# Front Side

335 mm

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS S4**

**AVIDEK 20 MG and 40 MG**

**gastro-resistant tablets**
**Pantoprazole sodium sesquihydrate**
**(contains mannitol)**

**Read all of this leaflet carefully before you start taking AVIDEK:**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider
- **AVIDEK** 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 **AVIDEK** is and what it is used for
2. What you need to know before you take **AVIDEK**
3. How to take **AVIDEK**
4. Possible side effects
5. How to store **AVIDEK**
6. Contents of the pack and other information


**1. What AVIDEK is and what it is used for**

**AVIDEK** is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine.

**AVIDEK 20 MG is used for treating:**
Mild reflux oesophagitis (inflammation of the oesophagus,a tube that runs from the throat to the stomach), and control of recurring symptoms in patients with healed reflux disease using an on-demand regimen.
Long-term treatment and prevention of relapse reflux disease.
Stomach ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Pantoprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
**AVIDEK 40 MG is used for treating:**
Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of stomach acid.
An infection with a bacterium called *Helicobacter pylori* in patients with duodenal ulcers and stomach ulcers in combination with two antibiotics (Eradication therapy).
Stomach and duodenal ulcers.
Zollinger-Ellison-Syndrome a digestive disorder that results in too much gastric acid.

**2. What you need to know before you take AVIDEK**

**Do not take AVIDEK**
- if you are hypersensitive (allergic) to pantoprazole or to any of the other ingredients of **AVIDEK** (see list under section 6);
- if you have serious liver problems.
- if you are taking medicines for HIV such as atazanavir or nelfinavir (antiretrovirals): These medicines may not work as well against your HIV infection if you take them with **AVIDEK**.
- **AVIDEK** must not be given to children as it is not known if it is safe and effective for them.

**Warnings and precautions**
Tell your doctor or healthcare professional before taking **AVIDEK**:
Take special care with **AVIDEK**

- If you have severe liver problems or if you ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking **AVIDEK** as a long-term treatment. In the case of a rise in liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment, as pantoprazole may lead to a reduced absorption of vitamin B12.
- If you are taking HIV protease inhibitors such as atazanavir or nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- If you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Taking a proton pump inhibitor like pantoprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist, or spine.
- If you are on **AVIDEK** for more than three months, it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- If you have ever had a skin reaction after treatment with a medicine that reduces stomach acid such as **AVIDEK.**
- If you get a rash on your skin, especially in areas exposed to the sun, you may need to stop your treatment with **AVIDEK**. Remember to also mention any other ill-effects like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A).

**Tell your doctor immediately if you notice any of the following symptoms:**
- An unintentional loss of weight
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice blood in your stools; which may be black or tarry in appearance
- you notice blood in your urine, reduction in urine output and fever.
- difficulty in swallowing or pain when swallowing
- chest pain
- stomach pain
- you look pale and feel weak (anaemia)
- severe and/or persistent diarrhoea, as **AVIDEK** has been associated with a small increase in infectious diarrhoea.

Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.

If you take **AVIDEK** on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

**Children and adolescents**

**AVIDEK** must not be given to children as it is unknown if it is safe and effective for them *{see "Do not take **AVIDEK**}*

**AVIDEK**
**20 mg / 40 mg**
PM04342696

**Other medicines and AVIDEK**

Always tell your doctor or healthcare provider if you are taking any other medicines. (This includes all complementary or traditional medicines).

**AVIDEK** may influence the effectiveness of other medicines, so tell your doctor if you are taking:
- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because **AVIDEK** may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening, or thinning of the blood. You may need further checks.
- Medicines used to treat HIV-infection, such as atazanavir.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your **AVIDEK** treatment because pantoprazole can increase levels of methotrexate in the blood.
- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose.
- Mycophenolate mofetil – pantoprazole may reduce exposure to the active metabolite, mycophenolic acid.
- Rifampicin – medicine used to treat tuberculosis.
- St John's Wort – medicine used for depression.

**AVIDEK with food and drink**

**AVIDEK** should be taken either before or during breakfast without chewing or breaking them, swallow them whole with some water.

**Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.
Safety in pregnancy and during lactation is unknown.

**Driving and using machines**

Pantoprazole does not adversely affect the ability to drive or use machines, however, adverse drug reactions such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machines.

**Sodium**

This medicine contains less than 1 mmol sodium per tablet, that is to say essentially "sodium-free".

**3. How to take AVIDEK**

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

Always take **AVIDEK** exactly as your doctor or pharmacist has told. Check with your doctor or pharmacist if you are not unsure.

The recommended dose is **AVIDEK 20 MG** to **AVIDEK 40 MG** once a day depending on your condition. Your doctor will prescribe an appropriate dose according to your condition.

**AVIDEK** tablets should be taken in the morning, swallowed whole with little water either before or during breakfast.
The gastro-resistant tablet should not be crushed because coating prevents pH sensitive degradation in the gut.

**Use in children and adolescents**

These tablets are not recommended for use in children due to limited data on safety and efficacy.

**If you take more AVIDEK than you should**
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. There are no known symptoms of overdose however as in any case of over dosage, treatment should be symptomatic and supportive measures should be utilised.

**If you forget to take AVIDEK**
Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

**If you stop taking AVIDEK**
Do not stop taking these tablets without first talking to your doctor or pharmacist. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

**AVIDEK can** have side effects.

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

If any of the following happens to you, stop taking **AVIDEK** and tell your doctor immediately, or go to the casualty department at your nearest hospital:
- severe allergic reaction to **AVIDEK** with swelling of the mouth, tongue, or face and/or throat,
- difficulty to breathe or swallow,
- red lumpy skin rash (hives)
- dizziness which may result in collapse

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AVIDEK**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- If you experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), and unexplained flu-like symptoms (symptoms of liver damage that can lead to liver failure).
- If you develop severe flu-like symptoms followed by severe skin blisters with redness around them, or a peeling rash, hives and/or mouth sores: These are symptoms of Stevens-Johnson syndrome, a sometimes-fatal form of allergic skin disease.
- Any other severe skin eruption or swelling, especially in the face, near the eyes and mouth and sometimes in the throat, causing narrowing and difficulty with breathing that can be fatal.
- Problems with passing urine or if you pass urine more often than usual and develop a fever and generally feel unwell, or if you notice blood in your urine.
- Watery stool/runny tummy that does not go away, stomach pain and fever (See Section 2).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The frequent side effects of **AVIDEK** are:
- Digestive tract problems such as stomach pain, runny tummy (watery stools), constipation and bloating (gas).
- Headache.

Other less frequent effects include:
- nausea (feeling sick),
- vomiting,
- dry mouth,
- feeling abnormally weak and tired,
- generally feeling unwell,
- swollen hands and feet,
- hypersensitivity (allergic reactions) (see above),
- not seeing clearly,
- blood test results showing: impaired liver function, increase of certain fats in the blood (triglycerides, cholesterol) and increase in billirubin (formed when red blood cells breakdown),
- weight changes,
- increase in body temperature,
- joint pain,
- muscle pain,
- increased risk of wrist, hip, and spine bone breaks,
- feeling of dizziness or feeling like 'spinning',
- taste disorders,
- feeling down,
- not sleeping well,
- feeling confused or baffled,
- inflammation of the small, narrow spaces in the tissue of the kidney that can cause kidney problems,
- decrease in the blood of the number of red, white cells and platelets (pancytopenia)
- white blood cells (leukopenia) (may increase the risk of inflammation/infection),
- platelets (thrombocytopenia) (may increase risk of bruising or bleeding),
- sharp drop in circulating granular white blood cells (agranulocytosis) - an acute disease marked by high fever.
- Over sensitivity to sunlight.
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**
Reporting suspected adverse reactions after authorisation of the medicine is important. Health care providers are asked to report any suspected adverse reactions to SAHPRA Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com.

**5. How to store AVIDEK**

Store at or below 25 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister/carton
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 AVIDEK 20 MG contains:**
**Each AVIDEK 20 MG** tablet contains 22,6 mg pantoprazole sodium sesquihydrate, equivalent to 20 mg pantoprazole base. Contains mannitol.

