Trametinib MEKINIST®

Patient information sheet V3, March 2024



WHAT IS MEKINIST® TRAMETINIB?

- A targeted therapy used to treat some types of melanoma and lung cancers.
- Prescribed and renewed by your oncologist or cancer specialist.
- Available from community pharmacies on presentation of your prescription.



- Two presentations are available:
- Oval, yellow, film-coated tablet dosed at 0.5 mg, with "GS" on one side and "TFC" on the other
- Round, pink, film-coated tablet dosed at **2 mg**, with "GS" on one side and "HMJ" on the other
- Store for up to 30 days at a temperature below 30°C after opening the bottle.
- Do not take the tablets out of the bottle to put them in a pillbox.
- Wash your hands carefully before and after handling the tablets.
- Do not throw away opened bottles, please return them to your pharmacist.

HOW TO TAKE THIS MEDICINE

When?	= 1 dose per day at a set time <u>not at mealtimes</u> (at least one hour before and two hours after a meal)
How?	Swallow the tablet(s) whole, with water, at the same time every day. Do not chew, cut, crush or dissolve them.

You can use your **medical diary*** and a **calendar** to note doses:

Do not stop taking or change how you take your treatment without consulting your doctor. This leaflet is not a prescription, please refer to your most recent prescription.

IF YOU FORGET TO TAKE YOUR MEDICINE OR VOMIT

- If it has been less than 12 hours since your dose was due, take the missed dose. Take your next dose at the usual time. Keep a record in your medical diary*.
- If it has been more than 12 hours since your dose was due, do not take the missed dose. Take your next dose at the usual time, do not take a double dose. Keep a record in your medical diary*.
 - If you throw up, do not take another dose. Take your next dose at the usual time. Keep a record in your medical diary*.

INTERACTION WITH OTHER MEDICINES AND OTHER INTERACTIONS



Check with **your doctor or pharmacist** that the medicines (prescribed or over-the-counter), other substances (foods, spices and plants, including **grapefruit** and **St. John's Wort**, probiotics, essential oils, food supplements, etc.) and derivative products you use are **compatible with your treatment**. The molecules they contain, their dose and how often they are taken can interact with your treatment and affect its effectiveness and the occurrence of side effects.



- You and your partner must use effective methods of contraception (condoms and another method) throughout treatment **and for 4 months after the last dose**.
- Stop breastfeeding during treatment.

Male and female fertility can be affected during treatment with trametinib. Your doctor can tell you more about the possibility of sperm/egg banking before starting treatment.

* Patient diary available (in French) at <u>www.omedit-fiches-cancer.fr</u>

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WHAT SIDE EFFECTS CAN OCCUR WITH MEKINIST® TRAMETINIB?

Like an meanines, trainetinio may cause side enects, although not everybody gets them.			
Side effects		Prevention	
	High blood pressure	Headaches, dizziness, and tinnitus are the first warning signs of high blood pressure. Measure your blood pressure (resting and sitting down, in the morning before breakfast and in the evening before going to bed; take three measurements two minutes apart); keep a record of your results. Exercise regularly (suitable activities) (30 minutes 3 times per week). Limit salt (max. 6 g per day) and alcohol. Eat a diet low in saturated fats (animal fats) and high in fibre.	
	Rash, dry skin, itching	Use soap-free gel or a dermatological bar. Avoid hot water. Pat dry. Use moisturiser (cream or milk). Avoid sun exposure, particularly between noon and 4pm. Wear protective clothing, even under a parasol (UVA reflection). Use SPF 50+ sun cream, applied 30 minutes before exposure and reapplied every 2 hours.	
	Tiredness, headache	Drink sufficient quantities (1.5 to 2 L water per day) and eat healthily, at regular intervals. Avoid using psychostimulants (e.g. coffee, tobacco, alcohol). Rest during the day, while maintaining up to moderate levels of activity. Establish a sleep schedule; avoid going to bed and getting up late. Take care when driving.	
Fyte	Digestive effects: constipation, diarrhoea, abdominal pain, nausea, vomiting, loss of appetite	Monitor your weight and remember to hydrate (1.5 to 2 L water per day). In case of constipation, eat foods rich in fibre (bran, grains, wholemeal bread, green vegetables, fruit and nuts) and exercise regularly. In case of diarrhoea, eat foods low in fibre (carbohydrates, carrots, bananas etc.). Avoid foods that can stimulate digestion (dairy products, raw fruit/vegetables, grains, fatty foods, spices). In case of nausea/vomiting, divide your meals into several small meals and eat slowly. Avoid fatty, fried or spicy foods, and foods that smell strongly. Avoid having an empty stomach (can worsen nausea). Drink between, rather than with, meals. Use your prescribed antiemetics if applicable.	
T _a	Joint and muscle pain	Remember to hydrate before, during and after exerting yourself. Exercise regularly (walking, swimming); warm up before exercising. Avoid repetitive movements and strenuous physical effort. Use a walking stick to support your joints.	
Ť	Swollen limbs	Eat a diet low in salt. Avoid tight clothing. If your legs swell, raise your feet when sitting. Wear compression stockings; put them on when getting up in the morning. Weigh yourself regularly. Consult your doctor if this type of swelling occurs.	
**	Risk of infection	Limit contact with people with infections. Wash your hands regularly. Disinfect all wounds thoroughly. Contact your doctor in case of temperature > 38°C, cough, shortness of breath/pain on breathing, pain when urinating/smelly urine, change in type/frequency of bowel movements (diarrhoea, constipation), or if you get a rash.	
-`@`-	Only the most commo your doctor or pharma	n side effects are listed here. For more information, read the Patient Leaflet included with your medicine or ask acist.	

Like all medicines, trametinib may cause side effects, although not everybody gets them.

You can also ask your <u>Regional Pharmacovigilance Centre</u> and report any side effects online: signalement-sante-gouv-fr



Remember to go for the lab tests prescribed by your doctor.

WHAT TO DO IF YOU EXPERIENCE SIDE EFFECTS

- Take the medicine prescribed to counteract the side effects, as prescribed.
- Follow the preventive measures.

Contact your doctor rapidly in case of:

- Reduced vision, blurred vision or loss of vision
- Pounding heart, dizziness, swollen legs
- Muscle pain associated with dark urine
- Blood in your stool, coughing up blood or vomiting blood
- Any persistent or worsening side effect



Note: