PACKAGING RESEARCH & DEVELOPMENT

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(Front Page)

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Leaflet Front Side

260 mm

ENKOBIST 200
PM04341973

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ENKOBIST 200 (Film-coated Tablet)
Entacapone 200 mg
Sugar free

Read all of this leaflet carefully before you start taking ENKOBIST 200
- 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.
- **ENKOBIST 200** 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 **ENKOBIST 200** is and what it is used for
2. What you need to know before you take **ENKOBIST 200**
3. How to take **ENKOBIST 200**
4. Possible side effects
5. How to store **ENKOBIST 200**
6. Contents of the pack and other information

1. What ENKOBIST 200 is and what it is used for

ENKOBIST 200 is a medicine that contains entacapone and is used together with levodopa to treat Parkinson's disease. **ENKOBIST 200** aids levodopa in relieving the symptoms of Parkinson's disease. **ENKOBIST 200** has no effect on relieving the symptoms of Parkinson´s disease unless taken with levodopa.

2. What you need to know before you take ENKOBIST 200

If you are pregnant or breast feeding your baby, please consult your health care provider for advice before taking this medicine**.**

Do not take ENKOBIST 200:
- if you are allergic to entacapone or any of the other ingredients of this medicine (listed in **Section 6**);
- if you have a tumour of the adrenal gland (known as pheochromocytoma; this may increase the risk of severe high blood pressure);
- if you are taking certain antidepressants (ask your doctor or pharmacist whether your antidepressive medicine can be taken together with **ENKOBIST 200**);
- if you have liver disease;
- if you have ever suffered from a rare reaction to antipsychotic medicines, called neuroleptic malignant syndrome (NMS). See **section 4 Possible side effects** for the characteristics of NMS;
- if you have ever suffered from a rare muscle disorder called rhabdomyolysis which was not caused by injury.

Warnings and precautions
Talk to your doctor before taking **ENKOBIST 200** if the following applies to you:
- if you have ever had a heart attack or any other diseases of the heart
- if you are taking a medicine which may cause dizziness or light-headedness (low blood pressure) when rising from a chair or bed;
- if you experience prolonged diarrhoea consult your doctor as it may be a sign of inflammation of the colon;
- if you experience diarrhoea, monitoring of your weight is recommended in order to avoid potentially excessive weight loss;
- if you experience increasing loss of appetite, weakness, exhaustion and weight loss within a relatively short period of time, a general medical evaluation including liver function should be considered.
- Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.
- As **ENKOBIST 200** tablets will be taken together with other levodopa medicines, please also read the package leaflets of these medicines carefully.
- The dose of other medicines to treat Parkinson's disease may need to be adjusted when you start taking **ENKOBIST 200**. Follow the instructions that your doctor has given you.
- Neuroleptic Malignant Syndrome (NMS) is a serious but rare reaction to certain medicines, and may occur especially when **ENKOBIST 200** and other medicines to treat Parkinson's disease are suddenly stopped or the dose is suddenly reduced. For the characteristics of NMS see **Section 4 Possible side effects**. Your doctor may advise you to slowly discontinue the treatment with **ENKOBIST 200** and other medicines to treat Parkinson's disease.
- **ENKOBIST 200** taken with levodopa may cause drowsiness and may cause you to sometimes suddenly fall asleep. If this happens, you should not drive or use any tools or machines (see **Driving and using machines**).
- You have a heart disease.

Use in children and adolescents
The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore, entacapone should not be used in this age group.

Other medicines and ENKOBIST 200
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Inform your doctor in particular if you are taking any of the following medicines:
- rimiterole, isoprenaline, adrenaline, noradrenaline, dopamine, dobutamine, alpha-methyldopa, apomorphine;
- antidepressants including desipramine, maprotiline, venlafaxine, paroxetine;
- warfarin, used to thin the blood;
- iron supplements. **ENKOBIST 200** may make it harder for you to digest iron. Therefore, do not take **ENKOBIST 200** and iron supplements at the same time. After taking one of them, wait at least 2 to 3 hours before taking the other.

ENKOBIST 200 with food and drink:
ENKOBIST 200 may be taken with or without food.

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 **ENKOBIST 200**.
Do not take **ENKOBIST 200** if you are pregnant. Inform your doctor immediately if you are pregnant or intend to become pregnant.
Do not breastfeed if you are taking **ENKOBIST 200**.

