NOVARTIS

MEQSEL (Trametinib)

0.5 and 2 mg tablets

Patient Information Leaflet

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SCHEDULING STATUS: **S4**

MEQSEL® 0.5 mg film-coated tablets

MEQSEL® 2 mg film-coated tablets

trametinib

MEQSEL contains sugar (mannitol)

Read all of this leaflet carefully before you start taking MEQSEL

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.**
- **MEQSEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

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

1. What MEQSEL is and what it is used for

MEQSEL belongs to a group of medicines called “selective MEK inhibitors”.

MEQSEL is a medicine used in combination with dabrafenib to treat people with melanoma (a form of skin cancer) that has spread to other parts of the body or cannot be removed by surgery.

MEQSEL is a medicine that can be used to treat people with melanoma (a form of skin cancer) that has spread to other parts of the body or cannot be removed by surgery.

MEQSEL is a medicine that is also used in combination with dabrafenib for the adjuvant treatment of adult patients with Stage III melanoma (a form of skin cancer) with BRAF V600 mutation, following complete resection.

MEQSEL is a medicine that is also used in combination with dabrafenib to treat people with a type of lung cancer called non-small cell adenocarcinoma.

MEQSEL is used in combination with dabrafenib. If you are taking these two medicines together, read the dabrafenib leaflet as well as this leaflet.

MEQSEL can only be used to treat melanomas or non-small cell adenocarcinoma with a change (mutation) in the BRAF gene, so your doctor must take tumour tissue samples first, to test whether MEQSEL is suitable for you.

MEQSEL is used in combination with dabrafenib for children of 6 years and older that are weighing at least 26 kg with low-grade glioma (LGG).

MEQSEL is used in combination with dabrafenib in both adults and children from 6 year of age for the treatment of solid tumours (type of cancer) that have advanced after previous treatment and there are no adequate alternatives available.

2. What you need to know before you take MEQSEL

Your doctor may decide to treat your melanoma with a combination of MEQSEL and dabrafenib. If you are taking these two medicines together, read the dabrafenib leaflet as well as this leaflet.

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

Do not take MEQSEL:

- If you are hypersensitive (allergic) to trametinib or any of the other ingredients of MEQSEL listed in section 6
- If you are pregnant or breastfeeding your baby.

If any of these apply to you, do not take MEQSEL and tell your doctor.

Warnings and precautions:

Take special care with MEQSEL:

Before using MEQSEL, tell your doctor if any of the following applies to you:

- if you have any **heart problems** such as heart failure so that you are short of breath, have difficulties breathing when lying down, swelling of the feet or legs or problems with the way your heart beats. Your doctor should check your heart function before you start taking MEQSEL and during treatment.
- if you have any **eye problems** including blockage of the vein draining the eye (retinal vein occlusion) or swelling in the eye which may be caused by fluid blockage (chorioretinopathy). Your doctor may arrange for you to have an eye examination before you take MEQSEL and while you are taking it.
- if you have any lung or breathing problems, including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue. Your doctor may arrange to check your lung function before you start taking MEQSEL.

- if you notice headaches, dizziness, or weakness, coughing up of blood or blood clots, vomit containing blood or that looks like “coffee grounds”, bleeding from nose, red or black stools that look like tar as these may be symptoms of serious bleedings.
- if you have any lung or breathing problems, including difficulty in breathing often accompanied by chest pain, fainting, rapid heart rate, bluish skin discoloration.
- if you develop a fever, or if you feel a fever coming on. Fever may be accompanied by severe chills, dehydration and low blood pressure. This can occur more often when you take MEQSEL together with dabrafenib.
- if you get swelling and pain in one part of the body. These may be symptoms of deep vein thrombosis.
- if you get diarrhoea, abdominal pain and fever. These are possible symptoms of an inflammation of the colon.
- if you get a rash like Stevens-Johnson syndrome or drug reaction with eosinophilia (DRESS).
- if you have a disease of excessive immune activation (Haemophagocytic lymphohistiocytosis (HLH).
- if you have a condition called tumour lysis syndrome (TLS), characterised by nausea, vomiting, shortness of breath, irregular heartbeat, clouding of urine, lethargy and joint discomfort.
- if you get stomach pain, nausea, vomiting of blood, black or bloody stools. These are possible symptoms of gastrointestinal perforation.

Other medicines and MEQSEL

Always tell your healthcare provider if you are taking any other medicine, including complementary medicines.

This includes medicines obtained without a prescription.

Keep a list of the medicines you take, so you can show it to your doctor, nurse or pharmacist when you get a new medicine.

