PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Boehringer Ingelheim

SEVCAD® 100 mg soft gelatin capsules
SEVCAD® 150 mg soft gelatin capsules
nintedanib
Sugar free

Read all of this leaflet carefully before you start taking SEVCAD
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- SEVCAD 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 SEVCAD is and what it is used for
SEVCAD contains the active substance nintedanib and it is used for the treatment of Idiopathic Pulmonary Fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype and systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults.

Idiopathic Pulmonary Fibrosis (IPF)
IPF is a condition in which the tissue in your lungs becomes thickened, stiff and scarred over time. As a result, scarring reduces the ability to transfer oxygen from the lungs into the bloodstream and it becomes difficult to breathe deeply. SEVCAD helps to reduce scarring and stiffening of the lungs.

Other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
Besides IPF, there are other conditions in which the tissue in your lungs becomes thickened, stiff, and scarred over time (lung fibrosis) and keeps worsening (progressive phenotype). Examples of these conditions are hypersensitivity pneumonitis, autoimmune ILDs (e.g. rheumatoid arthritis associated ILD), idiopathic nonspecific interstitial pneumonia, unclassifiable idiopathic interstitial pneumonia, and other ILDs. SEVCAD helps to reduce

further scarring and stiffening of the lungs.

Systemic sclerosis associated interstitial lung disease (SSc-ILD)
Systemic sclerosis (SSc), also known as scleroderma, is a rare chronic autoimmune disease that affects connective tissue in many parts of the body. SSc causes fibrosis (scarring and stiffening) of the skin and other internal organs such as the lungs. When the lungs are affected by fibrosis, it is called interstitial lung disease (ILD), and so the condition is called SSc-ILD. Fibrosis in the lungs reduces the ability to transfer oxygen into the bloodstream, and breathing capacity is reduced. SEVCAD helps to reduce further scarring and stiffening of the lungs.

2. What you need to know before you take SEVCAD

Do not take SEVCAD

- if you are hypersensitive (allergic) to nintedanib, peanuts or soya or any of the other ingredients of SEVCAD (listed in section 6).
- Do not take SEVCAD if you are pregnant.

Warnings and precautions

Take special care and talk to your doctor or pharmacist before taking SEVCAD:

- if you have or ever had liver problems,
- if you have or ever had problems with your kidney, or if an increased amount of protein has been detected in your urine,
- if you have or ever had bleeding problems,
- if you take blood-thinning medicines (such as warfarin, phenprocoumon or heparin) to prevent blood clotting,
- if you take pirfenidone as this may increase the risk of having diarrhoea, nausea, vomiting and liver problems,
- if you have or ever had problems with your heart (for example a heart attack) as your doctor will do tests to monitor your heart function,
- if you have recently had surgery. Nintedanib may affect the way your wounds heal. Therefore your treatment with SEVCAD will usually be stopped for a while if you are having a surgery. Your doctor will decide when to resume your treatment with SEVCAD,
- if you have high blood pressure,
- if you have abnormally high blood pressure in the blood vessels of the lungs (pulmonary hypertension),
- if you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.

Based on this information your doctor may do some blood tests, for example to check your liver function. Your doctor will discuss the results of these tests with you and decide whether you may receive SEVCAD.

Inform your doctor immediately while taking SEVCAD:

- if you get diarrhoea. Treating diarrhoea early is important (see section 4);
- if you vomit or feel sick (nausea);
- if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea coloured) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal, or feeling tired. These could be symptoms of serious liver problems;
- if you have severe pain in your stomach, fever, chills, sickness, vomiting, or abdominal rigidity or bloating, as these could be symptoms of a hole in the wall of your gut

("gastrointestinal perforation"). Also, tell your doctor if you had peptic ulcers or diverticular disease in the past, or are being concomitantly treated with anti-inflammatory drugs (NSAIDs) (used for pain relief and swelling) or steroids (used for inflammation and allergies), as this may increase the risk of gastrointestinal perforation;
- if you have a combination of severe pain or cramping in your stomach, red blood in your stool or diarrhoea as these could be symptoms of a bowel inflammation from inadequate blood supply;
- if you have pain, swelling, reddening, warmth of a limb as these could be symptoms of a blood clot in one of your veins (a type of blood vessel);
- if you have chest pressure or pain, typically on the left side of the body, pain in the neck, jaw, shoulder or arm, a fast heartbeat, shortness of breath, nausea, vomiting, as these could be symptoms of a heart attack;
- if you have any major bleeding;
- if you experience bruising, bleeding, fever, fatigue and confusion. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).

