PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTAFINLAR®

Dabrafenib Capsules

Read this carefully before you start taking **TAFINLAR®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TAFINLAR**.

Your cancer may be treated with TAFINLAR in combination with another medication called trametinib. When you take TAFINLAR with trametinib, read the Patient Medication Information leaflet for trametinib as well as this one.

Serious Warnings and Precautions

TAFINLAR should only be prescribed and managed by a healthcare professional who is experienced in the use of anti-cancer drugs. Serious side effects include:

- Taking TAFINLAR may cause severe fever
- TAFINLAR can harm an unborn baby
- Birth control using hormones (pills, injections, or patches) may not work as well while you are taking TAFINLAR
- TAFINLAR has not been studied in patients with moderate or severe liver problems
- Patients taking TAFINLAR have reported secondary cancers

Other serious side effects when taking TAFINLAR with trametinib include:

- Serious bleeding
- Blood clots

What is TAFINLAR used for?

Taking TAFINLAR **by itself** is used to:
- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.

Taking TAFINLAR **with trametinib** is also used to:
- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.
- help prevent melanoma from coming back. This is after the skin cancer was completely removed by surgery.
- treat a type of lung cancer. This type of cancer is called non-small cell lung cancer. These drugs are used together when this cancer has spread to other parts of the body.
- treat a type of brain tumour called glioma.

TAFINLAR should only be used for people who have a cancer that has a certain change in a gene called “BRAF”. Before taking TAFINLAR, you should have your cancer tested for this

change. Your healthcare professional will take a tumour tissue sample, to test whether TAFINLAR is suitable for you.

TAFINLAR capsules are not recommended for children less than 6 years of age or weighing less than 26kg.

How does TAFINLAR work?
TAFINLAR targets proteins made from the changed (mutated) BRAF gene. This slows down or stops growth of cancer cells.

What are the ingredients in TAFINLAR?
Medicinal ingredient: Dabrafenib mesylate
Non-medicinal ingredients: Colloidal silicon dioxide, iron oxide black, iron oxide red, hypromellose, magnesium stearate, microcrystalline cellulose, propylene glycol, shellac, titanium dioxide.

TAFINLAR comes in the following dosage forms:
Capsules: 50 mg and 75 mg dabrafenib (as dabrafenib mesylate)

Do not use TAFINLAR if:
- you are allergic to dabrafenib mesylate, or any of the other ingredients in TAFINLAR
- you do not have a particular change (mutation) in a gene called BRAF or if the mutation in BRAF is not known.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TAFINLAR. Talk about any health conditions or problems you may have, including if you:
- are pregnant, may be pregnant or are planning to become pregnant. You must use reliable non-hormonal birth control while receiving TAFINLAR and for at least 2 weeks after you stop TAFINLAR or for at least 16 weeks after stopping TAFINLAR with trametinib treatment. Pills, patches and injections are not effective in preventing pregnancies because they may not work as well while you are taking TAFINLAR; therefore, you should use an alternative effective method of birth control. You must make sure that you do not get pregnant while receiving TAFINLAR. If you do get pregnant, inform your healthcare professional immediately. TAFINLAR can harm an unborn baby.
- are breastfeeding. Do not breastfeed if you are taking TAFINLAR. If you wish to restart breastfeeding after TAFINLAR treatment, you must discuss this with your healthcare professional. Your healthcare professional will tell you when it is safe to breastfeed.
- are a male (who has had a vasectomy or not) with a female partner who is pregnant or may become pregnant. You should use condoms with spermicide during sexual intercourse while taking TAFINLAR and for at least 2 weeks after stopping TAFINLAR or for at least 16 weeks after stopping TAFINLAR with trametinib treatment.
- are a male. Men who take TAFINLAR may have a reduced count of sperm that may not return to normal levels after you stop taking TAFINLAR.
- have or have had a heart rhythm disorder such as irregular heartbeat, prolongation of the QT interval or any risk factors for Torsade de Pointes (dangerous rapid fluttering of the heart) such as diabetes, low potassium, magnesium or calcium levels, or a history of low heart rate, fainting, or loss of consciousness.
- have heart valve problems.
- have elevated blood sugar levels.

- have any liver problems. Your healthcare professional may take blood samples to monitor your liver function while you are taking TAFINLAR.
- have or have ever had any kidney problems.
- plan to have surgery, dental or other medical procedures.
- have any other medical conditions.

BEFORE you use TAFINLAR with trametinib also talk to your healthcare professional if you have:
- had bleeding problems or blood clots.
- heart problems such as heart failure or problems with the way your heart beats.
- unexplained stomach pain. This may be an inflamed pancreas (**pancreatitis**).
- eye problems including blockage of the vein draining the eye or swelling in the eye which may be caused by fluid leakage.
- any skin problems including rash or acne-like rash.
- high blood pressure.
- a low number of white blood cells.
- any lung or breathing problems, including **pneumonitis** (difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue).

Other warnings you should know about:

Fever (temperature 38°C or higher): Taking TAFINLAR may cause fever. Fever may happen more often or may be more severe when TAFINLAR is taken with trametinib. If you get a fever, or if you feel a fever coming on, stop taking TAFINLAR, or TAFINLAR and trametinib if you are taking both and tell your healthcare professional right away. In some cases, people with fever may develop severe chills, dehydration, low blood pressure, dizziness and kidney problems. Your healthcare professional may recommend that you stop taking TAFINLAR while they treat your fever with other medicines. Your healthcare professional will tell you if and when you can re-start TAFINLAR. You may receive a lower dose or your treatment may be stopped altogether.

