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What Meqsel is used for

MEQSEL is a prescription medicine used:

- alone or in combination with a medicine called dabrafenib to treat a type of skin cancer called melanoma:
 - that has spread to other parts of the body or cannot be removed by surgery, **and**
 - that has a certain type of abnormal “BRAF” gene.

MEQSEL should not be used to treat people who already have received a BRAF inhibitor for treatment of their melanoma, and it did not work or is no longer working.

- in combination with dabrafenib, to help prevent melanoma that has a certain type of abnormal “BRAF” gene from coming back after the cancer has been removed by surgery.
- in combination with dabrafenib to treat a type of lung cancer called non-small cell lung cancer (NSCLC):
 - that has spread to other parts of the body, **and**
 - that has a certain type of abnormal “BRAF” gene.
- in combination with dabrafenib to treat solid tumors in adults and children 6 years and older:
 - that cannot be removed by surgery or have spread to other parts of the body, and that have gotten worse (progressed) and you have no

satisfactory treatment options, **and**

- that have a certain type of abnormal “BRAF” gene.

MEQSEL is not for use in treating people with colorectal cancer. Your healthcare provider will perform a test to make sure that MEQSEL is right for you.

It is not known if MEQSEL used in combination with dabrafenib is safe and effective in children younger than 1 year of age.

It is not known if MEQSEL used alone is safe and effective in children.

How Meqsel works

Melanoma, non-small cell lung cancer and solid tumors have a particular change (mutation) in a gene called BRAF. This mutation in the gene may have caused the cancer to develop. Your medicine targets proteins made from this mutated gene and slows down or stops the development of your cancer.

Before you use Meqsel

- Before you start to use it

Before you take MEQSEL, tell your healthcare provider about all of your medical conditions, including if you:

- have had bleeding problems or blood clots
- have stomach problems
- have inflammation of the colon
- have heart problems
- have eye problems
- have lung or breathing problems
- have high blood pressure (hypertension)
- have liver or kidney problems
- have diabetes
- are pregnant or plan to become pregnant. MEQSEL can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a test to see if you are pregnant before starting treatment with MEQSEL.
- You should use effective birth control (contraception) during treatment with MEQSEL and for 4 months after your last dose of MEQSEL.
- Talk to your healthcare provider about birth control methods that may be right for you during this time.
- Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with MEQSEL.

Males (including those who have had a vasectomy) with a female partner who is able to become pregnant:

- Use condoms during sexual intercourse during treatment with MEQSEL and for at least 4 months after your last dose of MEQSEL.
- are breastfeeding or plan to breastfeed. It is not known if MEQSEL passes into your breast milk.
 - Do not breastfeed during treatment and for 4 months after your last dose of MEQSEL. Talk to your healthcare provider about the best way to feed your baby during this time.

- Taking other medicines

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How to use Meqsel

- How much to use

Trametinib Film-coated tablets (0.5mg and 2mg)

- Take or give MEQSEL exactly as your healthcare provider tells you to take or give it. Do not change your dose or stop MEQSEL unless your healthcare provider tells you.
- Your healthcare provider may change your dose of MEQSEL, temporarily stop, or completely stop your treatment with MEQSEL if you develop certain side effects.

- When to use it

MEQSEL tablets:

- Take MEQSEL 1 time each day, at the same time each day, about every 24 hours.
- Take MEQSEL at least 1 hour before or 2 hours after a meal.
- Take MEQSEL tablets whole. Do not crush or break MEQSEL tablets.
- If MEQSEL tablets are prescribed for your child 6 years of age or older, your child's healthcare provider will adjust their dose as your child grows.
- Tell your healthcare provider if you or your child is not able to swallow MEQSEL tablets whole.

- How long to use it

Take Meqsel for as long as your doctor recommends. Do not stop unless your doctor advises you to.

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

- If you forget to use it

- If you miss a dose of MEQSEL, take or give it as soon as you remember. **Do not take or give a missed dose of MEQSEL if it is less than 12 hours before your next scheduled dose.** Just skip the missed dose and take the next dose of MEQSEL at the regular time.
- If vomiting happens after taking or giving a dose of MEQSEL, do not take or give an additional

dose. Take or give the next dose of MEQSEL at your regular time.

