

Package leaflet: Information for the patient

Finlee® 10 mg dispersible tablets dabrafenib

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask the doctor, pharmacist or nurse.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to the doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- The information in this leaflet is for you or your child – but in the leaflet it will just say “your child”.

What is in this leaflet

1. What Finlee is and what it is used for
2. What you need to know before you give Finlee
3. How to give Finlee
4. Possible side effects
5. How to store Finlee
6. Contents of the pack and other information

1. What Finlee is and what it is used for

Finlee is a medicine that contains the active substance dabrafenib.

It is used in combination with another medicine (trametinib oral solution) in children aged 1 year and older to treat a type of brain tumour called glioma.

Finlee can be used in patients with:

- low-grade glioma
- high-grade glioma when the patient has received at least one radiation and/or chemotherapy treatment.

Finlee is used to treat patients whose brain tumour has a specific mutation (change) in the so-called BRAF gene. This mutation causes the body to make faulty proteins which in turn may cause the tumour to develop. The doctor will test for this mutation before starting treatment.

In combination with trametinib, Finlee targets these faulty proteins and slows down or stops the development of the tumour. **Also read the leaflet for trametinib oral solution.**

2. What you need to know before you give Finlee

Do not give Finlee

- **if your child is allergic** to dabrafenib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to the doctor before giving Finlee. The doctor needs to know if your child:

- has **eye problems** including blockage of the vein draining the eye (retinal vein occlusion) or swelling in the eye which may be caused by fluid leakage (chorioretinopathy).
- has **heart problems** such as heart failure or problems with the way their heart beats.

- has or has had any **kidney problems**.
- has or has had any **liver problems**.
- has or has had any **lung or breathing problems**, including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue.
- has or has had any **gastrointestinal problems** such as diverticulitis (inflamed pouches in the colon) or metastases to the gastrointestinal tract.

Before your child starts taking Finlee, during and after their treatment, the doctor will make checks to avoid complications.

Skin examination

Finlee may cause skin cancer. Usually, these skin changes remain local and can be removed with surgery and treatment with Finlee can be continued without interruption. The doctor may check your child's skin before and regularly during treatment.

Check your child's skin monthly during the treatment and for 6 months after they stop taking this medicine. **Tell the doctor** as soon as possible if you notice any changes to your child's skin such as a new wart, skin sore or reddish bump that bleeds or does not heal, or a change in the size or colour of a mole.

Children younger than 1 year old

The effects of Finlee in children younger than 1 year old are not known. Therefore, Finlee is not recommended in this age group.

Patients older than 18 years of age

Information on treating patients older than 18 years of age with glioma is limited, therefore continued treatment into adulthood should be assessed by the doctor.

Other medicines and Finlee

Before starting treatment, tell the doctor, pharmacist or nurse if your child is taking, has recently taken or might take any other medicines. This includes medicines obtained without a prescription.

Some medicines may affect how Finlee works or make it more likely that your child will have side effects. Finlee can also affect how some other medicines work. These include:

- medicines used for birth control (contraceptives) containing hormones, such as pills, injections, or patches
- medicines used to thin the blood, such as warfarin and acenocoumarol
- medicines used to treat heart conditions, such as digoxin
- medicines used to treat fungal infections, such as itraconazole, voriconazole and posaconazole
- medicines used to treat Cushing's disease, such as ketoconazole
- some medicines known as calcium channel blockers used to treat high blood pressure, such as diltiazem, felodipine, nicardipine, nifedipine or verapamil
- medicines used to treat cancer, such as cabazitaxel
- some medicines used to lower fat (lipids) in the blood stream, such as gemfibrozil
- some medicines used to treat certain psychiatric conditions, such as haloperidol
- some medicines known as antibiotics, such as clarithromycin, doxycycline and telithromycin
- some medicines used to treat tuberculosis (TB), such as rifampicin
- some medicines used to lower cholesterol levels, such as atorvastatin and simvastatin
- some medicines known as immunosuppressants, such as cyclosporin, tacrolimus and sirolimus
- some medicines known as anti-inflammatory medicines, such as dexamethasone and methylprednisolone
- some medicines used to treat HIV, such as ritonavir, amprenavir, indinavir, darunavir, delavirdine, efavirenz, fosamprenavir, lopinavir, nelfinavir, tipranavir, saquinavir and atazanavir
- some medicines used to help with sleep, such as diazepam, midazolam, zolpidem
- some medicines used for pain relief, such as fentanyl and methadone