Bleeding problems: TAFINLAR, when taken with trametinib, can cause serious bleeding problems, including in your brain, stomach, or bowel, and can lead to death. In some cases, people may develop brain tumours. Call your healthcare professional and get medical help right away if you have any unusual signs of bleeding including:
- headaches, dizziness, or feeling weak
- coughing up blood or blood clots
- vomiting blood or your vomit looks like “coffee grounds”
- red or black stools that look like tar

Blood clots: TAFINLAR, when taken with trametinib, can cause blood clots in your arms and legs, which can travel to your lungs or other parts of the body and can lead to death. Get medical help right away if you have any of the following symptoms:
- chest pain
- sudden shortness of breath or trouble breathing
- pain in your legs with or without swelling
- swelling in your arms or legs, especially one larger than the other
- a cool or pale arm or leg

Changes in your skin: If you notice any skin lesions or experience serious skin reactions while taking this medicine, talk to your healthcare professional as soon as possible.

You may develop a different type of skin cancer called cutaneous squamous cell carcinoma. Usually this cancer does not spread and can be removed with surgery. You can continue treatment with TAFINLAR.

You may also develop new skin cancers (melanomas). These are usually removed by surgery. You can continue treatment with TAFINLAR.

Your healthcare professional will check your skin for any new cancers before you start taking TAFINLAR. Your healthcare professional will also check your skin every 2 months while you take TAFINLAR. Your healthcare professional will check your skin again every 2 or 3 months for 6 months after you stop taking TAFINLAR.

Check your skin regularly while taking TAFINLAR for any of the following:
- new wart
- skin sore or reddish bump that bleeds or does not heal
- new moles or change in size or colour of an existing mole

Tell your healthcare professional as soon as possible if you get any of these symptoms - either for the first time or if they get worse or if you experience any of the following symptoms:
- rash, red skin, blistering of the lips, eyes, or mouth, skin peeling, with or without fever (**Stevens-Johnson syndrome**)
- widespread rash, fever and enlarged lymph nodes (**drug reaction with eosinophilia and systemic symptoms (DRESS).**

Inflammatory disease: TAFINLAR, when taken with trametinib, can cause an inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes called sarcoidosis. Common symptoms may include coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, and tender bumps on your skin. **Tell your healthcare professional if you get any of these symptoms**.

Eye problems: TAFINLAR can cause an eye problem called uveitis. This could damage your vision if it is not treated. Uveitis may develop rapidly; symptoms include:
- eye redness and irritation
- blurred vision
- eye pain
- increased sensitivity to light
- floating spots in front of your eyes

Contact your healthcare professional immediately if you get these symptoms. **It is very important to tell your healthcare professional immediately if you develop these symptoms,** especially if you have a painful, red eye that does not clear up quickly. They may arrange for you to see a specialist eye healthcare professional for a complete eye examination.

Liver problems: When TAFINLAR is taken with trametinib, it can cause problems with your liver. This may develop into serious conditions such as hepatitis and liver failure. These conditions may be fatal. Your healthcare professional will monitor you periodically.

Signs that your liver may not be working properly may include:
- loss of appetite
- nausea
- vomiting
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin

Decrease in white blood cells (neutropenia): TAFINLAR, when taken with trametinib, can cause a decrease in a certain kind of white blood cells. This may lead to infection, which can be life-threatening. Decrease in white blood cells may also lead to unexpected bruising or bleeding. Your healthcare professional will monitor you for signs of low blood cells. Signs that certain white cell counts are low may include:
- symptoms of infection (fever, chills, sore throat)
- bruise or bleed easily
- cold

Non-skin cancers: You may develop non-skin cancers while taking TAFINLAR. Your healthcare professional will monitor you for signs of non-skin cancers.

Heart problems: TAFINLAR has an effect on the electrical activity of the heart known as QT prolongation.

High blood sugar (Diabetes): TAFINLAR may cause an increase in blood sugar levels or worsening of diabetes. If you are diabetic your healthcare professional may monitor your blood sugar more frequently while you are on TAFINLAR.

Haemophagocytic lymphohistiocytosis or HLH: is a life-threatening blood disorder in which the body's ability to fight an illness (immune system) does not work normally. HLH affects multiple organs and produces several side effects. For more information on HLH and the other side effects, please see the table "Serious side effects and what to do about them".

Tumour Lysis syndrome or TLS: Treatment with TAFINLAR in combination with trametinib may cause you to develop TLS. This condition, which can be fatal, results from the fast death of cancer cells. For information on TLS side effects, please see the table "Serious side effects and what to do about them".

Driving and using machines: TAFINLAR can have side effects that may affect your ability to drive or use machines.

Avoid driving or using machines if you have problems with your vision or if you feel tired or weak, or if your energy levels are low.

Discuss with your healthcare professional if you are unsure about anything. Your disease, symptoms and treatment situation may affect your ability to drive or use machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions

TAFINLAR may decrease the effect of hormonal birth control. You may be at risk of getting pregnant if you are taking a hormonal birth control. You should use a different or additional non-hormonal method of birth control while you are taking TAFINLAR.

Do not start, stop or change any medicine without talking to your healthcare professional, nurse or pharmacist first.

The following may also interact with TAFINLAR:
- birth control using hormones such as pills, injections, or patches
- warfarin, to thin the blood
- medicines to treat fungal infections, such as ketoconazole
- some antibiotic medicines, such as clarithromycin or rifampin
- dexamethasone
- some medicines to treat HIV, such as ritonavir
- medicines to treat seizures, such as phenytoin, phenobarbital, or carbamazepine
- the anti-depressant medicine nefazodone
- medicines called statins used to treat high cholesterol
- the lipid lowering medicine gemfibrozil
- some medicines (called proton pump inhibitors) that reduce stomach acid (e.g. esomeprazole)
- the herbal product, St. John's wort
- medicines known to cause heart rhythm changes

Tell your healthcare professional if you are taking any of these. Your healthcare professional may decide to adjust your dose. Keep a list of the medicines you take, so you can show it to your healthcare professional when you get a new medicine.