**What AVIDEK 40 MG contains**
**Each AVIDEK 40 MG** tablet contains 45,1 mg pantoprazole sodium sesquihydrate, equivalent to 40 mg pantoprazole base. Contains mannitol.

**Other ingredients include:**
Excipients: Mannitol, crospovidone, sodium carbonate anhydrous, calcium stearate, hydroxypropylmethyl cellulose, povidone, propylene glycol, titanium dioxide, iron oxide yellow, methacrylic acid copolymer, triethyl citrate.

**What AVIDEK looks like and contents of the pack**

**AVIDEK 20 MG**
Yellow, oval, biconvex, enteric-coated tablets plain on both sides.
**AVIDEK 40 MG**
Yellow, oval, biconvex, enteric-coated tablets plain on both sides.

Blister pack:
Tablets are packed in cold form laminate, 25 µm OPA/45 µm Aluminum foil/60 µm PVC and Plain 25 µm Aluminum foil/6-8 gsm HSL as the lidding material.
Pack size for 20 mg: 28's
Pack size for 40 mg: 14's and 28's

HDPE container pack:
Pack size for 20 mg: 28's

Not all packs and pack size are necessarily marketed.

**7. Holder of Certificate of Registration**

**MACLEODS PHARMACEUTICALS SA (PTY) LTD**
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa

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**Registration numbers**
**AVIDEK 20 MG**: A 51/11.4.3/1128.124
**AVIDEK 40 MG**: A 51/11.4.3/1129.125

**Access to the corresponding Professional Information**
The corresponding professional information can be accessed at https://www.macleodssaproducts. co.za or email macleodsrsa@ macleodspharma.com or contact 011 682 1169

**Marketed by:**
United Pharma Marketing (Pty) Ltd

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# Back Side

335 mm

**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS: S4**

**AVIDEK 20 MG en 40 MG**

**gastro-bestande tablette**
**Pantoprasool natriumseskwihidraat**
**(Bevat mannitol)**

**Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy AVIDEK begin neem:**
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **AVIDEK** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

**Wat in hierdie inligtingstuk is**

1. Wat **AVIDEK** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **AVIDEK** neem
3. Hoe om **AVIDEK** te neem
4. Moontlike newe-effekte
5. Hoe om **AVIDEK** te bewaar
6. Inhoud van die pak en ander inligting


## 1. Wat AVIDEK is en waarvoor dit gebruik word

**AVIDEK** is 'n selektiewe “protonpomp inhibeerder”, 'n medisyne wat die hoeveelheid suur wat in jou maag geproduseer word, verminder. Dit word gebruik vir die behandeling van suurverwante siektetoestande van die maag en ingewande.

**AVIDEK 20 MG word gebruik vir die behandeling van:**
Ligte refluks esofagitis (ontsteking van die slukderm, 'n buis wat van die keel na die maag loop), en beheer van herhalende simptome in pasiënte met geneesde reflukssiekte deur 'n op-aanvraag-regime te gebruik.
Langtermyn behandeling en voorkoming van terugval reflukssiekte.
Maagsere wat veroorsaak word deur medisyne genaamd NSAIM's (nie-steroïed anti-inflammatoriese middels). Pantoprasool kan ook gebruik word om te keer dat maagsere vorm wanneer jy NSAIM's neem.
**AVIDEK 40 MG word gebruik vir die behandeling van:**
Refluks esofagitis. 'n Ontsteking van jou slukderm (die buis wat jou keel met jou maag verbind) wat gepaard gaan met die terugstroming van maagsuur.
'n Infeksie met 'n bakterie genaamd *Helicobacter pylori* in pasiënte met duodenale ulkusse en maagsere in kombinasie met twee antibiotika (Eradikasie behandeling).
Maag- en duodenale ulkusse.
Zollinger-Ellison-sindroom, 'n spysverterings versteuring wat te veel maagsuur tot gevolg het.

