Front Side

280 mm

BAQUIMAK
100 mg
PM04339674

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BAQUIMAK 100 mg (tablet)
Bedaquiline
Contains sugar: 152,91 mg lactose monohydrate

Read all of this leaflet carefully before you start taking BAQUIMAK 100 mg
- 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.
- **BAQUIMAK 100 mg** 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 **BAQUIMAK 100 mg** is and what it is used for
2. What you need to know before you take **BAQUIMAK 100 mg**
3. How to take **BAQUIMAK 100 mg**
4. Possible side effects
5. How to store **BAQUIMAK 100 mg**
6. Contents of the pack and other information

1. What BAQUIMAK 100 mg is and what it is used for

BAQUIMAK 100 mg is a type of antibiotic. Antibiotics are medicines that kill bacteria that cause disease.
BAQUIMAK 100 mg is used to treat tuberculosis (TB) when it has become resistant to other antibiotics. This is called multi-drug resistant TB.
BAQUIMAK 100 mg must always be taken together with other medicines for treating tuberculosis.
It is used in adults aged 18 years and over.

2. What you need to know before you take BAQUIMAK 100 mg

Do not take BAQUIMAK 100 mg:
- If you are allergic (hypersensitive) to bedaquiline or any of the other ingredients of this medicine, (listed in **section 6** below).
- If you have congenital QT prolongation, a heart rhythm disorder that can potentially cause fast, chaotic heartbeats.
- If you have uncontrolled irregular heartbeats.
- If you are using other medicines that may prolong the QTC interval and cause fast chaotic heartbeats, such as amiodarone (used to treat fast, irregular heartbeats), quinidine (used to treat irregular heartbeats) or sotalol (used to slow down heart rate).
- If you have liver disease.

Warnings and precautions
Talk to your doctor before taking **BAQUIMAK 100 mg** if.
- You have had an abnormal heart tracing (ECG) or heart failure.
- You have a personal or family history of a heart problem called "congenital long QT syndrome".
- You have any other diseases, including HIV infection.

Use in children and adolescents
Do not give **BAQUIMAK 100 mg** to children and adolescents (under 18 years of age). This is because it has not been studied in this age group.

Other medicines and BAQUIMAK 100 mg
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Take care if you are taking the following medicines:
- Rifampicin, rifapentine, rifabutin (used to treat some infections like tuberculosis)
- Ketoconazole (used to treat fungal infections)
- Efavirenz, etravine, lopinavir/ritonavir (used to treat HIV infection)
- Clofazimine used to (treat infections such as leprosy)
- Carbamazepine, phenytoin (used to treat epileptic fits)
- St John's wort a herbal (used to relieve anxiety)
- Ciprofloxacin, erythromycin, clarithromycin (used to treat infections)

BAQUIMAK 100 mg with food and drink:
BAQUIMAK 100 mg must be taken with food.
Swallow the tablets whole with water.
Do not drink alcohol while using **BAQUIMAK 100 mg.**

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **BAQUIMAK 100 mg**.

Do not take **BAQUIMAK 100 mg** if you are pregnant, are considering becoming pregnant or are breastfeeding.

Driving and using machines
You may feel dizzy after taking **BAQUIMAK 100 mg**. If this happens don't drive or operate machinery.
It is not always possible to predict to what extent **BAQUIMAK 100 mg** 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 **BAQUIMAK 100 mg** affects them.

3. How to take BAQUIMAK 100 mg

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

Always take **BAQUIMAK 100 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:
First two weeks:
- Take 400 mg (4 tablets of 100 mg) once a day

From week 3 to week 24:
- Take 200 mg (2 tablets of 100 mg) a day for 3 days of each week only
- There must be at least 48 hours in between each time you take **BAQUIMAK 100 mg**. For example, you may take **BAQUIMAK 100 mg** on Monday, Wednesday and Friday every week from week 3 onwards.