How to take TAFINLAR:

Take TAFINLAR:
- exactly as your healthcare professional has told you to. Check with your healthcare professional or pharmacist if you are not sure;
- twice per day on an empty stomach at least one hour before or two hours after a meal;
- at about the same time each day. Take your TAFINLAR about 12 hours apart, for example in the morning and again in the evening. Do not take the morning and evening doses of TAFINLAR at the same time;
- Swallow the capsules whole with a full glass of water, one after the other;
- Take TAFINLAR for as long as your healthcare professional recommends.
- If you take TAFINLAR with trametinib:
    - take trametinib with either the morning or the evening dose of TAFINLAR. Take trametinib at about the same time each day and do not take more than one dose of trametinib a day.

Usual dose:
Taking TAFINLAR by itself: in adults, the recommended daily dose of TAFINLAR is two 75 mg capsules (150 mg), twice a day.

Taking TAFINLAR with trametinib: in adults, the recommended daily dose is two 75 mg

capsules of TAFINLAR (150 mg) twice a day with 2 mg of trametinib once a day.

In children 6 years and older, the recommended daily dose of TAFINLAR capsules is based on body weight and is determined by your doctor.

Your healthcare professional may decide that you should take a lower dose if you get side effects or to temporarily interrupt the treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much TAFINLAR, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If the missed dose is less than 6 hours late, take it as soon as you remember. If the missed dose is more than 6 hours late, skip that dose and take your next dose at the usual time. Then continue to take your capsules at regular times as usual. **Do not take two doses at once to make up for a missed dose.**

What are possible side effects from using TAFINLAR?

These are not all the possible side effects you may feel when taking TAFINLAR. If you experience any side effects not listed here, contact your healthcare professional.

- Nausea, vomiting, or diarrhoea
- Constipation
- Decreased appetite
- Stomach ache
- Weight increased or decreased
- Dry mouth
- Sore mouth or mouth ulcers
- Chills
- Feeling weak, sick and tired
- Lack of energy
- Tiredness, chills, sore throat, joint or muscle aching (flu-like illness)
- Inflammation of the mucous membranes
- Swelling of the face, the hands, ankles or feet, localized tissue swelling
- Swelling around the eyes
- Low levels of water or fluid (dehydration)
- Headache
- Dizziness
- Thickening of the outer layers of the skin
- Skin effects such as rough scaly patches of skin brown or yellow to red thickening of skin, skin tags, or redness of the skin
- Skin effects such as rash, dryness, wart-like growths, or redness and/or swelling
- Peeling of the palms, fingers and soles of the feet which may be accompanied by tingling sensation and burning pain
- Rash, dry skin, itching, acne-like problem

- Increased sensitivity of the skin to sun
- Skin cracking
- Unusual hair loss or thinning
- Itching
- Excessive sweating
- Night sweats
- Nasal inflammation
- Urinary tract infections
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles
- Inflammation of the follicles in the skin
- Skin rash with pus-filled blisters
- Joint pain, muscle pain, or pain in the hands or feet
- Muscle spasms
- Cough
- Shortness of breath
- High blood pressure
- Low blood pressure
- Slow heart rate
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (peripheral neuropathy)

TAFINLAR can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how TAFINLAR is affecting your blood, liver, kidneys and muscles.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Dermatitis acneiform: Skin rash, acne-like rash, redness of the face, dry or itching skin	✓		
Fever (temperature 38°C or higher) that may happen with rigors, chills, low blood pressure or kidney problems			✓
Hyponatremia (low blood levels of sodium): tiredness, confusion, muscle twitching, convulsions			✓
Oedema: generalised swelling			✓
Papilloma of the skin: small non-cancerous lumps on the skin	✓		
Serious bleeding problems involving: • the brain (headaches, dizziness, feeling weak), • the lungs (coughing up blood or blood clots)			✓

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
• the intestine (vomiting blood or vomit looking like “coffee grounds”, red or black stools that look like tar)			
COMMON			
Atrioventricular block or bundle branch block (irregular heartbeat): shortness of breath, fatigue, dizziness, near fainting and fainting			✓
Cellulitis (infection of the deeper layers of the skin): red, swollen pain area of skin that can be warm or tender, fever, chills		✓	
Cutaneous squamous cell cancer including keratoacanthomas: skin sore, wart, or reddish bump that bleeds or does not heal		✓	
Ejection fraction decreased (the heart does not pump as well as it should): fatigue, bloating, fluttering in the chest, loss of appetite, nausea, shortness of breath, swelling		✓	
Eye problems: redness, pain, blurred vision, floating spots, sensitivity to light. These eye problems may also include: • **Uveitis** (inflammation of the inner layer of the eye): red, swollen eye, eye pain, burning or sensitivity to light, blurred vision, headache. ✓ • **Chorioretinopathy** (swelling in the eyes caused by leaking fluid): distorted, dimmed or blurred vision, dark area in the middle of your vision ✓ • **Retinal detachment** (splitting of the light-sensitive membrane in the back of the eye from its supporting layer): blurred or distorted vision (uncommon) ✓			
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		✓	
Kidney failure (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain			✓
New primary melanoma (mole which has irregular shape, border, or colour, is growing, or changing shape or colour, new skin lesion)		✓	