- medicines used to treat seizures (epilepsy), such as phenytoin, phenobarbital, primidone, valproic acid or carbamazepine
- medicines known as antidepressants, such as nefazodone and the herbal medicine St John's wort (*Hypericum perforatum*)

Tell the doctor, pharmacist or nurse if your child is taking any of these (or if you are not sure). The doctor may decide to adjust the dose.

Pregnancy, breast-feeding and fertility

Pregnancy

- If your child is pregnant, or if you think your child may be pregnant, ask the doctor or nurse for advice before taking this medicine. Finlee may potentially harm an unborn baby.
- If your child becomes pregnant while taking this medicine, tell the doctor immediately.

Breast-feeding

It is not known whether Finlee can pass into breast milk. If your child is breast-feeding, or planning to breast-feed, you must tell the doctor. You, your child and the doctor will decide if they will take Finlee or breast-feed.

Fertility

Finlee may reduce sperm count and this may not return to normal levels after stopping treatment with Finlee.

Taking Finlee with trametinib oral solution: Trametinib may impair fertility in both males and females.

Prior to starting treatment with Finlee, talk to the doctor about options to improve your child's chances to have children in the future.

Contraception

- If your child could become pregnant, they must use a reliable method of birth control (contraception) while they are taking Finlee in combination with trametinib oral solution and for at least 16 weeks following the last dose of Finlee in combination with trametinib.
- Birth control containing hormones (such as pills, injections or patches) may not work as well while taking Finlee in combination with trametinib oral solution. An alternative effective method of birth control should be used to avoid the risk of pregnancy while taking this combination of medicines. Ask the doctor or nurse for advice.

Driving and using machines

Finlee can have side effects that may affect your child's ability to drive, ride a bike/scooter, use machines, or take part in other activities that need alertness. If your child has problems with vision or feels tired or weak, or their energy levels are low, they should avoid such activities.

Descriptions of these effects can be found in section 4. Read all the information in this leaflet for guidance.

Discuss with the doctor, pharmacist or nurse if you are unsure about anything. Your child's disease, symptoms and treatment situation may also affect their ability to take part in such activities.

Finlee contains potassium

This medicine contains potassium, less than 1 mmol (39 mg) per maximum daily dose, i.e. essentially 'potassium-free'.

Finlee contains benzyl alcohol

This medicine contains <0.00078 mg benzyl alcohol in each dispersible tablet.

Benzyl alcohol may cause allergic reactions.

Ask the doctor or pharmacist for advice if your child is pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build up in your child's body and may cause side effects (called "metabolic acidosis").

Ask the doctor or pharmacist for advice if your child has a liver or kidney disease. This is because large amounts of benzyl alcohol can build up in your child's body and may cause side effects (called "metabolic acidosis").

3. How to give Finlee

Always give this medicine to your child exactly as the doctor, pharmacist or nurse has told you. Check with the doctor, pharmacist or nurse if you are not sure.

How much to give

The doctor will decide on the correct dose of Finlee based on your child's body weight.

The doctor may decide that your child should be given a lower dose if they get side effects.

How to give it

Please read the Instructions for Use at the end of this leaflet for details on how to prepare and give the dispersible tablets solution.

- Give **Finlee twice a day**. Giving Finlee at the same time each day will help you to remember when to give the medicine. Give each dose of Finlee about 12 hours apart. Trametinib oral solution is only taken once a day. Give trametinib oral solution with **either** the morning dose **or** the evening dose of Finlee.
- Give Finlee on an empty stomach, at least one hour before or two hours after a meal, this means that:
 - after taking Finlee, your child must wait **at least 1 hour** before eating.
 - after eating, your child must wait **at least 2 hours** before taking Finlee.
 - if necessary, breast-feeding and/or baby formula may be given on demand.

