react with dabrafenib are:-

- Antibiotics such as rifampicin, clarithromycin, erythromycin.
- Anti-fungals such as ketoconazole, fluconazole and itraconazole.
- Blood pressure medications such as diltiazem and verapamil.
- Anti-seizure medications such as carbamazepine, phenobarbitone and phenytoin.
- Drugs taken after a transplant such as cyclosporin.
- Hormones such as oestrogens and progesterones.
- St John's Wort.
- Drugs to reduce stomach acid.

Diet

You do not need to be on a special diet while on treatment; however, grapefruit and grapefruit juice can interact with your medication and should be avoided.

If you are diabetic, dabrafenib can interfere with your blood sugar control. Check your blood sugars regularly.

Sex, contraception and fertility

We recommend that you or your partner use a condom during sexual intercourse while receiving treatment. It is still possible to become pregnant or father a child while on this treatment. Pregnancy should be avoided as it is unknown whether this treatment is harmful to the unborn baby. Hormonal

contraception may not work as well in women taking dabrafenib. Do not breast feed during treatment.

Dabrafenib may damage sperm and cause sterility in men. If you plan to have children please discuss this with your doctor before commencing treatment.

Late side effects

The long term possible side effects of treatment with dabrafenib are not yet known. Please speak to your doctor if you wish to discuss this further.

Contacts

If you have any general questions or concerns about your treatment, please ring:-

- Jackie Hodgetts on **0161 446 3868**
- General enquires on **0161 446 3000**

For urgent advice ring The Christie Hotline on **0161 446 3658** (24 hours)

Your consultant is:

Your hospital number is:

Your key worker is:

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The Christie is committed to producing high quality, evidence based information for patients. Our patient information adheres to the principles and quality statements of the Information Standard. If you would like to have details about the sources used please contact **the-christie.patient.information@nhs.net**

For information and advice visit the cancer information centres at Withington, Oldham or Salford. Opening times can vary, please check before making a special journey.



Contact The Christie Hotline for
urgent support and specialist advice
The Christie Hotline: 0161 446 3658
Open 24 hours a day, 7 days a week