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Pancreatitis (inflammation of the pancreas): severe upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			✓
Panniculitis (inflammation of the fatty layer under the skin): large tender red bumps under the skin		✓	
Tubulointerstitial nephritis: high or low urine output, drowsiness, confusion, nausea as a sign of an inflamed kidney			✓
Venous thromboembolism (blood clots): chest pain, sudden shortness of breath or trouble breathing, pain in your legs with or without swelling, swelling in your arms and legs, or a cool, pale arm or leg			✓
UNCOMMON			
Allergic Reactions: rash, hives, swelling of the face, lips, tongue, or throat, difficulty swallowing or breathing			✓
Gastrointestinal complications: severe stomach pain, chills, fever, nausea, vomiting of blood, black or bloody stools, holes in the intestinal wall			✓
Pneumonitis (inflammation of the lung): shortness of breath, cough		✓	
Sarcoidosis (inflammatory disease mainly affecting the skin, lungs and eyes): coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, tender bumps on your skin		✓	
UNKNOWN			
Haemophagocytic lymphohistiocytosis or HLH (a blood disorder in which your ability to fight off an illness "immune system" does not work normally): multiple symptoms such as fever, swollen glands, bruising, skin rash, enlarged liver and/or spleen, kidney abnormalities, or heart problems occurring at the same time			✓
Tumour lysis syndrome (fast death of cancer cells): multiple symptoms such as irregular heartbeat, decrease in urination, confusion, severe nausea and vomiting, shortness of			✓

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
breath, muscle cramps or spasms, occurring at the same time			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store TAFINLAR between 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about TAFINLAR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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TAFINLAR is a registered trademark

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Dabrafenib tablets for oral suspension

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- TAFINLAR can harm an unborn baby
- Birth control using hormones (pills, injections, or patches) may not work as well while you are taking TAFINLAR
- TAFINLAR has not been studied in patients with moderate or severe liver problems
- Patients taking TAFINLAR have reported secondary cancers

Other serious side effects when taking TAFINLAR with trametinib include:

- Serious bleeding
- Blood clots

What is TAFINLAR used for?

Taking TAFINLAR **by itself** is used to:
- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.

Taking TAFINLAR **with trametinib** is also used to:
- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.
- help prevent melanoma from coming back. This is after the skin cancer was completely removed by surgery.
- treat a type of lung cancer. This type of cancer is called non-small cell lung cancer. These drugs are used together when this cancer has spread to other parts of the body.
- Treat a type of brain tumour called glioma.

TAFINLAR should only be used for people who have a cancer that has a certain change in a gene called “BRAF”. Before taking TAFINLAR, you should have your cancer tested for this change. Your healthcare professional will take a tumour tissue sample, to test whether

TAFINLAR is suitable for you.

TAFINLAR tablets for suspension are not recommended for children less than 1 year of age or who weigh less than 8 kg.

How does TAFINLAR work?
TAFINLAR targets proteins made from the changed (mutated) BRAF gene. This slows down or stops growth of cancer cells.

What are the ingredients in TAFINLAR?
Medicinal ingredient: Dabrafenib mesylate
Non-medicinal ingredients: Acesulfame potassium, artificial berry flavour, colloidal silicon dioxide, crospovidone, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose.
TAFINLAR comes in the following dosage forms:
Tablets for suspension: 10 mg dabrafenib (as dabrafenib mesylate)
Do not use TAFINLAR if:
- you are allergic to dabrafenib mesylate, or any of the other ingredients in TAFINLAR
- you do not have a particular change (mutation) in a gene called BRAF or if the mutation in BRAF is not known.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TAFINLAR. Talk about any health conditions or problems you may have, including if you:
- are pregnant, may be pregnant or are planning to become pregnant. You must use reliable non-hormonal birth control while receiving TAFINLAR and for at least 2 weeks after you stop TAFINLAR or for at least 16 weeks after stopping TAFINLAR with trametinib treatment. Pills, patches and injections are not effective in preventing pregnancies because they may not work as well while you are taking TAFINLAR; therefore, you should use an alternative effective method of birth control. You must make sure that you do not get pregnant while receiving TAFINLAR. If you do get pregnant, inform your healthcare professional immediately. TAFINLAR can harm an unborn baby.
- are breastfeeding. Do not breastfeed if you are taking TAFINLAR. If you wish to restart breastfeeding after TAFINLAR treatment, you must discuss this with your healthcare professional. Your healthcare professional will tell you when it is safe to breastfeed.
- are a male (who has had a vasectomy or not) with a female partner who is pregnant or may become pregnant. You should use condoms with spermicide during sexual intercourse while taking TAFINLAR and for at least 2 weeks after stopping TAFINLAR or for at least 16 weeks after stopping TAFINLAR with trametinib treatment.
- are a male. Men who take TAFINLAR may have a reduced count of sperm that may not return to normal levels after you stop taking TAFINLAR.
- have or have had a heart rhythm disorder such as irregular heartbeat, prolongation of the QT interval or any risk factors for Torsade de Pointes (dangerous rapid fluttering of the heart) such as diabetes, low potassium, magnesium or calcium levels, or a history of low heart rate, fainting, or loss of consciousness.
- have heart valve problems.
- have elevated blood sugar levels.
- have any liver problems. Your healthcare professional may take blood samples to monitor your liver function while you are taking TAFINLAR.
- have or have ever had any kidney problems.
- plan to have surgery, dental or other medical procedures.

- have any other medical conditions.

BEFORE you use TAFINLAR with trametinib also talk to your healthcare professional if you have:
- had bleeding problems or blood clots.
- heart problems such as heart failure or problems with the way your heart beats.
- unexplained stomach pain. This may be an inflamed pancreas (**pancreatitis**).
- eye problems including blockage of the vein draining the eye or swelling in the eye which may be caused by fluid leakage.
- any skin problems including rash or acne-like rash.
- high blood pressure.
- a low number of white blood cells.
- any lung or breathing problems, including **pneumonitis** (difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue).

Other warnings you should know about:

Fever (temperature 38°C or higher): Taking TAFINLAR may cause fever. Fever may happen more often or may be more severe when TAFINLAR is taken with trametinib. If you get a fever, or if you feel a fever coming on, stop taking TAFINLAR, or TAFINLAR and trametinib if you are taking both and tell your healthcare professional right away. In some cases, people with fever may develop severe chills, dehydration, low blood pressure, dizziness and kidney problems. Your healthcare professional may recommend that you stop taking TAFINLAR while they treat your fever with other medicines. Your healthcare professional will tell you if and when you can re-start TAFINLAR. You may receive a lower dose or your treatment may be stopped altogether.