If you give more Finlee than you should

If you give too much Finlee, **contact the doctor, pharmacist or nurse for advice**. If possible, show them the Finlee pack and this leaflet.

If you forget to give Finlee

If the missed dose is less than 6 hours late, give it as soon as you remember.

If the missed dose is 6 hours or more than 6 hours late, skip that dose. Give the next dose at the usual time and carry on giving Finlee at regular times as usual.

Do not give a double dose to make up for a forgotten dose.

If your child vomits after taking Finlee

If your child vomits after taking Finlee, do not give another dose until the next scheduled dose.

If you stop giving Finlee

Give Finlee for as long as the doctor recommends. Do not stop unless the doctor advises you to.

If you have any further questions on the use of this medicine, ask the doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop giving this medicine and seek urgent medical attention if your child has any of the following symptoms:

- coughing up of blood, passing blood in urine, vomit containing blood or that looks like “coffee grounds”, red or black stools that look like tar. These may be signs of bleeding.
- fever (temperature 38°C or above).
- chest pain or shortness of breath, sometimes with fever or cough. These may be signs of pneumonitis or inflamed lungs (interstitial lung disease).
- blurred vision, loss of vision or other vision changes. These may be signs of retinal detachment.
- eye redness, eye pain, increased sensitivity to light. These may be signs of uveitis.
- unexplained muscle pain, muscle cramps or muscle weakness, dark urine. These may be signs of rhabdomyolysis.
- strong abdominal pain. This may be a sign of pancreatitis.
- fever, swollen lymph glands, bruising or skin rash at the same time. These may be signs of a condition where the immune system makes too many infection-fighting cells that may cause various symptoms (called haemophagocytic lymphohistiocytosis).
- reddish patches on the trunk that are circular or target-shaped, with or without central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes. These may be signs of serious skin rashes, which can be life-threatening, and can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome), widespread rash, fever and enlarged lymph nodes (DRESS).

Other possible side effects

Very common (*may affect more than 1 in 10 people*)

- Headache
- Dizziness
- Cough
- Diarrhoea, feeling sick (nausea), being sick (vomiting), constipation, stomach ache
- Skin problems such as rash, acne-like rash, dry or itching skin, redness of skin
- Nail bed infection
- Pain in arms or legs or joints
- Lack of energy or feeling weak or tired
- Increase in weight
- Increase of liver enzymes seen in blood tests
- Decreased level of white blood cells (neutropenia, leukopenia)
- Decreased level of red blood cells (anaemia)

Common (*may affect up to 1 in 10 people*)

- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis)
- Frequent urination with pain or burning sensation (urinary tract infection)
- Skin effects including infection of the skin (cellulitis), inflammation of hair follicles in the skin, inflamed flaky skin (dermatitis exfoliative generalised), wart-like growths (skin papilloma), thickening of the outer layer of the skin (hyperkeratosis)
- Decreased appetite
- Low blood pressure (hypotension)
- High blood pressure (hypertension)
- Shortness of breath
- Sore mouth or mouth ulcers, inflammation of mucosa
- Inflammation of the fatty layer under the skin (panniculitis)
- Unusual loss of hair or thinning
- Red, painful hands and feet (hand-foot syndrome)

- Muscle spasms
- Chills
- Allergic reaction (hypersensitivity)
- Dehydration
- Eyesight problems including blurred vision
- Decreased heart rate (bradycardia)
- Tiredness, chest discomfort, light headedness, palpitations (ejection fraction decreased)
- Tissue swelling (oedema)
- Muscle pain (myalgia)
- Tiredness, chills, sore throat, joint or muscles aching (influenza-like illness)
- Abnormal test results related to creatine phosphokinase, an enzyme found mainly in heart, brain and skeletal muscle
- Increase in blood sugar level
- Low levels of sodium or phosphate in the blood
- Decreased level of blood platelets (cells that help blood to clot)