After week 2, do not take a total dose of more than 600 mg (6 tablets of 100 mg) **BAQUIMAK 100 mg** in total during a 7 day period.
You would have to take **BAQUIMAK 100 mg** for a 24 week course.
You may need to continue treatment beyond the 24 week course if you have extensive resistance to TB medicines in order to be cured. This may only be considered based on individual cases by your doctor.
You may need to keep taking your other medicines for TB for longer than 24 weeks. Check with your doctor or pharmacist.
Do not stop early because your TB infection could get worse or become resistant to **BAQUIMAK 100 mg** and other medicines. If you have the impression that the effect of **BAQUIMAK 100 mg** is too strong or too weak, tell your doctor or pharmacist.
BAQUIMAK 100 mg must always be taken together with other medicines for treating TB. Your doctor will decide which other medicines you should take with **BAQUIMAK 100 mg**.
Take **BAQUIMAK 100 mg** with food.
Do not skip doses.
Skipping doses or not completing the full course of therapy may:
make your treatment ineffective and your TB could get worse and increase the chance that the bacteria will become resistant to **BAQUIMAK 100 mg**.
This means your disease may not be treatable by **BAQUIMAK 100 mg** or other medicines in the future.

If you have the impression that the effect of **BAQUIMAK 100 mg** is too strong or too weak, talk to your doctor or pharmacist.

If you take more BAQUIMAK 100 mg then you should

If you take more **BAQUIMAK 100 mg** then you should, talk to your doctor straight away. Take the medicine pack with you.
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
In the event of an overdose, you may experience very fast and irregular heartbeats, sudden dizziness and chest pain.

If you forget to take **BAQUIMAK 100 mg**
During the first two weeks
- Do not take a double dose to make up for a forgotten dose.
- Take the next dose as usual.

From week 3 onwards
- Take the missed dose as soon as possible.
- Take the next planned dose no earlier than 24 hours.
- Do not take a dose of more than 600 mg (6 tablets of 100 mg) in total during a 7 day period. This should be taken as three doses of 200 mg per day at least 24 hours apart.

If you have missed a dose and you are not sure what to do, talk to your doctor or pharmacist.

If you stop taking BAQUIMAK 100 mg
Do not stop taking **BAQUIMAK 100 mg** without first talking to your doctor. If you stop taking **BAQUIMAK 100 mg** earlier than you should, your TB infection could get worse or become resistant to **BAQUIMAK 100 mg** and other medicines.
If you have further questions on the use of **BAQUIMAK 100 mg**, ask your doctor, pharmacist or nurse.

BAQUIMAK 100 mg contains lactose
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take **BAQUIMAK 100 mg**.
This medicine contains less than 1 mmol sodium per tablet, that is to say essentially 'sodium-free'.

4. Possible side effects

BAQUIMAK 100 mg can have side effects.
Not all side effects reported for **BAQUIMAK 100 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BAQUIMAK 100 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your healthcare provider right away if you experience any of the following:

- A change in your heartbeat (a fast or irregular heartbeat), or if you faint.
- Unexplained symptoms such as nausea or vomiting, stomach pain, fever, weakness, itching, unusual tiredness, loss of appetite, light coloured bowel movements, dark coloured urine, yellowing of your skin or the white of your eyes (jaundice).

Frequent side effects
- headache
- joint pain
- feeling dizzy
- feeling sick (nausea) or being sick (vomiting).
- diarrhoea
- increased liver enzymes shown in blood tests
- aching muscles, tender or weak muscles, not caused by exercise
- abnormal ECG called "QT prolongation"

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 or nurse. This includes any possible side effects not listed in this leaflet. 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 **BAQUIMAK 100 mg.**

5. How to store BAQUIMAK 100 mg

Store at or below 30 °C.
Protect from moisture.
Do not store in a refrigerator.
KEEP OUT OF THE REACH OF CHILDREN.

6. Contents of pack and other information

What BAQUIMAK 100 mg contains
The active ingredient is bedaquiline fumarate
The other ingredients are:
Microcrystalline cellulose
Corn starch
Colloidal silicon dioxide
Lactose monohydrate
Polysorbate 20
Croscarmellose sodium
Purified water

What BAQUIMAK 100 mg looks like and contents of the pack
BAQUIMAK 100 mg: White to off white, round biconvex, uncoated tablets, debossed with "J" & "47" on one side and plain on other side.