Bleeding problems: TAFINLAR, when taken with trametinib, can cause serious bleeding problems, including in your brain, stomach, or bowel, and can lead to death. In some cases, people may develop brain tumours. Call your healthcare professional and get medical help right away if you have any unusual signs of bleeding including:
- headaches, dizziness, or feeling weak
- coughing up blood or blood clots
- vomiting blood or your vomit looks like “coffee grounds”
- red or black stools that look like tar

Blood clots: TAFINLAR, when taken with trametinib, can cause blood clots in your arms and legs, which can travel to your lungs or other parts of the body and can lead to death. Get medical help right away if you have any of the following symptoms:
- chest pain
- sudden shortness of breath or trouble breathing
- pain in your legs with or without swelling
- swelling in your arms or legs, especially one larger than the other
- a cool or pale arm or leg

Changes in your skin: If you notice any skin lesions or experience serious skin reactions while taking this medicine, talk to your healthcare professional as soon as possible.

You may develop a different type of skin cancer called cutaneous squamous cell carcinoma.

Usually this cancer does not spread and can be removed with surgery. You can continue treatment with TAFINLAR.

You may also develop new skin cancers (melanomas). These are usually removed by surgery. You can continue treatment with TAFINLAR.

Your healthcare professional will check your skin for any new cancers before you start taking TAFINLAR. Your healthcare professional will also check your skin every 2 months while you take TAFINLAR. Your healthcare professional will check your skin again every 2 or 3 months for 6 months after you stop taking TAFINLAR.

Check your skin regularly while taking TAFINLAR for any of the following:
- new wart
- skin sore or reddish bump that bleeds or does not heal
- new moles or change in size or colour of an existing mole

Tell your healthcare professional as soon as possible if you get any of these symptoms - either for the first time or if they get worse or if you experience any of the following symptoms:
- rash, red skin, blistering of the lips, eyes, or mouth, skin peeling, with or without fever (**Stevens-Johnson syndrome**)
- widespread rash, fever and enlarged lymph nodes (**drug reaction with eosinophilia and systemic symptoms (DRESS).**

Inflammatory disease: TAFINLAR, when taken with trametinib, can cause an inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes called sarcoidosis. Common symptoms may include coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, and tender bumps on your skin. **Tell your healthcare professional if you get any of these symptoms**.

Eye problems: TAFINLAR can cause an eye problem called uveitis. This could damage your vision if it is not treated. Uveitis may develop rapidly; symptoms include:
- eye redness and irritation
- blurred vision
- eye pain
- increased sensitivity to light
- floating spots in front of your eyes

Contact your healthcare professional immediately if you get these symptoms. **It is very important to tell your healthcare professional immediately if you develop these symptoms,** especially if you have a painful, red eye that does not clear up quickly. They may arrange for you to see a specialist eye healthcare professional for a complete eye examination.

Liver problems: When TAFINLAR is taken with trametinib, it can cause problems with your liver. This may develop into serious conditions such as hepatitis and liver failure. These conditions may be fatal. Your healthcare professional will monitor you periodically. Signs that your liver may not be working properly may include:
- loss of appetite
- nausea
- vomiting
- pain in your stomach (abdomen)

- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin

Decrease in white blood cells (neutropenia): TAFINLAR, when taken with trametinib, can cause a decrease in a certain kind of white blood cells. This may lead to infection, which can be life-threatening. Decrease in white blood cells may also lead to unexpected bruising or bleeding. Your healthcare professional will monitor you for signs of low blood cells. Signs that certain white cell counts are low may include:

- symptoms of infection (fever, chills, sore throat)
- bruise or bleed easily
- cold

Non-skin cancers: You may develop non-skin cancers while taking TAFINLAR. Your healthcare professional will monitor you for signs of non-skin cancers.

Heart problems: TAFINLAR has an effect on the electrical activity of the heart known as QT prolongation.

High blood sugar (Diabetes): TAFINLAR may cause an increase in blood sugar levels or worsening of diabetes. If you are diabetic your healthcare professional may monitor your blood sugar more frequently while you are on TAFINLAR.

Haemophagocytic lymphohistiocytosis or HLH: is a life-threatening blood disorder in which the body's ability to fight an illness (immune system) does not work normally. HLH affects multiple organs and produces several side effects. For more information on HLH and the other side effects, please see the table "Serious side effects and what to do about them".

Tumour Lysis syndrome or TLS: Treatment with TAFLINLAR in combination with trametinib may cause you to develop TLS. This condition, which can be fatal, results from the fast death of cancer cells. For information on TLS side effects, please see the table "Serious side effects and what to do about them".

Driving and using machines: TAFINLAR can have side effects that may affect your ability to drive or use machines.

Avoid driving or using machines if you have problems with your vision or if you feel tired or weak, or if your energy levels are low.

Discuss with your healthcare professional if you are unsure about anything. Your disease, symptoms and treatment situation may affect your ability to drive or use machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions
TAFINLAR may decrease the effect of hormonal birth control. You may be at risk of getting pregnant if you are taking a hormonal birth control. You should use a different or additional non-hormonal method of birth control while you are taking TAFINLAR.

Do not start, stop or change any medicine without talking to your healthcare professional, nurse or pharmacist first.