Children and adolescents
SEVCAD should not be taken by children and adolescents under 18 years of age.

Other medicines and SEVCAD
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

SEVCAD can interact with certain other medicines. The following medicines are examples that may increase the levels of nintedanib in your blood, and hence may increase the risk for side effects (see section 4):
- a medicine used to treat fungal infections (ketoconazole)
- a medicine used to treat bacterial infections (erythromycin)
- a medicine that affects your immune system (ciclosporin).

The following medicines are examples that may lower the levels of nintedanib in your blood and thus may reduce the effectiveness of SEVCAD:
- an antibiotic used to treat tuberculosis (rifampicin)
- medicines to treat seizures (carbamazepine, phenytoin)
- a herbal medicine to treat depression (St. John's wort).

SEVCAD with food and drink
Take SEVCAD with food. Swallow the capsules whole with water. See section 3 "How to take SEVCAD".

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

Pregnancy
Do not take SEVCAD during pregnancy, as it can harm your unborn baby and cause birth defects.

You must have a pregnancy test done to ensure you are not pregnant before starting treatment with SEVCAD. Please talk to your doctor.

Contraception
- Women who can become pregnant must use a highly effective method of birth control to prevent pregnancy when they start taking SEVCAD, while they are taking SEVCAD and for at least 3 months after stopping treatment.
- You should discuss the most appropriate methods of contraception for you with your doctor.
- Vomiting and/or diarrhoea or other gastrointestinal conditions can affect the absorption of oral hormonal contraceptives, such as birth control pills, and may reduce their effectiveness. Therefore, if experiencing these, talk to your doctor to discuss an alternative more appropriate method of contraception.

Tell your doctor or pharmacist immediately if you become pregnant or think you may be pregnant during treatment with SEVCAD.

Breastfeeding
Do not breastfeed your infant during the treatment with SEVCAD since there may be a risk for harm to the breastfeeding child.

Driving and using machines
SEVCAD may influence your ability to drive and use machines.
You should not drive or use machines if you feel sick or until you know how SEVCAD affects you.

SEVCAD contains soya lecithin
If you are allergic to soya or peanuts, do not take SEVCAD (see section 2).

3. How to take SEVCAD
Do not share medicines prescribed for you with any other person.

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

The usual dose is one capsule of 150 mg 12 hourly (a total of 300 mg per day).
Take the capsules 12 hours apart at the same time every day, for example one capsule in the morning and one capsule in the evening. This ensures that a steady amount of nintedanib is maintained in your blood stream. Swallow the whole capsules with water and do not chew the capsules. It is recommended that you take the capsules with food, i.e. during or immediately before or after a meal. Do not open or crush the capsule (see section 5).

Do not take more than the usual dose of one SEVCAD 150 mg capsule 12 hourly.

If you do not tolerate the recommended dose of one SEVCAD 150 mg capsule 12 hourly (see possible side effects in section 4) your doctor may reduce the daily dose of SEVCAD. Do not reduce the dose or stop the treatment by yourself without consulting your doctor first.

Your doctor may reduce your usual dose to 100 mg 12 hourly (a total of 200 mg per day). In this case your doctor will prescribe SEVCAD 100 mg capsules for your treatment. Do not take

more than the usual dose of one SEVCAD 100 mg capsule 12 hourly if your daily dose was reduced to 200 mg per day.

If you do not tolerate the recommended dose of one SEVCAD 100 mg capsule 12 hourly (see possible side effects in section 4) your doctor may advise you to stop taking this medicine. Do not reduce the dose or stop the treatment by yourself without consulting your doctor first.

