



Dabrafenib: information for families

This information sheet explains what dabrafenib is, how it is given and some of the possible side effects. Each person reacts differently to medicines, so your child will not necessarily suffer from every side effect mentioned. If you have any questions or concerns, please speak to your doctor, nurse or pharmacist.

Please read this in conjunction with any patient information leaflet provided by the manufacturer. However, please note that this information sheet explains about the use of dabrafenib in children and young people so may differ from the manufacturer's information.

What is dabrafenib?

Dabrafenib is used to treat various types of cancer.

It is a 'biologic' medicine, that is, it works by stopping the process that makes cancer cells grow and divide.

How is it given?

Dabrafenib is given by mouth in a dose calculated for your child's weight so may change as your child gains or loses weight. The dose also depends on whether capsules or suspension is given.

It comes in the form of capsules in various strengths. It also comes as a dispersible tablet that can be dissolved in water before giving.

Dabrafenib capsules must be swallowed whole with a glass of water. The dose should be taken on an empty stomach – that is, one hour before food or two hours afterwards. You should aim to give each dose at the same times each day leaving an interval of approximately 12 hours between doses.

What are the side effects?

Allergic reaction

Some people receiving dabrafenib have an allergic reaction to the medicine. This reaction may be mild to severe.

Signs of a **mild** allergic reaction include skin rashes and itching, high temperature, shivering, redness of the face, a feeling of dizziness or headache. If you see any of these signs, please report them to a doctor or nurse.

Signs of a **severe** allergic reaction include any of the above, as well as shortness of breath. If you are in hospital and your child shows signs of a severe allergic reaction, call a doctor or nurse immediately.

Altered blood counts

There will be a temporary reduction in how well your child's bone marrow works. This means they may become anaemic (reduced blood cells), bruise or bleed more easily than usual, and have a higher risk of infection.

Your child's blood counts will be checked regularly to see how the bone marrow is working. Please tell your doctor if your child seems unusually tired, has bruising, bleeding, or any signs of infection, especially a high temperature.

Increased risk of infection

Tell the doctor if your child has any signs of infection, such as a high temperature, sore throat, upset tummy or pain when weeing. In most cases, they are not serious but it is best to check.

Upset stomach, nausea and vomiting

Anti-sickness medicines can be given to reduce or prevent these symptoms. Please tell your doctor or nurse if your child's sickness is very bad or lasts for more than a few days.

If your child has been prescribed anti-sickness medicine, they should have a dose 30 minutes before each dose of dabrafenib.

Skin changes

Commonly skin changes can occur while on treatment. This can include painful rashes on the limbs and moles. Any such changes should be reviewed by your doctor as soon as possible to ensure they can be treated appropriately.

Interactions with other medicines

Some medicines can react with dabrafenib, altering how well it works. Always check with your doctor or pharmacist before giving your child any other medicine, including medicines on prescription from your family doctor (GP), medicines bought from a pharmacy (chemist) or any herbal or complementary medicines.

Important

Alert card

We recommend that your child carries a biological therapy alert card at all times. This could be important if your child needs emergency treatment for any reason.

Chicken pox

If your child is on dabrafenib and has not had chickenpox but comes into contact with someone who has chicken pox or shingles (either face to face or longer than 15 minutes in the same room), you should report to your doctor immediately as your child may be at risk of developing a more severe form of the infection and may need special treatment. If your child gets chicken pox or shingles you should also report to your doctor immediately for antibiotics to be given. If you are unsure whether your child has had chicken pox prior to starting dabrafenib, their immunity should be checked with a simple blood test at that time and the result entered on the parent-held monitoring card.

Immunisations

Your doctor will advise you if your child should avoid immunisation while taking dabrafenib. Your child should NOT have any live vaccinations such as MMR, oral polio, chicken pox or BCG while taking Rituximab. Inactivated or killed vaccines such as influenza/flu, meningitis C, pneumococcal, hepatitis, Hib, tetanus, diphtheria, whooping cough/pertussis and the killed version of the polio immunisation are permitted if the patient is stable under treatment. If you have other children who need vaccines while your child is taking dabrafenib, they should have these as normal, but they should also receive the 'killed' or inactivated polio vaccine. If you have any questions about vaccines and immunisations, please ask your doctor.

Important

- Keep all medicines in a safe place where children cannot reach them
- Dabrafenib capsules and dispersible tablets should be kept in their original packaging in a cool, dry place away from direct sunlight or heat.
- If your child vomits after taking the dose, inform your doctor or nurse. Do not give them another dose.
- If you forget to give your child their dose, do not give them a double dose. Inform your doctor or nurse and keep to your child's regular schedule.
- If the doctor decides to stop treatment, return any remaining medicine to the pharmacist. Do not flush or throw it away.

Useful numbers

- GOSH switchboard 020 7405 9200
- Pharmacy medicines information 020 7829 8608 (Monday to Friday from 9am to 5pm)

Disclaimer

Please read this information sheet from GOSH alongside the patient information leaflet (PIL) provided by the manufacturer. If you do not have a copy of the manufacturer's patient information leaflet please talk to your pharmacist. A few products do not have a marketing authorisation (licence) as a medicine and therefore there is no PIL.

For children in particular, there may be conflicts of information between the manufacturer's patient information leaflet (PIL) and guidance provided by GOSH and other healthcare providers. For example, some manufacturers may recommend, in the patient information leaflet, that a medicine is not given to children aged under 12 years. In most cases, this is because the manufacturer will recruit adults to clinical trials in the first instance and therefore the initial marketing authorisation (licence) only covers adults and older children.

For new medicines, the manufacturer then has to recruit children and newborns into trials (unless the medicine is not going to be used in children and newborns) and subsequently amend the PIL with the approved information. Older medicines may have been used effectively for many years in children without problems but the manufacturer has not been required to collect data and amend the licence. This does not mean that it is unsafe for children and young people to be prescribed such a medicine 'off-licence/off-label'. However, if you are concerned about any conflicts of information, please discuss with your doctor, nurse or pharmacist.