The following may also interact with TAFINLAR:
- birth control using hormones such as pills, injections, or patches
- warfarin, to thin the blood
- medicines to treat fungal infections, such as ketoconazole
- some antibiotic medicines, such as clarithromycin or rifampin
- dexamethasone
- some medicines to treat HIV, such as ritonavir
- medicines to treat seizures, such as phenytoin, phenobarbital, or carbamazepine
- the anti-depressant medicine nefazodone
- medicines called statins used to treat high cholesterol
- the lipid lowering medicine gemfibrozil
- some medicines (called proton pump inhibitors) that reduce stomach acid (e.g. esomeprazole)
- the herbal product, St. John's wort
- medicines known to cause heart rhythm changes

Tell your healthcare professional if you are taking any of these. Your healthcare professional may decide to adjust your dose. Keep a list of the medicines you take, so you can show it to your healthcare professional when you get a new medicine.

How to take TAFINLAR:

Take TAFINLAR:
- exactly as your healthcare professional has told you to. Check with your healthcare professional or pharmacist if you are not sure;
- twice per day on an empty stomach at least one hour before or two hours after a meal;
- at about the same time each day. Take your TAFINLAR about 12 hours apart, for example in the morning and again in the evening. Do not take the morning and evening doses of TAFINLAR at the same time;
- Take TAFINLAR for as long as your healthcare professional recommends.
- Take trametinib with either the morning or the evening dose of TAFINLAR. Take trametinib at about the same time each day and do not take more than one dose of trametinib a day.

TAFINLAR tablets for suspension are to be taken as an oral suspension only and should not be swallowed whole, chewed, or crushed.
Please follow below Instructions for Use on how to prepare and take TAFINLAR tablets for suspension. Talk to your doctor or pharmacist if you are not sure.

INSTRUCTIONS FOR USE of TAFINLAR tablets for suspension

This "Instructions for Use" contains information on how to prepare and take TAFINLAR.

Important Information You Need to Know Before Taking TAFINLAR

- Read these Instructions for Use carefully before you use TAFINLAR for the first time and each time you get a refill. There may be new information.

- These instructions for use do not take the place of talking with your healthcare professional about you or your child's medical condition and treatment.
- Your healthcare professional or pharmacist should show you how to prepare and take or give a dose of TAFINLAR correctly. Always take or give TAFINLAR exactly as your healthcare professional tells you to.
- If you have any questions about how to prepare and take or give a dose of TAFINLAR, contact your healthcare professional or pharmacist.
- Always use the dosing cup that comes with your TAFINLAR pack. If your pack does not contain a dosing cup, contact your healthcare professional or pharmacist.
- If at any time TAFINLAR suspension gets on your or your child's skin, wash the area well with soap and water.
- If at any time TAFINLAR suspension gets in your or your child's eyes, rinse the eyes well with cool water.

IMPORTANT: Use only clean water to rinse. Do not use soap or dishwashing liquid to clean the dosing cup.

- Pregnant or breastfeeding women must avoid cleaning up a spillage due to a risk of harm to the baby.

You will receive your or your child's TAFINLAR prescription in a sealed bottle which contains tablets for suspension. You must dissolve the tablets in water before taking or giving TAFINLAR. Follow the instructions below to mix the tablets in water.

- Your TAFINLAR pack should contain:

1. 1 or 2 bottles containing TAFINLAR tablets for suspension
2. 2 reusable dosing cups

   Instructions leaflet and Patient Medication Information (this document)

   You will also need drinking water, which is not included in the TAFINLAR pack.

For administration via swallowing, go to Section A. For administration via feeding tube or via oral syringe, go to Section B.

SECTION A. Preparing and giving TAFINLAR by swallowing directly from the dosing cup


In case of spillage, follow the instructions in the **How to clean up spills** section.

To prepare and administer TAFINLAR, you will need:

- Your prescribed number of TAFINLAR tablets
- Dosing cup
- Stainless steel teaspoon
- Still drinking water

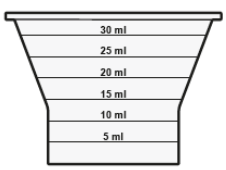
To administer orally (i.e., swallow the suspension), you can drink directly from the dosing cup.

Step 1. Wash and dry your hands before preparing TAFINLAR.

Add cool drinking water up to the markings on the dosing cup, according to the table below.

Note: the amount of water does not need to be exact.

Your dose	**Water volume**
1-4 tablets	Approximately 5 mL
5-15 tablets	Approximately 10 mL



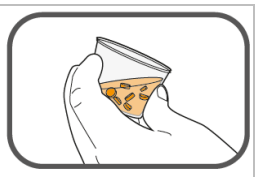
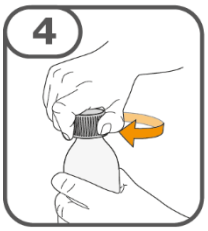
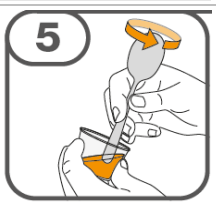
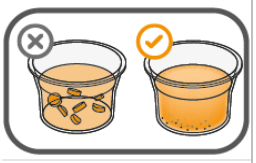
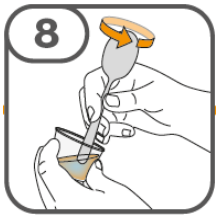
Step 2. Remove the bottle cap by pushing down and turning counterclockwise, as shown.

Do not throw away the cap.

If opening the bottle for the first time, remove the seal from the bottle.

Step 3. Count your prescribed number of tablets.

Note: The bottle contains 2 plastic canisters to keep the tablets dry. If either canister falls out, put it back into the bottle.