Uncommon (*may affect up to 1 in 100 people*)

- Inflammation of the intestines (colitis)
- Cracking of skin
- Night sweats
- Excessive sweating

In addition to the side effects described above, the following side effects have so far only been reported in adult patients, but may also occur in children:

- problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet and/or muscle weakness (peripheral neuropathy)
- dry mouth
- increased sensitivity of the skin to sun
- kidney failure
- benign skin tumour (acrochordon)
- inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes (sarcoidosis)
- inflammation of the kidneys
- a hole (perforation) in the stomach or intestines
- inflammation of the heart muscle which can result in breathlessness, fever, palpitations and chest pain

Reporting of side effects

If your child gets any side effects, talk to the doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Finlee

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and the carton after EXP. The expiry date refers to the last day of that month.

Administer the solution no later than 30 minutes after the tablets have dissolved.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Finlee contains

- The active substance is dabrafenib. Each dispersible tablet contains dabrafenib mesilate equivalent to 10 mg of dabrafenib.
- The other ingredients are: mannitol (E 421), microcrystalline cellulose (E 460), crospovidone (E 1202), hypromellose (E 464), acesulfame potassium (E 950) (see section 2), magnesium stearate (E 470b), artificial berry flavour (maltodextrin, propylene glycol [E 1520], artificial flavours, triethyl citrate [E 1505], benzyl alcohol [E 1519] [see section 2]), and colloidal anhydrous silica (E 551).

What Finlee looks like and contents of the pack

Finlee 10 mg dispersible tablets are white to slightly yellow, round tablets of 6 mm marked “D” on one side and “NVR” on the other.

The bottles are white plastic with threaded plastic closures.

The bottles also include a silica gel desiccant in small cylinder-shaped containers. The desiccants must be kept inside the bottle and must not be eaten.

Finlee 10 mg dispersible tablets are available in packs containing 1 or 2 bottles (210 or 420 dispersible tablets) and 2 dosing cups.

Marketing Authorisation Holder and Manufacturer

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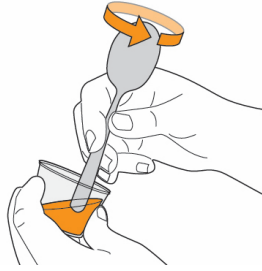
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

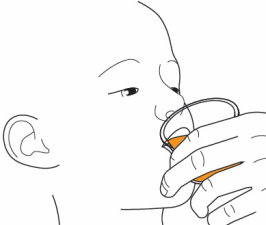
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This leaflet was last revised in 06/2024

INSTRUCTIONS FOR USE

| SECTION A ADMINISTRATION VIA DOSING CUP | |
|---|--|
| <p>You must dissolve the tablets in water before giving Finlee. Follow the instructions below to dissolve the tablets in water.</p> <p>If Finlee solution gets on your skin, wash the area well with soap and water.</p> <p>If Finlee solution gets in your eyes, rinse your eyes well with cool water.</p> <p>In case of spillage, follow the information in the “SPILLAGE CLEANING” section.</p> | |
| 1 | |
| Wash and dry your hands before administering Finlee. | |
| 2 | |
| Add still drinking water to the dosing cup: <ul style="list-style-type: none">○ About 5 ml for 1 to 4 tablets○ About 10 ml for 5 to 15 tablets | |
| 3 | |
| Remove the child-resistant cap by pushing down on the cap and turning it anti-clockwise. | |
| 4 |  |
| Count the prescribed number of tablets into your hand and put them in the dosing cup. | |
| The bottle contains 2 plastic canisters with silica gel desiccant to keep the tablets dry. | |
| Put the canisters back into the bottle if they fall out. | |
| Do not throw the canisters away. | |
| Close the bottle with the cap. Store the closed bottle in the carton out of sight and reach of children. | |
| 5 |  |
| Slightly tilt the dosing cup and gently stir with the handle of a stainless steel teaspoon until the tablets are fully dissolved (it may take 3 minutes or more). The solution will be cloudy white when it is ready. | |
| Administer the solution no later than 30 minutes after the tablets have dissolved. | |