Driving and using machines
ENKOBIST 200 taken together with levodopa may lower your blood pressure, which may make you feel light-headed or dizzy. Be particularly careful when you drive or when you use tools or machinery.
In addition, **ENKOBIST 200** taken with levodopa may make you feel very drowsy, or cause you to sometimes suddenly fall asleep.
Do not drive or operate machinery if you experience these side effects.

3. How to take ENKOBIST 200

Do not share medicines prescribed for you with any other person.
Always take **ENKOBIST 200** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
ENKOBIST 200 are taken together with medicines containing levodopa (either levodopa/carbidopa preparations or levodopa/benserazide preparations). You may also use other medicines to treat Parkinson's disease at the same time.
The recommended dose of **ENKOBIST 200** is one 200 mg tablet with each levodopa dose.
The maximum recommended dose is 10 tablets per day, i.e. 2000 mg of **ENKOBIST 200**.
If you are receiving dialysis for renal insufficiency, your doctor may tell you to increase the time between doses.

If you have the impression that the effect of **ENKOBIST 200** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ENKOBIST 200 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.

If you forget to take ENKOBIST 200
It is important to take your **ENKOBIST 200** tablets regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking ENKOBIST 200
If **ENKOBIST 200** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **ENKOBIST 200** for as long as your doctor has prescribed.

4. Possible side effects

ENKOBIST 200 can have side effects.
Some of the side effects are often caused by the increased effects of levodopa therapy and are most common at the start of treatment. If you experience such effects at the start of treatment with **ENKOBIST 200** you should contact your doctor who may decide to adjust your dosage of levodopa.

Frequent side effects:
- Uncontrollable movements with difficulty in performing voluntary movements (dyskinesias);
- headache;
- tremor;
- excessive movements (hyperkinesias), worsening of symptoms of Parkinson´s disease;
- moving or spinning sensation (vertigo);
- prolonged muscle cramps (dystonia);
- dizziness;
- feeling sick (nausea);
- being sick (vomiting), diarrhoea, abdominal pain, constipation, dry mouth;
- harmless reddish-brown discoloration of urine;
- tiredness, increased sweating, fall;
- leg cramps;
- hallucinations (seeing/hearing/feeling/smelling things that are not really there);
- sleeplessness, vivid dreams, and confusion;
- heart or artery disease events (e.g. chest pain);

Less frequent side effects
- heart attack;
- rashes;
- hives;
- abnormal results in liver function test;
- agitation;
- decreased appetite, weight loss.

Side effects with unknown frequency:
- Inflammation of the colon (colitis);
- inflammation of the liver (hepatitis) with yellowing of the skin and whites of the eyes;
- discolouration of skin, hair, beard and nails;
- **ENKOBIST 200** taken with levodopa may rarely make you feel very drowsy during the day, and cause you to suddenly fall asleep;
- Neuroleptic Malignant Syndrome (NMS) is a rare severe reaction to medicines used to treat disorders of the nervous system. It is characterised by stiffness, muscle twitching, shaking, agitation and confusion, coma, high body temperature, increased heart rate, and unstable blood pressure;
- a rare severe muscle disorder (rhabdomyolysis) which causes pain, tenderness and weakness of the muscles and may lead to kidney problems;
- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
  - Strong impulse to gamble excessively despite serious personal or family consequences.
  - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example an increased sexual drive.
  - Uncontrollable excessive shopping or spending
  - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)

Tell your doctor if you experience any of these behaviours; they will discuss ways of managing or reducing the symptoms.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Not all the side effects reported for **ENKOBIST 200** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking **ENKOBIST 200**, please consult your healthcare provider for advice.

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 "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. By reporting side effects, you can help provide more information on the safety of **ENKOBIST 200.**

5. How to store ENKOBIST 200

Store at or below 25 °C (room temperature). Protect from light.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What ENKOBIST 200 contains
The active ingredient is entacapone.
The other ingredients are:
Contains microcrystalline cellulose, corn starch, croscarmellose sodium, povidone, magnesium stearate and film coating containining hypromellose, titanium dioxide (CI 77891), propylene glycol, talc, red iron oxide (CI 77491) and yellow iron oxide (CI 77492).

What ENKOBIST 200 looks like and contents of the pack
ENKOBIST 200: Brown coloured, oval shaped, biconvex, film coated tablets debossed with "L 7" on one side and plain surface on the other side.

Round, white HDPE container with screw neck with white polypropylene closure with pulp and heat seal liner.
Pack size 100 tablets

Holder of Certificate of Registration and Manufacturer
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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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.