Put your prescribed number of tablets into the water in your dosing cup.	
Step 4. Place the cap back onto the bottle and turn it clockwise to close it.	
Step 5. Tilt the dosing cup. Gently stir the water and tablets with the handle of a teaspoon until the tablets are fully dissolved. It may take **3 minutes** (or more) to fully dissolve the tablets. Once they are dispersed, the suspension should be cloudy white. **Administer the suspension no later than 30 minutes after the tablets have been dispersed** If more than 30 minutes have passed, dispose of the suspension into the trash and restart from the beginning of Section A. If you are not sure how to dispose of the TAFINLAR oral suspension, ask your healthcare professional	 
Step 6. Drink the suspension from the dosing cup. **IMPORTANT:** after swallowing, there will be drug residue inside the cup. The residue may be difficult to see. Follow steps 7 – 9 to administer all residue and get a full dose.	
Step 7. Add approximately 5mL of water to the empty dosing cup.	
Step 8. Stir with the handle of a teaspoon to loosen the remaining residue.	

Step 9. Drink the suspension.
Important: If the dose is 1-4 tablets: Perform Steps 7-9 once.

If the dose is 5-15 tablets: Perform Steps 7-9 twice.

It is important to perform these steps so that you take or give the full dose of TAFINLAR.

Step 10. Go to the cleaning steps in Section C.

SECTION B. Preparing and giving TAFINLAR via feeding tube or oral syringe

Important administration information
Ensure all the tablets are fully dispersed before administering the suspension.

Minimum size of the feeding tube:

Your dose	Minimum size
1 – 3 tablets	10 French
4 – 15 tablets	12 French

Wash and dry your hands before administering TAFINLAR.

In case of spillage, follow the instructions in the **How to clean up spills** section.

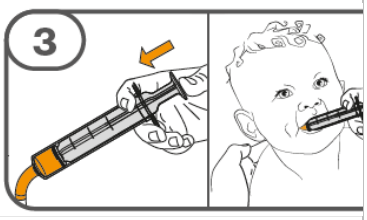
Step 1. **Follow Steps 1-5 in Section A to disperse the tablets.** If using a feeding tube, flush the tube with still drinking water then go to Step 2.

Step 2. **Withdraw all of the suspension** from the dosing cup into a syringe compatible with the feeding tube or oral administration. Ask your healthcare professional if you are not sure what syringe to use.

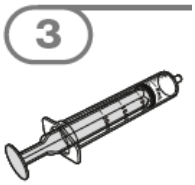
Step 3. If administering the dose by a feeding tube, dispense the suspension into the feeding tube according to the tube manufacturer's instructions.

If administering via oral syringe, place the end of the oral syringe inside the mouth with the tip touching the inside of either cheek. If administering to a child, make sure they are sitting upright.

Slowly push the plunger all the way down to deliver the full dose of TAFINLAR.



WARNING: giving TAFINLAR directly into the throat or pushing the plunger too fast may cause choking.	
Step 4. **Add approximately 5mL of water** to the empty dosing cup	
Step 5. **Stir** with the handle of a teaspoon to loosen the remaining residue.	
Step 6. **Withdraw** the suspension into the syringe.	
Step 7. **Dispense** the suspension into the feeding tube or into the inside of the cheek. **Important: Perform Steps 4-7 a total of three (3) times to give a full dose.** It is important to perform these steps so that you take or give the full dose of TAFINLAR.	
You must **administer all drug residue**. Repeat Step 4 to Step 7 a total of **three times** to give a full dose.	
Step 8. After repeating Step 4 to Step 7 a total of three times, flush the feeding tube with still drinking water. Then go to the cleaning steps in Section C.	
SECTION C. Cleaning the dosing cup and syringe (if used)	
Use only clean water to clean the dosing cup. Do not use soap or dishwashing liquid for the dosing cup.	

Step 1. Rinse the dosing cup using clean cool water immediately after dosing. Shake off excess water then wipe dry using clean paper towels. **Note:** Always keep the dosing cup away from other kitchen items.	
Step 2. Rinse the teaspoon in clean cold water, then wash in warm soapy water and dry using clean paper towels. Alternatively, you can wash the teaspoon in a dishwasher.	
Step 3. Clean the syringe as instructed by your healthcare professional or according to the manufacturer's instructions.	

SECTION D. How to throw away (dispose of) TAFINLAR that is expired or no longer needed, or old dosing cups

Throw away (dispose of) unused TAFINLAR tablets or suspension, or old dosing cups into the trash. Do not pour suspension down the drain. Ask your healthcare professional or pharmacist about how to safely throw away TAFINLAR tablets if you are not sure.

How to clean up spills

Follow these steps if you spill any TAFINLAR oral suspension:

1. Put on plastic gloves.
2. Soak up the suspension completely using an absorbent material, such as paper towels soaked with either a mixture of water and household disinfectant or with ethanol 70% (or higher grade).
3. Repeat the cleaning with fresh soaked absorbent material at least three times until the area is clean.
4. Dry the area with paper towels.
5. Throw away all the disposable materials used to clean the spillage into a sealable plastic bag.
6. Dispose of the bag in accordance with local regulations.

Wash your hands well with soap and water.

What should I do if TAFINLAR oral suspension comes into contact with my or my child's skin or gets in my eyes?

If at any time TAFINLAR suspension gets on your or your child's skin, wash the area well with soap and water.

If at any time TAFINLAR suspension gets in your or your child's eyes, rinse the eyes well with cool water.

How should I store TAFINLAR

- Store the TAFINLAR bottle with the two plastic canisters inside and the cap tightly closed. The canisters help keep your medicine dry and protect it from moisture.
- Store the bottle and dosing cups in the original packaging
- Store at 15°C to 25°C.
- Keep this medicine out of sight and reach of children.
- After suspension (tablets dispersed in water) in the provided dosing cup, keep the suspension at 15-25°C. Discard suspension if not administered within 30 minutes after preparation.

Usual dose:
The recommended dose of TAFINLAR Tablets for suspension is based on body weight and is determined by your doctor.

