



# Trametinib: information for families

**This information sheet explains what trametinib 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 trametinib in children and young people so may differ from the manufacturer's information.

## What is trametinib?

Trametinib 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.

In the UK, trametinib is currently unlicensed for children and young people aged less than 18 years. Medicines are often used outside of their license (off-label) in children because clinical trial data is not available for a specific use. Prescribing medicines 'off label' is not necessarily hazardous but should be explained and agreed before use.

## How is it given?

Trametinib 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 tablets or liquid is given.

It comes in tablets in various strengths and also comes as a powder that is made up into an oral liquid by the pharmacy. The tablets 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 time(s) each day.

For guidance on how to give your child medicines, please read our information sheet or watch our video podcast available on our website at [www.gosh.nhs.uk/conditions-and-treatments/medicines-information](http://www.gosh.nhs.uk/conditions-and-treatments/medicines-information)

## Effects on the unborn child

Trametinib must not be given to girls who may be pregnant or are likely to become pregnant in the near future. If your daughter is ten years old or older, we will ask her about her periods and any possibility that she could be pregnant. We will also carry out a pregnancy test on a fresh urine sample. If your daughter is sexually active, she must use a reliable form of contraception.

## What are the side effects?

### Allergic reaction

Some people receiving trametinib 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.

### **Changes in heart function**

These medicines may affect the muscle of your child's heart and how well it works. Before starting treatment, your child will have a test called an echocardiogram (ECHO). This will also be used to monitor the heart during the course of treatment and at long-term follow up clinics. The total amount of these drugs will be carefully calculated to minimise the risk of heart damage.

### **Raised blood pressure**

Trametinib may cause an increase in blood pressure. This will be monitored closely with each dose and additional medicines to bring blood

pressure back to a normal range may be suggested.

### **Fluid retention**

If you notice any swelling or puffiness around your child's limbs, especially the ankles, please tell your doctor or nurse.

### **Cough**

This can be a sign of fluid building up around the lungs. If your child develops a cough, breathing difficulties and/or chest pain, tell your doctor immediately.

### **Skin changes**

Trametinib can cause dry and itchy skin, an acne like facial rash, swelling and inflammation around the fingernails and toes and new moles. Please tell your doctor or nurse if your child develops a rash. They will advise you on the appropriate treatment to use.

### **Upset stomach causing vomiting, diarrhoea and/or constipation**

Please tell your doctor or nurse if your child has diarrhoea and/or constipation which is very bad or continues for more than a few days. Your child should continue to drink plenty of fluids and increase the amount of fibre eaten. Sometimes additional medicines may be prescribed to reduce these effects.

### **Hair loss**

Your child may lose all their hair or it may become thinner. This is temporary and the hair will grow back once the treatment has finished.

### **Lethargy and tiredness**

Trametinib can make your child feel more tired than usual. This will improve with time.

## Secondary cancer

If your child is given trametinib for a long time, there is a very small risk of developing a secondary cancer after many years. If you feel you would like more information, please discuss it with your doctor.

## Interactions with other medicines

Some medicines can react with trametinib, 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 trametinib 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 trametinib, 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 during treatment with trametinib. Your child should NOT have any live vaccinations such as MMR, oral polio, chicken pox or BCG while taking trametinib. 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 trametinib, 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.

### Storage

- Keep all medicines and tablets in a safe place where children cannot reach them.
- Trametinib tablets should be kept in the fridge.
- Trametinib powder should be kept in the fridge before reconstitution. Once made up, it must be kept at room temperature for a maximum of 35 days.
- If your child vomits straight after taking the dose, inform your local doctor or nurse, as your child may need to take another one. Do not give them another dose without informing the doctor or nurse.
- If you forget to give your child a dose, do not give a double dose. Inform your doctor or nurse and keep to your child's regular schedule.

## 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.