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PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

ENKOBIST 200 mg (Filmbedekte Tablet)
Entakapoon 200 mg
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy ENKOBIST 200 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
- **ENKOBIST 200** 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 inligtingstuk

1. Wat **ENKOBIST 200** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **ENKOBIST 200** neem
3. Hoe om **ENKOBIST 200** te neem
4. Moontlike newe-effekte
5. Hoe om **ENKOBIST 200** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat ENKOBIST 200 is en waarvoor dit gebruik word

ENKOBIST 200 is 'n medisyne wat entakapoon bevat en word saam met levodopa gebruik om Parkinson se siekte te behandel. **ENKOBIST 200** help levodopa om die simptome van Parkinson se siekte te verlig.
ENKOBIST 200 het geen effek op die verligting van die simptome van Parkinson se siekte, tensy dit saam met levodopa geneem word nie.

2. Wat jy behoort te weet voordat jy ENKOBIST 200 neem

Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.
Moet nie ENKOBIST 200 neem nie:
- indien jy allergies is vir entakapoon of enige van die ander bestanddele van hierdie medisyne (gelys in **Afdeling 6**);
- indien jy 'n gewas van die bynier het (bekend as feochromositoom; dit kan die risiko van ernstige hoë bloeddruk verhoog);
- indien jy sekere antidepressante gebruik (vra vir jou dokter of apteker of jou antidepressiewe medisyne saam met **ENKOBIST 200** geneem kan word of nie);
- indien jy lewersiekte het;
- indien jy al ooit aan 'n seldsame reaksie op antipsigotiese medisyne, naamlik neuroleptiese maligne sindroom (NMS), gely het. Sien **afdeling 4 Moontlike newe-effekte**, vir die kenmerke van NMS;
- indien jy al ooit aan 'n seldsame spier versteuring, naamlik rabdomiolise gely het, wat nie deur besering veroorsaak is nie.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **ENKOBIST 200** neem, indien die volgende op jou van toepassing is:
- indien jy al ooit 'n hartaanval of enige ander hartsiektes gehad het
- indien jy 'n middel neem wat duiseligheid of lighoofdigheid (lae bloeddruk) kan veroorsaak wanneer jy uit 'n stoel of bed opstaan;
- indien jy aanhoudende diaree ervaar, raadpleeg jou dokter, aangesien dit 'n teken van ontsteking van die kolon kan wees;
- indien jy diaree ervaar, word monitering van jou gewig aanbeveel om sodoende potensieel oormatige gewigsverlies te vermy;
- indien jy toenemende verlies aan eetlus, swakheid, uitputting en gewigsverlies binne 'n relatief kort tydperk ervaar, moet 'n algemene mediese evaluering, insluitend lewerfunksie, oorweeg word.
- Vertel jou dokter indien jy of jou gesin/versorger agterkom dat jy drange of lus ontwikkel om op maniere op te tree wat vir jou ongewoon is, en jy nie die impuls, dryfkrag of versoeking kan weerstaan om sekere aktiwiteite uit te voer wat skadelik vir jouself of ander kan wees nie. Dit word impulsbeheer versteurings genoem, en kan gedrag insluit soos verslawende dobbelary, oormatige eet of besteding, 'n abnormale hoë seksdrang of 'n toename in seksuele gedagtes of gevoelens. Jou dokter sal moontlik jou dosis moet aanpas of staak.
- Aangesien **ENKOBIST 200** tablette saam met ander levodopa medisyne geneem sal word, lees asseblief ook die inligtingstuk van hierdie medisyne sorgvuldig deur.
- Die dosering van ander medisyne om Parkinson se siekte te behandel kan moontlik aangepas word wanneer jy **ENKOBIST 200** begin neem. Volg die instruksies wat jou dokter vir jou gegee het.
- Neuroleptiese maligne sindroom (NMS) is 'n ernstige maar seldsame reaksie op sekere medisyne, en kan veral voorkom wanneer **ENKOBIST 200** en ander medisyne om Parkinson se siekte te behandel, skielik gestaak word of die dosis skielik verminder word. Vir die kenmerke van NMS sien **Afdeling 4 Moontlike newe-effekte**. Jou dokter kan jou aanraai om stadig die behandeling met **ENKOBIST 200** en ander medisyne vir die behandeling van Parkinson se siekte, te staak.
- **ENKOBIST 200** wat saam met levodopa geneem word, kan lomerigheid veroorsaak en kan veroorsaak dat jy soms skielik aan die slaap raak. Indien dit gebeur, moet jy nie bestuur of enige gereedskap of masjiene gebruik nie (sien **Bestuur en gebruik van masjienerie**).
- Jy het 'n hartsiekte.