Taking MEQSEL with food and drink

It is important to take MEQSEL on an empty stomach, because food may affect the way the medicine is absorbed into your body. Take MEQSEL with a full glass of water.

You must take MEQSEL at least 1 hour before a meal or 2 hours after a meal, so:

- after taking MEQSEL wait **at least 1 hour** before eating or, after eating, wait **at least 2 hours** before taking MEQSEL.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MEQSEL.

You must not take MEQSEL if you are pregnant.

Breast-feeding is not recommended during treatment with MEQSEL.

Women who might get pregnant (women of child-bearing age)

Women who might get pregnant must use highly effective contraception while taking MEQSEL during treatment and for four months after stopping treatment with MEQSEL.

MEQSEL may decrease the efficacy of hormonal contraceptives and an alternate method of contraception, such as barrier methods, should be used.

Male patients must use a condom during intercourse and not father a child during therapy and for 4 months after stopping treatment with MEQSEL.

Driving and using machinery

Do not drive or use machines until you know if MEQSEL affects your performance.

It is not always possible to predict to what extent MEQSEL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MEQSEL affects them.

3. How to take MEQSEL

Do not share medicines prescribed for you with any other person.

Always take MEQSEL exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose prescribed by your doctor.

MEQSEL is for oral use only.

The usual dose of MEQSEL is one 2 mg tablet once a day.

Your doctor will tell you how long your treatment with MEQSEL will last. Your doctor may decide that you should take a lower dose if you get side effects.

Do not take any more MEQSEL than your doctor has recommended.

Taking MEQSEL together with dabrafenib

Swallow the MEQSEL tablets and the dabrafenib capsules, with a full glass of water.

Take MEQSEL in combination with dabrafenib exactly as your healthcare provider tells you.

Do not change your dose or stop MEQSEL in combination with dabrafenib unless your healthcare provider tells you. When MEQSEL and dabrafenib are taken in combination take the once daily dose of MEQSEL at the same time each day with either the morning or the evening dose of dabrafenib.

Do not take more than one dose of MEQSEL a day and do not take the morning and evening doses of dabrafenib at the same time.

If you take too much MEQSEL or dabrafenib, call your doctor or go to the nearest hospital right away. Take MEQSEL tablets and dabrafenib capsules with you when possible.

If you take more MEQSEL than you should

If you take too many tablets of MEQSEL, contact your doctor, nurse or pharmacist for advice. If neither is available, contact the nearest hospital or poison centre. If possible, show them the MEQSEL pack.

If you forget to take MEQSEL

If the missed dose is less than 12 hours late, take it as soon as you remember.

If the missed dose is more than 12 hours late, skip that dose and take your next dose at the usual time. Then carry on taking your tablet at regular times as usual.

Do not take a double dose to make up for a missed dose.

If you stop taking MEQSEL

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

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

4. Possible Side Effects

MEQSEL can have side effects.

Not all side effects reported for MEQSEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEQSEL, please consult health care professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you experience a feeling like your heart is pounding, racing or beating irregularly, dizziness, tiredness, feeling lightheaded, shortness of breath, swelling in the legs
- If you experience symptoms of bleeding; headaches, dizziness, or weakness, coughing up of blood or blood clots, vomit containing blood or that looks like “coffee grounds”, bleeding from nose, red or black stools that look like tar
- If you experience any vision problems; colour dots, halo (seeing a blurred outline around objects), blurred vision
- If you notice a rash (acne-like rash)
- If you have a fever, low blood pressure and dizziness.

These are all very serious side effects. If you have them, you may have had a serious reaction to MEQSEL. You may need serious medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- skin rash, acne-like rash, redness of the face, dry or itching skin
- diarrhoea
- feeling sick (nausea), being sick (vomiting)
- constipation
- stomachache
- dry mouth
- lack of energy or feeling weak or tired
- swelling of the hands or feet
- unusual hair loss or thinning
- high blood pressure

- fever (high temperature)
- cough
- shortness of breath
- bleeding (haemorrhage)
- skin rash with pus-filled blisters
- redness, chapping or cracking of the skin
- nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles
- red, painful hands and feet
- nose bleeds
- sore mouth or mouth ulcers, inflammation of mucous membranes
- swelling of the face, localised tissue swelling
- blurred vision
- swelling around the eyes
- eyesight problems
- changes in how the heart pumps blood (left ventricular dysfunction)
- decrease in the heart rate
- abnormal blood test results related to the liver, decreased red blood cells (anaemia), abnormal test related to creatine phosphokinase, an enzyme found mainly in heart, brain, and skeletal muscle
- dehydration (low levels of water or fluid)
- allergic reaction (hypersensitivity)
- blockage of the vein draining the eye (retinal vein occlusion)
- swelling in the eye caused by fluid leakage (chorioretinopathy)
- swelling of nerves at the back of the eye (papilloedema), separation of the light-sensitive membrane in the back of the eye (the retina) from its supporting layers (retinal detachment).
- inflammation of the lung (pneumonitis or interstitial lung disease)