Your doctor will tell you how long your treatment with SEVCAD will last. Do not stop treatment early because it will affect the management of your condition.
If you have the impression that the effect of SEVCAD is too strong or too weak, tell your doctor or pharmacist.

If you take more SEVCAD than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take SEVCAD
Do not take two capsules together if you have forgotten to take your earlier dose. You should take your next 100 mg or 150 mg dose of SEVCAD as planned at the next scheduled time recommended by your doctor or pharmacist.

If you stop taking SEVCAD
Do not stop taking SEVCAD without consulting your doctor first. It is important to take SEVCAD every day, as long as your doctor prescribes it for you.

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

4. Possible side effects
SEVCAD can have side effects.
Not all side effects reported for SEVCAD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SEVCAD, please consult your healthcare provider for advice.

You need to pay special attention if you get the following side effects during treatment with SEVCAD:

Diarrhoea is frequently experienced
Diarrhoea may lead to dehydration: a loss of fluid and important salts (electrolytes, such as sodium or potassium) from your body. At the first signs of diarrhoea drink plenty of fluids and contact your doctor immediately. Start appropriate anti-diarrhoeal treatment, e.g. with loperamide, as soon as possible.

The following other side effects were observed during treatment with SEVCAD:

Idiopathic pulmonary fibrosis (IPF)
Frequent
- Feeling sick (nausea)
- Pain in the lower body (abdomen)
- Abnormal liver test results
- Vomiting

- Loss of appetite
- Weight loss
- Bleeding
- Rash
- Headache

Less frequent
- Pancreatitis
- Inflammation of the large bowel
- Serious liver problems
- Low platelet count (thrombocytopenia)
- High blood pressure (hypertension)
- Jaundice, that is a yellow colour to the skin and whites of the eyes due to high levels of bilirubin
- Itching
- Heart attack
- Hair loss (alopecia)
- Increased amount of protein in your urine (proteinuria)

Not known (cannot be estimated from the available data)
- Renal failure
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)

Other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
Frequent
- Feeling sick (nausea)
- Vomiting
- Loss of appetite
- Pain in the lower body (abdomen)
- Abnormal liver test results
- Weight loss
- High blood pressure (hypertension)
- Bleeding
- Serious liver problems
- Rash
- Headache

Less frequent
- Pancreatitis
- Inflammation of the large bowel
- Low platelet count (thrombocytopenia)
- Jaundice, that is a yellow colour to the skin and whites of the eyes due to high levels of bilirubin
- Itching
- Heart attack
- Hair loss (alopecia)
- Increased amount of protein in your urine (proteinuria)

Not known (cannot be estimated from the available data)
- Renal failure
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)

Systemic sclerosis associated interstitial lung disease (SSc-ILD)
Frequent
- Feeling sick (nausea)
- Vomiting
- Pain in the lower body (abdomen)
- Abnormal liver test results
- Bleeding
- High blood pressure (hypertension)
- Loss of appetite
- Weight loss
- Headache

Less frequent
- Inflammation of the large bowel
- Serious liver problems
- Renal failure
- Low platelet count (thrombocytopenia)
- Rash
- Itching

Not known (cannot be estimated from the available data)
- Heart attack
- Pancreatitis
  -Jaundice, that is a yellow colour to the skin and whites of the eyes due to high levels of bilirubin
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)
- Hair loss (alopecia)
- Increased amount of protein in your urine (proteinuria)

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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SEVCAD.

5. How to store SEVCAD
Store at or below 25 ° C.
Store in the original package in order to protect from moisture.
In order to protect from moisture, do not store in the bathroom.
Store all medicines out of reach of children.

If you are in contact with the content of the capsule, wash off your hands immediately with plenty of water (see section 3).
Do not use after the expiry date stated on the carton and the blister strips.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SEVCAD contains

The active substance is nintedanib.
Each soft gelatin capsule contains 100 mg or 150 mg nintedanib (as esilate).