Contents of the pack:
Tablets are packed in a round white 150 cc HDPE container with absorbent cotton and closed with a white continuous thread closure packed in an outer carton. Pack sizes include 188s tablets.
Tablets are packed in aluminium foil laminated on one side and laminated to Alu PVC on the other side. Pack sizes include 6's tablets.

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

This leaflet was last revised in
30 January 2024

Registration numbers
BAQUIMAK 100 mg: 58/20.2.3/0103

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.

335 mm

Back Side

280 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

BAQUIMAK 100 mg (tablet)
Bedakwillien
Bevat suiker: 152,91 mg laktosemonohidraat

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy BAQUIMAK 100 mg begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **BAQUIMAK 100 mg** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit kan hulle skade aandoen, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **BAQUIMAK 100 mg** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **BAQUIMAK 100 mg** neem
3. Hoe om **BAQUIMAK 100 mg** te neem
4. Moontlike newe-effekte
5. Hoe om **BAQUIMAK 100 mg** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat BAQUIMAK 100 mg is en waarvoor dit gebruik word

BAQUIMAK 100 mg is 'n soort antibiotikum. Antibiotika is medisyne wat bakterieë, wat siektes veroorsaak, doodmaak.
BAQUIMAK 100 mg word gebruik om tuberkulose (TB) te behandel wanneer dit weerstandig geword het teen ander antibiotika. Dit word multi-middelweerstandige TB genoem.
BAQUIMAK 100 mg moet altyd saam met ander medisyne geneem word vir die behandeling van tuberkulose.
Dit word gebruik in volwassenes, ouderdom 18 jaar en ouer.

2. Wat jy behoort te weet voordat jy BAQUIMAK 100 mg neem

Moet nie BAQUIMAK 100 mg neem nie:
- Indien jy allergies is (hipersensitief) vir bedakwillien of enige van die ander bestanddele van hierdie medisyne (gelys in **afdeling 6** hieronder).
- Indien jy aangebore QT-verlenging het, 'n hartritme-versteuring wat moontlik vinnige, chaotiese hartkloppings kan veroorsaak.
- Indien jy onbeheerde onreëlmatige hartkloppings het.
- Indien jy ander medisyne gebruik wat die QTC-interval kan verleng en vinnige chaotiese hartkloppings kan veroorsaak, soos amiodaroon (wat gebruik word om vinnige, onreëlmatige hartkloppings te behandel), kinidien (wat gebruik word om onreëlmatige hartkloppings te behandel) of sotalol (wat gebruik word om harttempo te vertraag).
- Indien jy lewersiekte het.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **BAQUIMAK 100 mg** neem indien:
- Jy 'n abnormale hartopsporing (EKG) of hartversaking gehad het.
- Jy 'n persoonlike- of familiegeskiedenis van 'n hartprobleem genaamd 'aangebore lang QT-sindroom' het.
- Jy enige ander siektes, insluitend MIV-infeksie het.

Gebruik in kinders en adolessente
Moet nie **BAQUIMAK 100 mg** aan kinders en adolessente (jonger as 18 jarige ouderdom) gee nie. Dit is omdat dit nie in hierdie ouderdomsgroep bestudeer is nie.

Ander medisyne en BAQUIMAK 100 mg
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Neem spesiale sorg indien jy die volgende medisyne gebruik:
- Rifampisien, rifapentien, rifabutien (gebruik om infeksies soos tuberkulose te behandel)
- Ketokonasool (wat gebruik word om swambesmetting te behandel)
- Efavirens, etravien, lopinavir/ritonavir (wat gebruik word om MIV-infeksie te behandel)
- Klofasimien (wat gebruik word om infeksies soos melaatsheid te behandel)
- Karbamasepien, fenitoïen (gebruik om epileptiese aanvalle te behandel)
- St Johannes kruid, ('n kruie wat gebruik word om angs te verlig)
- Siprofloksasien, eritromisien, klaritromisien (wat gebruik word om infeksies te behandel)

BAQUIMAK 100 mg met voedsel en drank:
BAQUIMAK 100 mg moet saam met kos geneem word.
Sluk die tablette heel, met water.
Moet nie alkohol drink terwyl **BAQUIMAK 100 mg** gebruik word nie.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **BAQUIMAK 100 mg** neem.