- If you use too much (overdose)

If you take too many tablets of MEQSEL, contact your doctor, nurse or pharmacist for advice. If possible, show them the MEQSEL pack and this leaflet.

While you are using it

- Things you must not do

Do not use MEQSEL for a condition for which it was not prescribed. Do not give MEQSEL to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about MEQSEL that is written for health professionals.

Side effects

MEQSEL may cause serious side effects, including:

- **Risk of new skin cancers.** MEQSEL, when used with dabrafenib, may cause skin cancers, called cutaneous squamous cell carcinoma, keratoacanthoma, basal cell carcinoma, or melanoma. Talk to your healthcare provider about your risk for these cancers.

Check your skin and tell your healthcare provider right away about any skin changes, including a:

- new wart
- skin sore or reddish bump that bleeds or does not heal
- change in size or color of a mole

Your healthcare provider should check your skin before treatment with MEQSEL and dabrafenib, every 2 months during treatment with MEQSEL and dabrafenib, and for up to 6 months after you stop taking MEQSEL and dabrafenib to look for any new skin cancers.

Your healthcare provider should also check for cancers that may not occur on the skin. Tell your healthcare provider about any new symptoms that develop during treatment with MEQSEL with dabrafenib.

- **bleeding problems.** MEQSEL can cause serious bleeding problems, especially in your brain or stomach, that can lead to death. Call your healthcare provider and get medical help right away if you have any signs of bleeding, including:
 - headaches, dizziness, or feeling weak
 - cough up blood or blood clots
 - vomit blood or your vomit looks like "coffee grounds"
 - red or black stools that look like tar
- **inflammation of the intestines, or tears (perforation) of the stomach or intestines.** MEQSEL can cause inflammation of your intestines, or tears in the stomach or intestines that can lead to death. Tell your healthcare provider right away if you have any of the following symptoms:
 - bleeding. See "bleeding problems" above.
 - diarrhea (loose stools) or more bowel movements than usual
 - stomach-area (abdominal) pain or tenderness
 - fever
 - nausea
- **blood clots.** MEQSEL can cause blood clots in your arms or legs, which can travel to your lungs and can lead to death. Get medical help right away if you have 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
- a cool, pale arm or leg
- **heart problems**, including heart failure. Your healthcare provider should check your heart function before and during treatment with MEQSEL. Call your healthcare provider right away if you have any of the following signs and symptoms of a heart problem:
 - feeling like your heart is pounding, racing, or beating irregularly
 - shortness of breath
 - swelling of your ankles and feet
 - feeling lightheaded
- **eye problems**. MEQSEL can cause severe eye problems that might lead to blindness. Call your healthcare provider right away if you get these symptoms of eye problems:
 - blurred vision, loss of vision, or other vision changes
 - see color dots
 - halo (seeing blurred outline around objects)
 - eye pain, swelling, or redness
- **lung or breathing problems**. MEQSEL can cause lung or breathing problems. Tell your healthcare provider if you have any new or worsening symptoms of lung or breathing problems, including:
 - shortness of breath
 - cough
- **fever**. Fever is common during treatment with MEQSEL and dabrafenib, but it may also be serious. When taking MEQSEL with dabrafenib, fever may happen more often or may be more severe. In some cases, chills or shaking chills, too much fluid loss (dehydration), low blood

pressure, dizziness, or kidney problems may happen with the fever.

Call your healthcare provider right away if you get a fever during treatment with MEQSEL.

Your healthcare provider may temporarily or permanently stop your treatment or change your dose of MEQSEL with dabrafenib if you have fevers. Your healthcare provider will treat you as needed for your fever and any signs and symptoms of infection and should check your kidney function during and after you have had severe fever.

- **serious skin reactions**. Skin rash is a common side effect of MEQSEL. MEQSEL can also cause other skin reactions. In some cases, these rashes and other skin reactions can be severe or serious and may need to be treated in a hospital or lead to death.

Tell your healthcare provider if you get a skin rash or acne that bothers you or worsens.