The other ingredients are:
Capsule fill: Triglycerides, medium-chain, hard fat, soya lecithin (E322)
Capsule shell: Gelatin, glycerol (85 %), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

What SEVCAD looks like and contents of the pack

SEVCAD 100 mg soft gelatin capsules are peach-coloured, opaque, oblong soft gelatin capsules marked in dark grey on one side with the Boehringer Ingelheim company symbol and "100", and containing a bright yellow viscous suspension.
SEVCAD 150 mg soft gelatin capsules are brown-coloured, opaque, oblong soft gelatin capsules marked in dark grey on one side with the Boehringer Ingelheim company symbol and "150", and containing a bright yellow viscous suspension.

SEVCAD soft gelatin capsules are packed in blister strips, consisting of a printed aluminium lidding foil and an aluminium-based forming foil.
Each blister strip consists of 10 soft gelatin capsules; 6 blister strips are packed per printed cardboard carton, in packs of 60 capsules.

Holder of Certificate of Registration

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SEVCAD 100 mg: 52/26/0153
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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

SEVCAD® 100 mg sagte gelatienkapsules
SEVCAD® 150 mg sagte gelatienkapsules

Boehringer Ingelheim

nintedanib
Suikervry

Lees die hele pamflet deeglik deur voordat jy SEVCAD begin neem

- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy verdere vrae het, raadpleeg asseblief jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- SEVCAD is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat SEVCAD is en waarvoor dit gebruik word

SEVCAD bevat die aktiewe middel nintedanib en word gebruik vir die behandeling van idiopatiese pulmonêre fibrose (IPF), ander chroniese fibroserende interstisiële longsiektes (ILS) met ’n progressiewe fenotipe en sistemiese sklerose gepaardgaande met interstisiële longsiekte (SSk-ILS) by volwassenes.

Idiopatiese pulmonêre fibrose (IPF)

IPF is ’n toestand waarby die weefsel in jou longe met verloop van tyd dikker en stywer word en letsels vorm. Gevolglik verminder die letsels die vermoë van die longe om suurstof na die bloedstroom oor te dra en word dit moeilik om diep asem te haal. SEVCAD help om letsels en verstywing van die longe te verminder.

Ander chroniese fibroserende interstisiële longsiektes (ILS) met ’n progressiewe fenotipe

Behalwe IPF, is daar ander toestande waarby die weefsel in jou longe mettertyd verdik, styf word en letsels opdoen (longfibrose) en aanhou agteruitgaan (progressiewe fenotipe). Voorbeelde van hierdie siektetoestande is hipersensitiwiteit pneumonitis, outo-immuun ILS (bv. rumatoïede artritis geassosieer met ILS), idiopatiese nie-spesifieke interstisiële longontsteking, nie-klassifiseerbare idiopatiese interstisiële longontsteking en ander ILS. SEVCAD help om verdere letsels en verharding van die longe te verminder.

Sistemiese sklerose geassosieer met interstisiële longsiekte (SSk-ILS)

Sistemiese sklerose (SSk), ook bekend as skleroderma, is ’n seldsame chroniese outo-

immuunsiekte wat bindweefsel in baie dele van die liggaam aantas. SSk veroorsaak fibrose (littekens en verharding) van die vel en ander interne organe, soos die longe. As die longe deur fibrose aangetas word, word dit interstisiële longsiekte (ILS) genoem, en daarom word die siektetoestand SSk-ILS genoem. Fibrose in die longe verminder die vermoë om suurstof na die bloedstroom oor te dra en die asemhalingsvermoë word verminder. SEVCAD help om verdere letsels en verharding van die longe te verminder.

2. Wat jy moet weet voordat jy SEVCAD neem

Moet nie SEVCAD neem nie

- As jy hipersensitief (allergies) is vir nintedanib, grondboontjies of soja, of vir enige van die ander bestanddele van SEVCAD (gelys in afdeling 6).
- Moet nie SEVCAD neem as jy swanger is nie.