| | |
|---|--|
| <p>6</p> <p>Ensure that your child drinks all of the solution from the dosing cup.</p> |  |
| <p>7</p> <p>Add about 5 ml of still drinking water to the empty dosing cup and stir with the handle of the stainless steel teaspoon (there will be tablet residue inside the dosing cup which may be difficult to see).</p> | |
| <p>8</p> <p>Ensure that your child also drinks all of this solution from the dosing cup.</p> | |
| <p>9</p> <p>If 5 to 15 prescribed tablets: repeat Steps 7 to 8.</p> | |
| <p>10</p> <p>For cleaning instructions, see “SECTION C”.</p> | |

SECTION B ADMINISTRATION VIA ORAL SYRINGE OR FEEDING TUBE

Feeding tube minimum size:

| Your dose | Minimum size |
|------------------|---------------------|
| 1 to 3 tablets | 10 French gauge |
| 4 to 15 tablets | 12 French gauge |

| | |
|--|--|
| <p>1</p> <p>Follow Steps 1 to 5 in “SECTION A” to dissolve the tablets, then move to Step 2 in this section.</p> | |
| <p>2</p> <p>Withdraw all of the solution from the dosing cup into a syringe compatible with a feeding tube or oral administration.</p> | |

| | |
|--|--|
| <p>3a</p> <p>Administering via oral syringe: Place the end of the oral syringe inside the mouth with the tip touching the inside of either cheek.</p> <p>Slowly push the plunger all the way down to give the full dose.</p> <p>WARNING: Administering Finlee to the throat or pushing the plunger too fast may cause choking.</p> |  |
| <p>3b</p> <p>Administering via feeding tube: Dispense the solution into the feeding tube as per the feeding tube manufacturer's instructions.</p> | |
| <p>4</p> <p>Add about 5 ml of still drinking water to the empty dosing cup and stir with the handle of the stainless steel teaspoon to loosen the residue (there will be tablet residue inside the cup which may be difficult to see).</p> | |
| <p>5</p> <p>Withdraw all of the solution from the dosing cup into a syringe compatible with a feeding tube or oral administration.</p> | |
| <p>6</p> <p>Dispense the solution into the feeding tube or into the inside of the cheek.</p> | |
| <p>7</p> <p>Repeat Steps 4 to 6 a total of 3 times to give a full dose.</p> | |
| <p>8</p> <p>For cleaning instructions, see "SECTION C".</p> | |

SECTION C CLEANING

Dosing cup

- Rinse the dosing cup with water immediately after dosing. Do not use hot water as the dosing cup may deform.
- Shake off excess water then wipe dry using clean paper towels.
- Always keep the dosing cup away from other kitchen items to avoid contamination.
- If both of your dosing cups become dirty and cannot be cleaned with water only, contact your pharmacist for a new dosing cup.

Teaspoon

- Hand wash the teaspoon with warm, soapy water or wash it in a dishwasher.

Oral Syringe

If used, clean the oral syringe as follows:

1. Fill a glass with warm, soapy water.
2. Place the oral syringe into the glass with the warm, soapy water.
3. Pull water into the oral syringe and empty again 4 to 5 times.
4. Separate the plunger from the barrel.
5. Rinse the glass, plunger and barrel under warm tap water.
6. Leave the plunger and barrel on a dry surface to air dry before next use.

You can use the dosing cup for up to 4 months after first use. After 4 months, throw away the dosing cup in the household waste.

SPILLAGE CLEANING

Follow these steps if you spill any Finlee solution:

1. Put on plastic gloves.
2. Soak up the solution completely using an absorbent material, such as paper towels soaked with a mixture of water and household disinfectant.
3. Repeat the cleaning with fresh soaked absorbent material at least 3 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. Ask the pharmacist how to throw away the plastic bag.
7. Wash your hands well with soap and water.