Tell your healthcare provider right away if you develop any new or worsening symptoms of a severe skin reaction, including:

- blisters or peeling of your skin
- mouth sores
- blisters on your lips, or around your mouth or eyes
- high fever or flu-like symptoms
- enlarged lymph nodes

- **increased blood sugar (hyperglycemia)**. Some people may develop high blood sugar or worsening diabetes during treatment with MEQSEL and dabrafenib. If you are diabetic, your healthcare provider should

check your blood sugar levels closely during treatment with MEQSEL and dabrafenib. Your diabetes medicine may need to be changed. Tell your healthcare provider if you have any of the following symptoms of severe high blood sugar:

- increased thirst
- urinating more often than normal or urinating an increased amount of urine

- **hemophagocytic lymphohistiocytosis (HLH)**. MEQSEL when taken with dabrafenib may increase the risk of a type of overactivity of the immune system (hemophagocytic lymphohistiocytosis) that can cause fever, swollen glands, bruising, or skin rash. If you experience a combination of these symptoms, call your healthcare provider right away.

The most common side effects of MEQSEL when taken alone include:

- rash
- diarrhea. Call your healthcare provider if you get severe diarrhea.
- swelling of the face, arms, or legs

The most common side effects of MEQSEL when taken with dabrafenib in people with melanoma that has spread to other parts of the body or cannot be removed by surgery include:

- fever
- rash
- nausea
- chills
- diarrhea
- vomiting
- high blood pressure (hypertension)
- swelling of the face, arms, or legs

The most common side effects of MEQSEL when taken with

Trametinib Film-coated tablets (0.5mg and 2mg)

dabrafenib to help prevent melanoma from coming back after the cancer has been removed by surgery include:

- fever
- tiredness
- nausea
- headache
- rash
- chills
- diarrhea
- vomiting
- joint aches
- muscle aches

The most common side effects of MEQSEL when taken with dabrafenib in people with NSCLC include:

- fever
- tiredness
- nausea
- vomiting
- diarrhea
- dry skin
- decreased appetite
- rash
- swelling of your face, arms, and legs
- chills
- bleeding
- cough
- shortness of breath

The most common side effects of MEQSEL when taken with dabrafenib in adults with solid tumors that cannot be removed by surgery or have spread to other parts of the body include:

- fever
- tiredness
- nausea
- rash
- chills
- headache
- bleeding
- cough
- vomiting
- constipation
- diarrhea

- muscle and joint aches
- swelling of your arms and legs

MEQSEL can cause new or worsening high blood pressure (hypertension). Your healthcare provider should check your blood pressure during treatment with MEQSEL. Call your healthcare provider right away if you develop high blood pressure, your blood pressure worsens, or you have severe headache, lightheadedness, blurry vision, or dizziness.

MEQSEL may cause fertility problems in females. This could affect your ability to become pregnant. Talk to your healthcare provider if this is a concern for you.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Meqsel

- Storage

- Keep out of the reach and sight of children.
- Do not take this medicine after the expiry date shown on the pack. The expiry date refers to the last day of that month.
- Store in a refrigerator (2° to 8°C). This medicine is to be protected from light and moisture.
- Store in the original container.
- Keep the bottle tightly closed.
- Do not remove the desiccant.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Meqsel is supplied as tablets of 0.5 mg and 2 mg.

- **0.5 mg tablets:** yellow, modified oval, biconvex, film-coated tablets, approximately 5.0 x 9.0 mm, with the company logo debossed on one face and “TT” on the opposing face.
- **2 mg tablets:** pink, round, biconvex, film-coated tablets, approximately 7.6 mm, with the company logo debossed on one face and “LL” on the opposing face.

- Ingredients

- Active ingredient(s)

Trametinib

- Inactive ingredients

Tablet core: Mannitol, microcrystalline cellulose, hypromellose, croscarmellose sodium, magnesium stearate (vegetable source), sodium laurylsulfate, colloidal silicon dioxide.

Tablet film-coating: Hypromellose, titanium dioxide, polyethylene glycol, iron oxide yellow (for 0.5 mg tablets), polysorbate 80 and iron oxide red (for 2 mg tablets)

- MAL number:

0.5mg: MAL24016005ARZ

2mg: MAL24016004ARZ

Manufacturer

Novartis Pharma Stein AG
Schaffhauserstrasse
4332, Stein
Switzerland

Product Registration Holder

Novartis Corporation (Malaysia) Sdn. Bhd.
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Trametinib Film-coated tablets (0.5mg and 2mg)

PI Version

2 Sep 2024

Date of revision

28 Aug 2025

Serial Number

NPRA (R1) 22/025

NPRA (R1/AI2)19032025/007