Waarskuwings en voorsorgmaatreëls

Wees versigtig en praat met jou dokter of apteker voordat jy SEVCAD neem:

- as jy tans of voorheen lewer probleme het/gehad het,
- as jy tans of voorheen nier probleme het/gehad het, of as daar ’n verhoogde hoeveelheid proteïen in jou urien opgespoor is,
- as jy tans of voorheen bloedingsprobleme het/gehad het,
- as jy bloedverdunnende medisyne neem (soos warfarien, fenprokumon of heparien) om bloedstolling te voorkom,
- as jy pirfenidoon neem, aangesien dit die risiko vir diarree, naarheid, braking en lewerprobleme kan verhoog,
- as jy tans of voorheen probleme met jou hart gehad het (byvoorbeeld ’n hartaanval) want jou dokter sal toetse doen om jou hart te monitor,
- as jy onlangs ’n operasie ondergaan het. Nintedanib kan die manier waarop jou wonde genees aantas. Daarom sal jou behandeling met SEVCAD gewoonlik ’n rukkie gestaak word as jy ’n operasie ondergaan. Jou dokter sal besluit wanneer jou behandeling met SEVCAD kan voortgaan,
- as jy hoë bloeddruk het,
- as jy buitengewoon hoë bloeddruk in die bloedvate van die longe het (pulmonêre hipertensie),
- as jy ’n aneurisme (vergroting en verswakking van ’n bloedvatwand) of ’n skeur in ’n bloedvatwand het of gehad het.

Op grond van hierdie inligting kan jou dokter bloedtoetse doen, byvoorbeeld om jou lewerfunksie na te gaan. Jou dokter sal die resultate van hierdie toetse met jou bespreek en besluit of jy SEVCAD kan kry.

Lig jou dokter dadelik in terwyl jy SEVCAD neem:

- as jy diarree kry. Dit is belangrik dat diarree vinnig behandel word (sien afdeling 4);
- as jy braak of naar voel;
- as jy onverklaarbare simptome het, soos geel verkleuring van jou vel of die wit deel van jou oë (geelsug), donker of bruin (teekleurige) urien, pyn aan die regter bokant van jou maagarea (buik), makliker bloei of kneusplekke kry as gewoonlik, of moeg voel. Dit kan tekens wees van ernstige lewerprobleme;
- as jy erge maagpyn, koors, kouekoors, naarheid, braking, of buikstyfheid of opgeblasenheid het, aangesien dit simptome kan wees van ’n gat in ’n dermwand (“gastroïntestinale perforasie”). Lig ook jou dokter in as jy voorheen maagswere of

divertikulêre siekte gehad het, of as jy gelyktydig met anti-inflammatoriese middels (NSAIM's) (gebruik vir pynverligting en swelling) of steroïede (gebruik vir inflammasie en allergieë) behandel word, aangesien dit die risiko van gastroïntestinale perforasie kan verhoog;
- as jy 'n kombinasie van erge pyn of krampe in jou maag, rooi bloed in jou stoelgang of diarree het, aangesien dit simptome kan wees van 'n derminflammasie weens onvoldoende bloedtoevoer;
- as jy pyn, swelling, rooiheid, warmte van 'n ledemaat het, want dit kan simptome van 'n bloedklont in jou are ('n soort bloedvat) wees;
- as jy drukking op die bors of pyn het, veral aan die linkerkant van jou lyf, nekpyn, pyn in die kakebeen, skouer of arm, 'n vinnige hartklop, kortasemigheid, naarheid, braking, want dit kan simptome van 'n hartaanval wees;
- as jy ernstige bloeding kry
- as jy kneusing, bloeding, koors, moegheid en verwarring ervaar. Dit kan 'n teken wees van skade aan bloedvate, bekend as trombotiese mikroangiopatie (TMA).

Kinders en adolessente
SEVCAD moet nie deur kinders en adolessente jonger as 18 jaar geneem word nie.

Ander medisynes en SEVCAD
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

SEVCAD kan 'n interaksie hê met sekere ander medisynes. Die volgende is voorbeelde van medisynes wat jou bloedvlakke van nintedanib kan verhoog; gevolglik kan dit die risiko vir newe-effekte verhoog (sien afdeling 4):
- 'n medisyne wat gebruik word om swaminfeksies te behandel (ketokonasool)
- 'n medisyne wat gebruik word om bakteriële infeksies te behandel (eritromisien)
- 'n medisyne wat jou immuunstelsel aantas (siklosporien).