Moet nie **BAQUIMAK 100 mg** neem indien jy swanger is, dit oorweeg om swanger te raak of borsvoed nie.

Bestuur en gebruik van masjinerie
Jy kan duiselig voel nadat jy **BAQUIMAK 100 mg** geneem het. Wanneer dit gebeur, moet nie bestuur of masjinerie bedryf nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **BAQUIMAK 100 mg** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem nie, totdat hulle bewus is van die mate waartoe **BAQUIMAK 100 mg** hulle beïnvloed.

3. Hoe om BAQUIMAK 100 mg te neem

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

Neem altyd **BAQUIMAK 100 mg** presies soos jou dokter jou beveel het. Raadpleeg jou dokter of apteker indien jy onseker is.

Die gewone dosis is:
Eerste twee weke:
- Neem 400 mg (4 tablette van 100 mg) een keer per dag

Vanaf week 3 tot week 24:
- Neem 200 mg (2 tablette van 100 mg) per dag vir slegs 3 dae van elke week
- Daar moet ten minste 48 uur wees tussen elke keer wanneer jy **BAQUIMAK 100 mg** neem. Jy kan byvoorbeeld vanaf week 3, **BAQUIMAK 100 mg** op Maandae, Woensdae en Vrydae van elke week neem.

Na week 2, moet nie in totaal oor 'n 7 dag periode, 'n totale dosis van meer as 600 mg (6 tablette van 100 mg) **BAQUIMAK 100 mg** neem nie.
Jy sal **BAQUIMAK 100 mg** moet gebruik vir 'n 24 weke kursus.
Jy sal dalk langer as die 24 weke kursus moet aangaan met behandeling om genees te word, indien jy uitgebreide weerstand teen TB-medisyne het. Gebaseer op individuele gevalle, mag dit slegs deur jou dokter oorweeg word.
Dit mag nodig wees dat jy jou ander medisyne vir TB vir langer as 24 weke moet neem. Raadpleeg jou dokter of apteker.
Moet nie vroeër ophou nie, aangesien jou TB-infeksie kan erger word of weerstandig raak teen **BAQUIMAK 100 mg** en ander medisyne. Indien jy die indruk het dat die effek van **BAQUIMAK 100 mg** te sterk of te swak is, vertel jou dokter of apteker.
BAQUIMAK 100 mg moet altyd saam met ander medisyne geneem word vir die behandeling van TB. Jou dokter sal besluit watter ander medisyne jy saam met **BAQUIMAK 100 mg** moet neem.
Neem **BAQUIMAK 100 mg** met kos.
Moet nie dosisse oorslaan nie.
Om dosisse oor te slaan of nie die volle kursus van behandeling te voltooi nie, kan:
jou behandeling oneffektief maak en jou TB kan erger word en dit verhoog die kans dat die bakterieë weerstandig sal word teen **BAQUIMAK 100 mg**.
Dit beteken dat jou siekte in die toekoms moontlik nie met **BAQUIMAK 100 mg** of ander medisyne behandel sal kan word nie.

Indien jy onder die indruk is dat die effek van **BAQUIMAK 100 mg** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer BAQUIMAK 100 mg neem as wat jy behoort te neem
Indien jy meer **BAQUIMAK 100 mg** neem as wat jy behoort te neem, moet jy onmiddellik met jou dokter praat. Neem die medisynepak saam met jou.
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
In die geval van 'n oordosering, kan jy baie vinnige en onreëlmatige hartklop, skielike duiseligheid en borskaspyn ervaar.

Indien jy vergeet om **BAQUIMAK 100 mg** te neem
Gedurende die eerste twee weke
- Moet nie 'n dubbele dosis neem om vir 'n vergete dosis op te maak nie.
- Neem die volgende dosis soos gewoonlik.

Vanaf week 3 vorentoe
- Neem die oorgeslane dosis so gou as moontlik.
- Neem die volgende beplande dosis nie gouer as 24 uur nie.
- Moet nie in totaal, oor 'n 7 dag periode, 'n dosis van meer as 600 mg (6 tablette van 100 mg) neem nie. Dit moet geneem word as drie dosisse van 200 mg per dag ten minste 24 uur uitmekaar.