Gebruik in kinders en adolessente
Die veiligheid en doeltreffendheid in kinders en adolessente (jonger as 18 jarige ouderdom) is nie vasgestel nie en daarom moet entakapoon nie in hierdie ouderdomsgroep gebruik word nie.
Ander medisyne en ENKOBIST 200
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Stel veral jou dokter in kennis indien jy enige van die volgende medisyne gebruik:
- rimiterool, isoprenalien, adrenalien, noradrenalien, dopamien, dobutamien, alfa-metieldopa, apomorfien;
- antidepressante insluitend desipramien, maprotilien, venlafaksien, paroksetien;
- warfarien, wat gebruik word om die bloed te verdun;
- ysteraanvullings. **ENKOBIST 200** kan dit vir jou moeiliker maak om yster te verteer. Moet dus nie **ENKOBIST 200** en ysteraanvullings gelyktydig neem nie. Nadat jy een van hulle geneem het, wag ten minste 2 tot 3 ure voordat jy die ander neem.

ENKOBIST 200 met voedsel en vloeistof
ENKOBIST 200 kan met of sonder kos geneem word.

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 **ENKOBIST 200** neem.
Moet nie **ENKOBIST 200** neem indien jy swanger is nie. Stel onmiddellik jou dokter in kennis indien jy swanger is of van plan is om swanger te raak.
Moet nie borsvoed as jy **ENKOBIST 200** neem nie.

Bestuur en gebruik van masjinerie
ENKOBIST 200 geneem saam met levodopa kan jou bloeddruk verlaag, wat jou lighoofdig of duiselig kan laat voel. Wees veral versigtig wanneer jy bestuur of wanneer jy gereedskap of masjinerie gebruik.
Daarbenewens kan **ENKOBIST 200** wat saam met levodopa geneem word, jou baie lomerig laat voel of soms veroorsaak dat jy skielik aan die slaap raak.
Moet nie bestuur of masjinerie beheer indien jy hierdie newe-effekte ervaar nie.

3. Hoe om ENKOBIST 200 te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **ENKOBIST 200** presies soos jou dokter jou beveel het. Jy moet met jou dokter of apteker bevestig, indien jy nie seker is nie.
ENKOBIST 200 word saam met medisyne wat levodopa bevat (óf levodopa/karbidopa preparate óf levodopa/benserasied preparate) geneem. Jy kan ook terselfdertyd ander medisyne gebruik om Parkinson se siekte te behandel.
Die aanbevole dosis van **ENKOBIST 200** is een 200 mg tablet met elke levodopa dosis.
Die maksimum aanbevole dosis is 10 tablette per dag, dit wil sê 2 000 mg van **ENKOBIST 200.**
Indien jy dialise vir renale ontoereikendheid ontvang, kan jou dokter jou beveel om die tyd tussen dosisse te verleng.
Indien jy onder die indruk is dat die effek van **ENKOBIST 200** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ENKOBIST 200 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.

Indien jy vergeet om ENKOBIST 200 te neem
Dit is belangrik om jou **ENKOBIST 200** tablette gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis.
Moet nie twee dosisse op dieselfde tyd neem, om vir 'n vergete dosis op te maak nie

Indien jy ophou om ENKOBIST 200 te neem
Indien **ENKOBIST 200** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **ENKOBIST 200** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

ENKOBIST 200 kan newe-effekte hê.
Sommige van die newe-effekte word dikwels veroorsaak deur die verhoogde effekte van levodopa behandeling en is die mees algemeenste met die aanvang van behandeling. Indien jy sulke effekte ervaar met die aanvang van behandeling met **ENKOBIST 200**, moet jy jou dokter kontak wat moontlik kan besluit om jou levodopa se dosering aan te pas.