Die volgende is voorbeelde van medisynes wat jou bloedvlakke van nintedanib kan verlaag; gevolglik kan dit die doeltreffendheid van SEVCAD verminder:
- 'n antibiotikum wat vir die behandeling van tuberkulose gebruik word (rifampisien)
- medisynes wat gebruik word om stuipe te behandel (bv. karbamasepien, fenitoïen)
- 'n kruiemiddel om depressie te behandel (Sint Janskruid).

SEVCAD met kos en vloeistowwe
Neem SEVCAD met jou kos. Sluk die kapsules heel in, met water. Sien ook afdeling 3 "Hoe om SEVCAD te neem".

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy SEVCAD neem.

Swangerskap
Moet nie SEVCAD tydens swangerskap neem nie, want dit kan skadelik wees vir jou ongebore baba en geboorte-afwykings veroorsaak.

Jy moet 'n swangerskapstoets laat doen om seker te maak dat jy nie swanger is voordat jy met die behandeling met SEVCAD begin nie. Praat asseblief met jou dokter.

Voorbehoeding
- Vroue wat swanger kan raak, moet 'n hoogs doeltreffende metode van geboortebeperking gebruik om swangerskap te voorkom wanneer hulle begin met die gebruik van SEVCAD, terwyl hulle SEVCAD neem en vir ten minste 3 maande nadat die behandeling gestaak is.
- Jy moet die mees geskikte metodes van voorbehoeding met jou dokter bespreek.
- Braking en/of diarree of ander gastroïntestinale siektes kan die opname van mondelikse hormonale voorbehoedmiddels, soos geboortebeperkingspille, beïnvloed en die doeltreffendheid daarvan verminder. Gevolglik moet jy, as jy dit ondervind, jou dokter kontak om 'n alternatiewe, meer geskikte voorbehoedmetode te bespreek.

Lig jou dokter of apteker dadelik in as jy swanger raak of dink jy kan swanger wees tydens jou behandeling met SEVCAD.

Borsvoeding
Moet nie jou baba tydens die behandeling met SEVCAD borsvoed nie, want dit kan moontlik skadelik vir die suigeling wees.

Bestuur en gebruik van masjinerie
SEVCAD kan jou vermoë om te bestuur en masjinerie te hanteer aantas.
Jy moet nie bestuur of masjinerie gebruik as jy naar voel nie, of voordat jy nie weet hoe SEVCAD jou aantas nie.

SEVCAD bevat sojalesitien
As jy allergies is vir soja of grondboontjies moet jy nie SEVCAD neem nie (sien afdeling 2).

3. Hoe om SEVCAD te neem
Moet nie medisyne wat vir jou voorgeskryf is met 'n ander persoon deel nie.

Neem SEVCAD altyd presies soos jou dokter of apteker jou aangeraai het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

Die normale dosis is een kapsule van 150 mg 12-uurliks (altesaam 300 mg per dag).
Neem die kapsules 12 uur uitmekaar, op dieselfde tye elke dag, bv. een kapsule in die oggend en een kapsule in die aand. Dit verseker dat 'n konstante hoeveelheid nintedanib in jou bloedstroom gehandhaaf word. Sluk die hele kapsule in met water en moet nie die kapsules kou nie. Dit word aanbeveel dat jy die kapsules met kos neem, naamlik tydens, of net voor of net na 'n maaltyd. Moet nie die kapsule oopmaak of fynmaak nie (sien afdeling 5).

Moet nie meer as die gewone dosis van een 150 mg kapsule 12-uurliks neem nie.

As jy die aanbevole dosis van een 150 mg kapsule 12-uurliks nie kan verdra nie (sien moontlike newe-effekte in afdeling 4), kan jou dokter die daaglikse dosis van SEVCAD verminder. Moet nie die dosis verminder of die behandeling self staak sonder om eers jou dokter te raadpleeg nie.

Jou dokter kan jou normale dosis tot 100 mg 12-uurliks verminder (altesaam 200 mg per dag). In hierdie geval sal jou dokter SEVCAD 100 mg kapsules vir jou behandeling voorskryf. Moet

nie meer as die gewone dosis van een 100 mg kapsule 12-uurliks neem as jou daaglikse dosis tot 200 mg per dag verminder word nie.