- heart pumping less efficiently, causing shortness of breath, extreme tiredness and swelling in ankles and legs (heart failure)
- breakdown of muscle tissue (rhabdomyolysis)
- urinary tract infection
- dizziness
- chills
- high temperature
- rash, dry skin, itching, acne-like problem
- decreased appetite
- headache
- joint pain, muscle pain, or pain in the hands or feet
- nasal inflammation
- low levels of white blood cells
- low blood pressure
- excessive sweating
- skin effects including rough scaly patches of skin, skin rash with pus-filled blisters, brown or yellowish thickening of the skin, skin tags, skin cracking, wart-like growths or redness and swelling of the palms, fingers and soles of the feet, cutaneous squamous cell carcinoma (a type of skin cancer), inflammation of the fatty layer underneath the skin, papilloma (a type of skin tumour which is usually not harmful), infection of the skin (cellulitis), inflammation of hair follicles in the skin
- flu-like illness
- muscle spasms
- swelling of face
- night sweats
- kidney disorder that may result in decreased urine output

- decrease in number of blood platelets (cells that help blood to clot)
- decrease in number of red blood cells (anaemia) and a type of white blood cells (leukopenia)
- low levels of sodium in the blood
- increase in some substances (enzymes) produced by the liver
- increase in creatine phosphokinase, an enzyme found mainly in heart, brain, and skeletal muscle
- increase in blood sugar level
- low levels of phosphate in the blood
- inflammation of pancreas
- acute kidney failure, inflammation of kidneys
- new primary melanoma
- muscle disorder with abnormal breakdown of muscle tissue, causing pain, fever and red-brown urine
- inflammatory disease mainly affecting the skin, lungs and eyes (sarcoidosis)
- heart condition (atrioventricular block and bundle branch block) with the following signs and symptoms, light-headedness or dizziness, palpitations, fatigue, chest pain, shortness of breath and fainting spells.
- excessive immune activation (Haemophagocytic lymphohistiocytosis (HLH) characterised by fever, rash, confusion even seizures.
- tumour lysis syndrome (TLS) characterised by nausea, vomiting, shortness of breath, irregular heartbeat, clouding of urine, lethargy and joint discomfort.
- numbness and tingling feeling in the feet and hands (peripheral neuropathy).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MEQSEL.

5. How to store MEQSEL

Do not store above 25°C. Store in the original package to protect from light and moisture. Keep the bottle tightly closed. Contains desiccant, do not remove or eat.

6. Contents of the pack and other information

What MEQSEL contains:

The active ingredient in **MEQSEL** film coated tablets is trametinib.

MEQSEL 0,5 mg film-coated tablets contains trametinib dimethyl sulfoxide equivalent to 0,5 mg of free base.

MEQSEL 2 mg film-coated tablets contains trametinib dimethyl sulfoxide equivalent to 2 mg of free base**.**

The other ingredients are:

Mannitol, microcrystalline cellulose, hypromellose, croscarmellose sodium, magnesium stearate (vegetable source), sodium lauryl sulfate, colloidal silicon dioxide.

Film-coating excipients:

Hypromellose, titanium dioxide, polyethylene glycol,

For 0.5 mg tablets: Opadry yellow (contains hypromellose, titanium dioxide, macrogol, iron oxide yellow).

For 2 mg tablets: Opadry pink (contains hypromellose, titanium dioxide, macrogol, polysorbate 80, iron oxide red).

MEQSEL contains sugar (mannitol).

What MEQSEL looks like and contents of the pack:

MEQSEL 0.5 mg

Yellow, ovaloid biconvex film-coated tablet with beveled edges, unscored with Novartis logo on one side, "TT" on the other side.

MEQSEL 2 mg

Pink, round biconvex film-coated tablet with beveled edges, unscored with Novartis logo on one side, "LL" on the other side.

MEQSEL 0.5 and 2 mg tablets are packed in HDPE bottles with child resistant polypropylene closures.

This product is packaged with a desiccant**.**

Pack sizes: 7 or 30 tablets per bottle.

Holder of Certificate of Registration

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