## 2. Wat jy behoort te weet voordat jy AVIDEK neem

**Moet nie AVIDEK neem nie:**
- indien jy hipersensitief (allergies) vir pantoprasool of vir enige van die ander bestanddele van **AVIDEK** is (sien lys onder afdeling 6).
- indien jy ernstige lewerprobleme het.
- indien jy medisyne vir MIV gebruik soos atasanavir of nelfinavir (antiretrovirale middels): Hierdie medisyne mag dalk nie so goed teen jou MIV-infeksie werk, indien jy dit saam met **AVIDEK** neem nie.
- **AVIDEK** moet nie aan kinders gegee word nie, aangesien dit nie bekend is of dit veilig en effektief vir hulle is nie.

**Waarskuwings en voorsorgmaatreëls**
Vertel jou dokter of professionele gesondheidsorgwerker voordat jy **AVIDEK** neem:
Neem spesiale sorg met **AVIDEK**
- Indien jy ernstige lewerprobleme het of indien jy al ooit in die verlede probleme met jou lewer gehad het. Hy sal jou lewerensieme meer gereeld nagaan, veral wanneer jy **AVIDEK** as 'n langtermynbehandeling neem. In die geval van 'n verhoging in lewerensieme moet die behandeling gestaak word.
- Indien jy verminderde liggaamstore, of risikofaktore vir verminderde vitamien B12 het en pantoprasool as langtermynbehandeling ontvang, aangesien pantoprasool tot 'n verminderde opname van vitamien B12 kan lei.
- Indien jy MIV protease inhibeerders soos atasanavir of nelfinavir (vir die behandeling van MIV-infeksie) gelyktydig saam met pantoprasool neem, vra jou dokter vir spesifieke advies.
- Indien jy osteoporose het, of as jy kortikosteroïede neem (wat die risiko van osteoporose kan verhoog). Die neem van 'n protonpomp inhibeerder soos pantoprasool, veral oor 'n tydperk van meer as een jaar, kan jou risiko van fraktuur in die heup, pols of ruggraat effens verhoog.
- Indien jy vir langer as drie maande op **AVIDEK** is, is dit moontlik dat die vlakke van magnesium in jou bloed kan daal. Lae vlakke van magnesium kan gesien word as moegheid, onwillekeurige spiersametrekkings, disoriëntasie, konvulsies, duiseligheid, verhoogde harttempo. Indien jy enige van hierdie simptome kry, vertel asseblief onmiddellik jou dokter. Lae vlakke van magnesium kan ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. Jou dokter kan besluit om gereelde bloedtoetse uit te voer om jou magnesiumvlakke te monitor.
- Indien jy al ooit 'n velreaksie gehad het na behandeling met 'n middel wat maagsuur verminder, soos **AVIDEK**.
- Indien jy 'n uitslag op jou vel kry, veral in areas wat aan die son blootgestel is, moet jy dalk jou behandeling met **AVIDEK** staak. Onthou om ook enige ander nadelige effekte, soos pyn in jou gewrigte, te noem.
- Indien jy 'n spesifieke bloedtoets (Chromogranien A) moet ondergaan.

**Vertel onmiddellik jou dokter indien jy enige van die volgende simptome opmerk:**
- Onbeplande gewigsverlies
- braking, veral wanneer dit herhaal word
- braking van bloed; dit kan voorkom as donker koffie spikkels in jou braaksel
- jy sien bloed in jou stoelgang; wat swart of teeragtig in voorkoms kan wees
- jy merk bloed in jou uriene op, 'n afname in uriene uitset, en koors
- sukkel om te sluk, of ervaar pyn tydens sluk
- borskaspyn
- maagpyn
- jy lyk bleek en voel swak (anemie)
- ernstige en/of aanhoudende diaree, aangesien **AVIDEK** geassosieer is met 'n geringe toename in aansteeklike diaree.

Jou dokter kan moontlik besluit dat jy 'n paar toetse benodig om kwaadaardige siektes uit te sluit, omdat pantoprasool ook die simptome van kanker verlig, en vertraging in die diagnose daarvan kan veroorsaak. Indien jou simptome voortduur ten spyte van jou behandeling, sal verdere ondersoeke oorweeg word.

Indien jy **AVIDEK** op 'n langtermynbasis neem (langer as 1 jaar), sal jou dokter jou waarskynlik onder gereelde toesig hou. Jy moet enige nuwe en buitengewone simptome en omstandighede aanmeld, wanneer jy jou dokter sien.