As jy die aanbevole dosis van een 100 mg SEVCAD kapsule 12-uurliks nie kan verdra nie (sien moontlike newe-effekte in afdeling 4), kan jou dokter jou aanraai om hierdie medisyne te staak. Moet nie die dosis verminder of die behandeling self staak sonder om eers jou dokter te raadpleeg nie.

Jou dokter sal jou inlig hoe lank jou behandeling met SEVCAD sal aanhou. Moet nie die behandeling voortydig staak nie want dit sal die beheer oor jou siektetoestand affekteer. Indien jy die indruk kry dat die effek van SEVCAD te sterk of te swak is, lig jou dokter of apteker in.

Indien jy meer SEVCAD neem as wat jy moes
In geval van oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.

Indien jy vergeet het om SEVCAD te neem
Moet nie twee kapsules gelyktydig neem as jy vergeet het om jou vorige dosis te neem nie. Jy moet jou volgende 100 mg of 150 mg dosis van SEVCAD op die volgende geskeduleerde tyd neem, soos deur jou dokter of apteker aanbeveel.

Indien jy ophou om SEVCAD te neem
Moet nie ophou om SEVCAD te neem sonder dat jy eers jou dokter geraadpleeg het nie. Dit is belangrik om SEVCAD elke dag te neem, vir so lank as wat jou dokter dit vir jou voorgeskryf het.

Indien jy nog vrae het oor die gebruik van SEVCAD, raadpleeg jou dokter of apteker.

4. Moontlike newe-effekte
SEVCAD kan newe-effekte hê.
Nie alle newe-effekte wat vir SEVCAD aangemeld is, word by hierdie pamflet ingesluit nie. Indien jou algemene gesondheid agteruitgaan, of jy enige ongunstige effekte ervaar terwyl jy SEVCAD neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Jy moet tydens die behandeling met SEVCAD spesiaal aandag gee indien jy die volgende newe-effekte kry:

Diarree word dikwels ervaar:
Diarree kan lei tot dehidrasie: ’n verlies aan vloeistof en belangrike soute (elektroliete, soos natrium of kalium) uit jou liggaam. Drink baie vloeistowwe by die eerste tekens van diarree en kontak dadelik jou dokter. Begin geskikte behandeling teen diarree, bv. met loperamied, sodra moontlik.

Die volgende ander newe-effekte is tydens behandeling met SEVCAD waargeneem:

Idiopatiese pulmonêre fibrose (IPF)
Dikwels
- Siek gevoel (naarheid)
- Pyn in die onderste deel van die liggaam (buik)

- Abnormale lewertoetsresultate
- Braking
- Verlies aan eetlus
- Gewigsverlies
- Bloeding
- Uitslag
- Hoofpyn

Minder dikwels
- Pankreatitis
- Inflammasie van die dikderm
- Ernstige lewerprobleme
- Lae plaatjietelling (trombositopenie)
- Hoë bloeddruk (hipertensie)
- Geelsug, dit is ’n geel kleur van die vel en oogwitte vanweë hoë vlakke van bilirubien
- Jeuking
- Hartaanval
- Haarverlies (alopesie)
- Verhoogde hoeveelheid proteïen in jou urien (proteïenurie)

Onbekend (kan nie uit die beskikbare data geskat word nie)
- Nierversaking
- ’n Vergroting en verswakking van ’n bloedvatwand of ’n skeur in ’n bloedvatwand (aneurismes en slagaardisseksies)

Ander chroniese fibroserende interstisiële longsiektes (ILS) met ’n progressiewe fenotipe
Dikwels
- Siek gevoel (naarheid)
- Braking
- Verlies aan eetlus
- Pyn in die onderste deel van die liggaam (buik)
- Abnormale lewertoetsresultate
- Gewigsverlies
- Hoë bloeddruk (hipertensie)
- Bloeding
- Ernstige lewerprobleme
- Uitslag
- Hoofpyn