Gereelde newe-effekte:
- onbeheerbare bewegings en sukkel om vrywillige bewegings uit te voer (diskinesie);
- hoofpyn;
- bewing;
- oormatige bewegings (hiperkinesie), verergering van simptome van Parkinson se siekte,
- beweeg of draai sensasie (vertigo);
- langdurige spierkrampe (distonie);
- duiseligheid;
- voel siek (naarheid);
- siek wees (braking), diaree, abdominale pyn, hardlywigheid, droë mond;
- onskadelike rooibruin verkleuring van uriene;
- moegheid, verhoogde sweet, val;
- beenkrampe;
- hallusinasies (sien/hoor/voel/ruik dinge wat nie regtig daar is nie);
- slapeloosheid, intense drome en verwarring;
- hart- of slagaarsiekte gebeure (bv. borskaspyn);

Minder gereelde newe-effekte
- hartaanval;
- uitslag;
- galbulte;
- abnormale resultate in lewerfunksietoets;
- rusteloosheid;
- verminderde eetlus, gewigsverlies

Newe-effekte met onbekende frekwensie:
- ontsteking van die kolon (kolitis);
- ontsteking van die lewer (hepatitis) met vergeling van die vel en wit van die oë;
- verkleuring van vel, hare, baard en naels;
- **ENKOBIST 200** wat saam met levodopa geneem word, kan jou selde gedurende die dag baie lomerig laat voel en veroorsaak dat jy skielik aan die slaap raak;
- neuroleptiese maligne sindroom (NMS) is 'n seldsame ernstige reaksie op medisyne wat gebruik word om versteurings van die senuweestelsel te behandel. Dit word gekenmerk deur styfheid, spiertrekkings, bewing, rusteloosheid en verwarring, koma, hoë liggaamstemperatuur, verhoogde harttempo en onstabiele bloeddruk;
- 'n seldsame ernstige spierafwyking (rabdomiolise) wat pyn, teerheid en swakheid van die spiere veroorsaak en kan lei tot nierprobleme;
- onvermoë om die impuls, dryfkrag of versoeking te weerstaan om 'n aktiwiteit uit te voer wat skadelik vir jouself of ander kan wees, wat kan insluit:
  - sterk impuls om buitensporig te dobbel ten spyte van ernstige persoonlike- of gesinsgevolge.
  - veranderde of verhoogde seksuele belangstelling en gedrag wat vir jou of ander van beduidende kommer is, byvoorbeeld 'n verhoogde seksuele drang.
  - onbeheerbare oormatige koop of besteding
  - oormatige eet (eet groot hoeveelhede kos in 'n kort tydperk) of kompulsiewe eet (eet meer kos as normaal en meer as wat nodig is om jou honger te stil)

Vertel jou dokter indien jy enige van hierdie gedrag ervaar; hulle sal maniere bespreek om die simptome te bestuur of te verminder.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.
Nie al die newe-effekte wat vir **ENKOBIST 200** aangemeld is, is in hierdie inligtingstuk ingesluit nie.
Indien jou algemene gesondheid versleg of indien jy enige nadelige effekte ervaar terwyl jy **ENKOBIST 200** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk genoem is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van 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.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **ENKOBIST 200**.

5. Hoe om ENKOBIST 200 te bewaar

Bewaar by of benede 25°C (kamertemperatuur).Beskerm teen lig.
BEWAAR BUITE DIE BEREIK VAN KINDERS.
Stoor in die oorspronklike verpakking/houer.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel 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 pak en ander inligting

Wat ENKOBIST 200 bevat
Die aktiewe bestanddeel is entakapoon.
Die ander bestanddele is :
Bevat mikrokristallyne sellulose, mieliestysel, natriumkruiskarmellose, povidoon, magnesiumstearaat en filmbedekking wat hipromellose, titaandioksied (CI 77891), propileenglikol, talk, rooi ysteroksied (CI 77491) en geel ysteroksied (CI 77492) bevat.

Hoe ENKOBIST 200 lyk en inhoud van die pak
ENKOBIST 200: Bruinkleurige, ovaalvormige, bikonvekse, filmbedekte tablette gemerk met "L 7" aan die een kant en gewone oppervlak aan die ander kant.
Ronde, wit HDPE houer met skroefnek met wit polipropileen sluiting met pulp en hitte-seëlvoering.
Verpakkingsgrootte: 100 tablette

Houer van die Sertifikaat van Registrasie en Vervaardiger
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
19 April 2022

Registrasienommer
49/5.4.1/1067

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

Note : Exclusion of PI from text matter as per commercial requirement and change in dimensions.

1. Product: ENKOBIST 200(Entacapone Tablets 200 mg)	
2. Country: South Africa (Private Market)	**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 260 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04341973**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 41023 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03914501**
15. Revision no: 01	**16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Entacapone\SA Private market\02\Entacapone Tablets 200 PIL -PM04341973.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	04/03/2026 				

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.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03914501	30/08/22	27/10/2022
2) Exclusion of PI from text matter as per commercial requirement and change in dimensions.	PM04341973		