Indien jy 'n dosis oorgeslaan het en jy is onseker oor wat om te doen, praat met jou dokter of apteker.

Indien jy ophou om BAQUIMAK 100 mg te neem
Moet nie ophou om **BAQUIMAK 100 mg** te neem sonder om eers met jou dokter te praat nie. Indien jy vroeër as wat jy moet ophou om **BAQUIMAK 100 mg** te neem, kan jou TB-infeksie erger word of weerstandig raak teen **BAQUIMAK 100 mg** en ander medisyne.
Indien jy verdere vrae het oor die gebruik van **BAQUIMAK 100 mg**, vra jou dokter, apteker of verpleegkundige.

BAQUIMAK 100 mg bevat laktose
Pasiënte met seldsame oorerflike probleme van galaktose-intoleransie, totale laktase tekort of glukose-galaktose wanabsorpsie moet nie **BAQUIMAK 100 mg** neem nie.
Hierdie medisyne bevat minder as 1 mmol natrium per tablet, dit wil sê in wese 'natriumvry'.

4. Moontlike newe-effekte

BAQUIMAK 100 mg kan newe-effekte hê.
Nie alle newe-effekte wat vir **BAQUIMAK 100 mg** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ondervind terwyl jy **BAQUIMAK 100 mg** gebruik, kontak asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Lig onmiddellik jou gesondheidsorgverskaffer in as jy enige van die volgende ervaar:

- 'n Verandering in jou hartklop ('n vinnige of onreëlmatige hartklop), of as jy flou word.

Onverklaarbare simptome soos naarheid of braking, maagpyn, koors, swakheid, gejeuk, ongewone moegheid, verlies aan eetlus, ligkleurige dermbewegings, donkerkleurige uriene, vergeling van jou vel of die wit van jou oë (geelsug).

Gereelde newe-effekte
- hoofpyn
- gewrigspyn
- duiselig voel
- siek voel (naarheid) of siek wees (braking).
- diaree
- verhoogde lewerensieme wat in bloedtoetse aangedui word
- seer spiere, gevoelige- of swak spiere, nie veroorsaak deur oefening nie
- abnormale EKG genaamd "QT verlenging"

Indien jy enige newe-effekte ervaar wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form",** wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **BAQUIMAK 100 mg.**

5. Hoe om BAQUIMAK 100 mg te bewaar

Bewaar by of benede 30°C.
Beskerm teen vog.
Moet nie in 'n yskas stoor nie.
HOU BUITE DIE BEREIK VAN KINDERS.

6. Inhoud van die pak en ander inligting

Wat BAQUIMAK 100 mg bevat
Die aktiewe bestanddeel is bedakwillienfumaraat
Die ander bestanddele is:
Mikrokristallyne sellulose
Mielie-stysel
Kolloïdale silikondioksied
Laktosemonohidraat
Polisorbaat 20
Natriumkroskarmellose
Gesuiwerde water

Hoe BAQUIMAK 100 mg lyk en inhoud van die pak
BAQUIMAK 100 mg: Wit tot naaswit, ronde bikonveks, onbedekte tablette, bedruk met "J" & "47" aan die een kant en glad aan die ander kant.

Inhoud van die pak:
Tablette word verpak in 'n ronde wit 150 cc HDPE-houer met absorberende katoen en gesluit met 'n wit deurlopende draad sluiting wat in 'n buitenste karton verpak is. Pakgroottes sluit 188 tablette in.
Tablette word verpak in aluminiumfoelie wat aan die een kant gelamineer is en aan die ander kant gelamineer is tot Alu PVC. Pakgroottes sluit 6 tablette in.

7. HOUER VAN DIE REGISTRASIESERTIFIKAAT

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
30 Januarie 2024

Registrasienommer
BAQUIMAK 100 mg: 58/20.2.3/0103

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

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: BAQUIMAK 100 mg (BEDAQUILINE TABLETS 100 MG)	
2. Country: SOUTH AFRICA-TENDER	**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 280 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04339674**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40381 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. File Name : Z:\South Africa\Bedaquiline\01\Bedaquiline 100 mg Tablets PIL - PM04339674.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	15/08/2025 				

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	PM04339674		