Your healthcare professional may decide that you should take a lower dose if you get side effects or to temporarily interrupt the treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much TAFINLAR, contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:
If the missed dose is less than 6 hours late, take it as soon as you remember. If the missed dose is more than 6 hours late, skip that dose and take your next dose at the usual time. Then continue to take your capsules at regular times as usual. **Do not take two doses at once to make up for a missed dose.**

What are possible side effects from using TAFINLAR?

These are not all the possible side effects you may feel when taking TAFINLAR. If you experience any side effects not listed here, contact your healthcare professional.

- Nausea, vomiting, or diarrhoea
- Constipation
- Decreased appetite
- Stomach ache
- Weight increased or decreased
- Dry mouth
- Sore mouth or mouth ulcers
- Chills
- Feeling weak, sick and tired

- Lack of energy
- Tiredness, chills, sore throat, joint or muscle aching (flu-like illness)
- Inflammation of the mucous membranes
- Swelling of the face, the hands, ankles or feet, localized tissue swelling
- Swelling around the eyes
- Low levels of water or fluid (dehydration)
- Headache
- Dizziness
- Thickening of the outer layers of the skin
- Skin effects such as rough scaly patches of skin brown or yellow to red thickening of skin, skin tags, or redness of the skin
- Skin effects such as rash, dryness, wart-like growths, or redness and/or swelling
- Peeling of the palms, fingers and soles of the feet which may be accompanied by tingling sensation and burning pain
- Rash, dry skin, itching, acne-like problem
- Increased sensitivity of the skin to sun
- Skin cracking
- Unusual hair loss or thinning
- Itching
- Excessive sweating
- Night sweats
- Nasal inflammation
- Urinary tract infections
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles
- Inflammation of the follicles in the skin
- Skin rash with pus-filled blisters
- Joint pain, muscle pain, or pain in the hands or feet
- Muscle spasms
- Cough
- Shortness of breath
- High blood pressure
- Low blood pressure
- Slow heart rate
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (peripheral neuropathy)

TAFINLAR can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how TAFINLAR is affecting your blood, liver, kidneys and muscles.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Dermatitis acneiform: Skin rash, acne-like rash, redness of the face, dry or itching skin	✓		
Fever (temperature 38°C or higher) that may happen with rigors, chills, low blood pressure or kidney problems			✓
Hyponatremia (low blood levels of sodium): tiredness, confusion, muscle twitching, convulsions			✓
Oedema: generalised swelling			✓
Papilloma of the skin: small non-cancerous lumps on the skin	✓		
Serious bleeding problems involving: • the brain (headaches, dizziness, feeling weak), • the lungs (coughing up blood or blood clots) • the intestine (vomiting blood or vomit looking like “coffee grounds”, red or black stools that look like tar)			✓
COMMON			
Atrioventricular block or bundle branch block (irregular heartbeat): shortness of breath, fatigue, dizziness, near fainting and fainting			✓
Cellulitis (infection of the deeper layers of the skin): red, swollen pain area of skin that can be warm or tender, fever, chills		✓	
Cutaneous squamous cell cancer including keratoacanthomas: skin sore, wart, or reddish bump that bleeds or does not heal		✓	
Ejection fraction decreased (the heart does not pump as well as it should): fatigue, bloating, fluttering in the chest, loss of appetite, nausea, shortness of breath, swelling		✓	
Eye problems: redness, pain, blurred vision, floating spots, sensitivity to light. These eye problems may also include: • **Uveitis** (inflammation of the inner layer of the eye): red, swollen eye, eye pain, burning or sensitivity to light, blurred vision, headache. ✓ • **Chorioretinopathy** (swelling in the eyes caused by leaking fluid): distorted, dimmed or blurred vision, dark area in the middle of your vision ✓			

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
• **Retinal detachment** (splitting of the light-sensitive membrane in the back of the eye from its supporting layer): blurred or distorted vision (uncommon)		✓	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		✓	
Kidney failure (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain			✓
New primary melanoma (mole which has irregular shape, border, or colour, is growing, or changing shape or colour, new skin lesion)		✓	
Pancreatitis (inflammation of the pancreas): severe upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			✓
Panniculitis (inflammation of the fatty layer under the skin): large tender red bumps under the skin		✓	
Tubulointerstitial nephritis: high or low urine output, drowsiness, confusion, nausea as a sign of an inflamed kidney			✓
Venous thromboembolism (blood clots): chest pain, sudden shortness of breath or trouble breathing, pain in your legs with or without swelling, swelling in your arms and legs, or a cool, pale arm or leg			✓
UNCOMMON			
Allergic Reactions: rash, hives, swelling of the face, lips, tongue, or throat, difficulty swallowing or breathing			✓
Gastrointestinal complications: severe stomach pain, chills, fever, nausea, vomiting of blood, black or bloody stools, holes in the intestinal wall			✓
Pneumonitis (inflammation of the lung): shortness of breath, cough		✓	
Sarcoidosis (inflammatory disease mainly affecting the skin, lungs and eyes): coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, tender bumps on your skin		✓	
UNKNOWN			

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Haemophagocytic lymphohistiocytosis or HLH (a blood disorder in which your ability to fight off an illness "immune system" does not work normally): multiple symptoms such as fever, swollen glands, bruising, skin rash, enlarged liver and/or spleen, kidney abnormalities, or heart problems occurring at the same time			✓
Tumour lysis syndrome (fast death of cancer cells): multiple symptoms such as irregular heartbeat, decrease in urination, confusion, severe nausea and vomiting, shortness of breath, muscle cramps or spasms, occurring at the same time			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store TAFINLAR between 15°C to 25°C.
Protect from moisture. Do not remove desiccant.
Keep out of reach and sight of children.

After suspension (tablets dispersed in water) in the provided dosing cup, keep the suspension at 15-25°C. Discard suspension if not administered within 30 minutes after preparation.

If you want more information about TAFINLAR:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-

products/drug-product-database.html); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised: May 29, 2024

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