**Kinders en adolessente**
**AVIDEK** moet nie aan kinders gegee word nie, aangesien dit onbekend is of dit veilig en doeltreffend vir hulle is (sien “Moet nie **AVIDEK** neem nie).

**Ander medisyne en AVIDEK**
Vertel altyd vir jou dokter of gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
**AVIDEK** kan die doeltreffendheid van ander medisyne beïnvloed, so vertel vir jou dokter indien jy enige van die volgende neem:
- Medisyne soos ketokonasool, itrakonasool en posakonasool (wat gebruik word om swambesmettings te behandel) of erlotinib (gebruik vir sekere soorte kanker) omdat **AVIDEK** hierdie en ander medisyne kan verhoed om behoorlik te werk.
- Warfarien en fenprokoumon, wat die verdikking, of verdunning van die bloed beïnvloed. Jy sal dalk verdere ondersoeke nodig hê.
- Medisyne wat gebruik word om MIV-infeksie te behandel, soos atasanavir.
- Metotreksaat (gebruik om rumatoïede artritis, psoriase en kanker te behandel) – as jy metotreksaat neem, kan jou dokter jou behandeling met **AVIDEK** tydelik staak, omdat pantoprasool die vlakke van metotreksaat in die bloed kan verhoog.
- Fluvoksamien (gebruik om depressie en ander psigiatriese siektes te behandel) – as jy fluvoksamien neem, kan jou dokter die dosis verminder.
- Mikofenolaatmofetil – pantoprasool kan blootstelling aan die aktiewe metaboliet, mikofenolsuur, verminder.
- Rifampisien – medisyne wat gebruik word om tuberkulose te behandel.
- Sint Johanneskruid – medisyne wat vir depressie gebruik word.

**AVIDEK met kos en vloeistowwe**
**AVIDEK** moet óf voor óf tydens ontbyt geneem word sonder om dit te kou of te breek, sluk dit heel, met 'n bietjie water.

**Swangerskap en borsvoeding**
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, vra jou dokter, apteker of ander gesonheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

**Bestuur en gebruik van masjinerie**
Pantoprasool beïnvloed nie die vermoë om te bestuur of masjiene te gebruik nadelig nie, maar nadelige geneesmiddelreaksies soos duiseligheid en visuele versteurings kan voorkom. Indien jy aangetas word, moet jy nie bestuur of masjienerie hanteer nie.

**Natrium**
Hierdie medisyne bevat minder as 1 mmol natrium per tablet, dit wil sê in wese “natriumvry”.

## 3. Hoe om AVIDEK te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **AVIDEK** presies soos jou dokter of apteker jou beveel het. Jy moet jou dokter of apteker raadpleeg indien jy nie seker is nie.

Die aanbevole dosis is **AVIDEK 20 MG** tot **AVIDEK 40 MG** een keer per dag, afhangende van jou toestand. Jou dokter sal 'n gepaste dosis volgens jou toestand voorskryf.

**AVIDEK** tablette moet in die oggend geneem word, heel ingesluk met 'n bietjie water, voor of tydens ontbyt.
Die gastro-bestande tablet moet nie fyngedruk word nie, want die deklaag verhoed pH-sensitiewe afbraak in die ingewande.

**Gebruik in kinders en adolessente**
As gevolg van beperkte data oor veiligheid en doeltreffendheid, word hierdie tablette nie aanbeveel vir gebruik in kinders nie.

**Indien jy meer AVIDEK neem as wat jy behoort te neem**
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Daar is geen bekende simptome van oordosering nie, maar in enige geval van oordosering moet behandeling simptomaties wees en ondersteunende maatreëls moet gebruik word.

**Indien jy vergeet om AVIDEK te neem**
Moet nie 'n dubbele dosis neem om op te maak vir 'n vergete dosis nie. Neem jou volgende normale dosis op die gewone tyd.