Minder dikwels
- Pankreatitis
- Inflammasie van die dikderm
- Lae plaatjietelling (trombositopenie)
- Geelsug, dit is ’n geel kleur van die vel en oogwitte vanweë hoë vlakke van bilirubien
- Jeuk
- Hartaanval
- Haarverlies (alopesie)
- Verhoogde hoeveelheid proteïen in jou urien (proteïenurie)

Onbekend (kan nie uit die beskikbare data geskat word nie)
- Nierversaking
- ’n Vergroting en verswakking van ’n bloedvatwand of ’n skeur in ’n bloedvatwand (aneurismes en slagaardisseksies)

Sistemiese sklerose geassosieer met interstisiële longsiekte (SSk-ILS)
Dikwels
- Siek gevoel (naarheid)
- Braking
- Pyn in die onderste deel van die liggaam (buik)
- Abnormale lewertoetsresultate
- Bloeding
- Hoë bloeddruk (hipertensie)
- Verlies aan eetlus
- Gewigsverlies
- Hoofpyn

Minder dikwels
- Inflammasie van die dikderm
- Ernstige lewerprobleme
- Nierversaking
- Lae plaatjietelling (trombositopenie)
- Uitslag
- Jeuk

Onbekend (kan nie uit die beskikbare data geskat word nie)
- Hartaanval
- Pankreatitis
- Geelsug, dit is ’n geel kleur van die vel en oogwitte vanweë hoë vlakke van bilirubien
- ’n Vergroting en verswakking van 'n bloedvatwand of ’n skeur in 'n bloedvatwand (aneurismes en slagaardisseksies)
- Haarverlies (alopesie)
- Verhoogde hoeveelheid proteïen in jou urien (proteïenurie)

Indien jy enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte ervaar, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van SEVCAD te verskaf.

5. Hoe om SEVCAD te bewaar
Bewaar teen of benede 25 °C.
Hou dit in die oorspronklike pakkie om dit teen vog te beskerm.
Om die inhoud teen vog te beskerm moet jy dit nie in die badkamer bêre nie.
Bêre alle medisyne buite bereik van kinders.

As jy in kontak met die inhoud van die kapsule kom, moet die hande onmiddellik met baie water afgewas word (sien afdeling 3).
Moet nie na die vervaldatum, wat op die karton en die stulpstroke aangedui word, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat SEVCAD bevat

Die aktiewe middel is nintedanib.
Elke sagte gelatienkapsule bevat 100 mg of 150 mg nintedanib (as esilaat).

Die ander bestanddele is:
Kapsule-inhoud: Mediumketting trigliseriede, hardevet, sojalesitien (E322)
Kapsuledop: Gelatien, gliserol (85 %), titaandioksied (E171), rooi ysteroksied (E172), geel ysteroksied (E172)

Hoe SEVCAD lyk en wat die inhoud van die pakkie is

SEVCAD 100 mg sagte gelatienkapsules is perskekleurige, ondeursigtige, langwerpige sagte gelatienkapsules, aan één kant in donker grys gemerk met die Boehringer Ingelheim maatskappy simbool en die getal “100” en dit bevat ’n helder geel viskeuse suspensie.
SEVCAD 150 mg sagte gelatienkapsules is bruinkleurige, ondeursigtige, langwerpige sagte gelatienkapsules, aan één kant in donker grys gemerk met die Boehringer Ingelheim maatskappy simbool en die getal “150” en dit bevat ’n helder geel viskeuse suspensie.

SEVCAD sagte gelatienkapsules word verpak in stolpverpakkingstroke, saamgestel uit ’n bedrukte aluminium dekblad en ’n aluminium gebaseerde vormblad.
Elke stolpverpakkingstrook bevat 10 sagte gelatienkapsules; 6 stolpverpakkingstroke word verpak in ’n bedrukte kartonhouer, in pakke met 60 kapsules.

Houer van die Registrasiesertifikaat

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Hierdie pamflet was voorheen hersien in

07 Junie 2024

Registrasienommer

SEVCAD 100 mg: 52/26/0155
SEVCAD 150 mg: 52/26/0156