**Indien jy staak om AVIDEK te gebruik**
Moet nie ophou om hierdie tablette te neem sonder om eers met jou dokter of apteker te praat nie. Indien jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

## 4. Moontlike newe-effekte

**AVIDEK** kan newe-effekte hê.
Nie al die newe-effekte wat vir **AVIDEK** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ondervind terwyl jy **AVIDEK** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **AVIDEK** en lig onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- ernstige allergiese reaksie op **AVIDEK** met swelling van die mond, tong, of gesig en/of keel,
- moeilike asemhaling of sluk,
- rooi knopperige veluitslag (galbulte)
- duiseligheid wat kan lei tot ineenstorting

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **AVIDEK** gehad. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- Indien jy jeuk, regterbo-buikpyn, donker uriene, geel vel/oë (geelsug) en onverklaarbare griepagtige simptome (simptome van lewerskade wat tot lewerversaking kan lei) ervaar.
- Indien jy ernstige griepagtige simptome ontwikkel gevolg deur erge velblase met rooiheid rondom hulle, of 'n afskilferende uitslag, galbulte en/of mondsere: Hierdie is simptome van Stevens-Johnson-sindroom, 'n soms-dodelike vorm van allergiese velsiekte.
- Enige ander ernstige veluitbarsting of swelling, veral in die gesig, naby die oë en mond en soms in die keel, wat vernouing en probleme met asemhaling veroorsaak wat dodelik kan wees.
- Probleme met urinering of as jy meer gereeld as gewoonlik urineer en koors ontwikkel en oor die algemeen onwel voel, of as jy bloed in jou uriene opmerk.
- Waterige stoelgang/loperige maag wat nie weggaan nie, maagpyn en koors (Sien Afdeling 2).

Hierdie is alles ernstige newe-effekte. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.

Vertel jou dokter indien jy enige van die volgende waarneem:

Die gereelde newe-effekte van **AVIDEK** is:
- Spysverteringskanaalprobleme soos maagpyn, loperige maag (waterige stoelgang), hardlywigheid en opgeblasenheid (winde).
- Hoofpyn.

Ander minder gereelde newe-effekte sluit in:
- naarheid (voel siek),
- braking,
- droë mond,
- voel abnormaal swak en moeg,
- voel oor die algemeen onwel,
- geswelde hande en voete,
- hipersensitiwiteit (allergiese reaksies) (sien hierbo),
- kan nie duidelik sien nie,
- bloedtoetsresultate wat toon: ingekorte lewerfunksie, toename in sekere vette in die bloed (trigliseriede, cholesterol) en toename in bilirubien (gevorm wanneer rooibloedselle afbreek),
- veranderinge in gewig,
- toename in liggaamstemperatuur,
- gewrigspyn,
- spierpyn,
- verhoogde risiko van gewrig-, heup- en ruggraatbeen breuke,
- gevoel van duiseligheid of voel soos 'tol',
- smaakversteurings,
- voel neerslagtig,
- slaap nie lekker nie,
- verbysterd of verward voel,
- ontsteking van die klein, nou spasies in die weefsel van die nier wat nierprobleme kan veroorsaak,
- afname in die aantal van rooi-, wit selle en bloedplaatjies (pansitopenie) in die bloed,
- witbloedselle (leukopenie) (kan die risiko van inflammasie/ infeksie verhoog),
- bloedplaatjies (trombositopenie) (kan die risiko van kneusing of bloeding verhoog),
- skerp daling in sirkulerende granulêre witbloedselle (agranulositose) - 'n akute siekte gekenmerk deur hoë koors,
- oorgevoeligheid teenoor sonlig.

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie.

**Aanmelding van newe-effekte**
Dit is belangrik om vermoedelike nadelige reaksies aan te meld, na goedkeuring van die medisyne. Gesondheidsorgverskaffers word gevra om enige vermoedelike nadelige reaksies aan SAHPRA via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com.

## 5. Hoe om AVIDEK te bewaar

Bewaar by of benede 25 °C (kamertemperatuur). Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum, wat aangebring is op die stulpstrook/karton, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) gooi nie.

## 6. Inhoud van die verpakking en ander inligting

**Wat AVIDEK 20 MG bevat:**
Elke **AVIDEK 20 MG** tablet bevat 22,6 mg pantoprasool natriumseskwihidraat, gelykstaande aan 20 mg pantoprasool basis. bevat mannitol.

**Wat AVIDEK 40 MG bevat**
Elke **AVIDEK 40 MG** tablet bevat 45,1 mg pantoprasool natriumseskwihidraat, gelykstaande aan 40 mg pantoprasool basis. bevat mannitol.

**Ander bestanddele sluit in:**
Hulpstowwe: Mannitol, kruispovidoon, anhidriese natriumkarbonaat, kalsiumstearaat, hidroksipropielmetielsellulose, povidoon, propileenglikol, titaandioksied, geel ysteroksied, metakriliese suurkopolimeer, triëtielsitraat.

**Hoe AVIDEK lyk en inhoud van die verpakking**
**AVIDEK 20 MG**
Geel, ovaal, bikonvekse, enteries-bedekte tablette, glad aan beide kante.
**AVIDEK 40 MG**
Geel, ovaal, bikonvekse, enteries-bedekte tablette, glad aan beide kante.

Stulpverpakking:
Tablette word verpak in koue vorm laminaat, 25 µm OPA/45 µm aluminiumfoelie/60 µm PVC en gewone 25 µm aluminiumfoelie/ 6-8 gsm HSL as die dekmateriaal.
Verpakkingsgroottes vir 20 mg: 28's
Verpakkingsgroottes vir 40 mg: 14's en 28's

HDPE-houerverpakking:
Pakgrootte vir 20 mg: 28's

Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

## 7. Houer van die Sertifikaat van Registrasie

**MACLEODS PHARMACEUTICALS SA (Edms) Bpk**
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

**Hierdie inligtingstuk was hersien in**
21 Junie 2022

**Registrasienommers**
**AVIDEK 20 MG**: A51/11.4.3/1128.124
**AVIDEK 40 MG**: A51/11.4.3/1129.125

**Toegang tot die ooreenstemmende Professionele Inligting**
Die ooreenstemmende professionele in ligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

**Bemark Deur:**
United Pharma Marketing (Edms) Bpk

UNICORN

2602A322

335 mm

PACKAGING RESEARCH & DEVELOPMENT

*Restricted Circulation*

**(Front Page)**

# ARTWORK / PRINTPROOF APPROVAL FORM

| | | | | | | |
|---|---|---|---|---|---|---|
| **1. Product: AVIDEK 20/40 MG (Pantoprazole Tablets 20/40 mg)** | | | | | | |
| **2. Country: South Africa - UNICORN** | | | **3. Packaging component: Patient Information Leaflet** | | | |
| **4. No. of Colours: 1 Colour** | | | **5. Pantone Shade No.: Black** | | | |
| **6. Specification: 40 gsm bible paper** | | | | | | |
| **7. Machine Layout No.: NA** | | | **8. Dimensions: 335 (L) x 335 (W) mm** | | | |
| **9. Design / Style: Booklet** | | | **10. Item code No.: PM04342696** | | | |
| **11. Artwork has been made: Actual Size** | | | **12. Pharma code No.: 41251 mini** | | | |
| **13. Barcode/NDC no: NA** | | | **14. Supersedes Item code No: NA** | | | |
| **15. Revision no: 00** | | | **16. A/W File name: G:\Regulated_Artwork\SOUTH AFRICA\Pantoprazol\Unicorn\Avidek Leaflet - PM04342696.cdr** | | | |
| **Approved By:** | | | **17. Location: Daman** | | | |
| **PRD** | **M.A. HOLDER** | **RAD** | **QC** | **PRODN** | **QA** | **UNICORN** |
| | 11/05/2026 | | | | | Jeanine Janse van Rensburg \| Head of Technical Affairs \| Responsible Pharmacist 2026.05.12 18:08:13 +02'00' |

**Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.**

**Instructions to Vendor** :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

**Format No: FRM/SOP/CO/CQA/021/03-003**

| Reason for revision : | Item code | Artwork Send for Printing Date | Artwork Implementation Date |
|---|---|---|---|
| 1) New Artwork for South Africa - UNICORN | PM04342696 | | |