SCHEDULING STATUS S0

1. NAME OF THE MEDICINE
ANLAC SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 ml contains 3,3 g lactulose

3. PHARMACEUTICAL FORM
Syrup.
A clear, viscous liquid, colourless or pale brownish yellow. It may be a supersaturated solution or may contain crystals which disappear on heating.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
For the treatment of constipation.
For the treatment of hepatic encephalopathy (hepatic coma).

4.2 Posology and method of administration
Constipation:
Adults:
Starting dose: 30 ml (6 x 5 ml medicine measures)
Maintenance dose: 15 – 30 ml (3 - 6 x 5 ml medicine measures)
Children (6 – 14 years):
Starting dose: 15 ml (3 x 5 ml medicine measures)
Maintenance dose: 10 – 15 ml (2 - 3 x 5 ml medicine measures)
Children (1 – 5 years):
Starting dose: 10 ml (2 x 5 ml medicine measures)
Maintenance dose: 5 – 10 ml (1 - 2 x 5 ml medicine measures)
Children (<1 year):
Starting dose: 5 ml (1 x 5 ml medicine measures)
Maintenance dose: 2,5 – 5 ml (0,5 - 1 x 5 ml medicine measure)

Portal systemic encephalopathy:
The initial dose of 30 – 50 ml, 3 times daily; subsequently adjusted to produce 2 – 3 soft stools each day.

4.3 Contraindications
- Patients with cramps, colic, nausea, vomiting, intestinal obstruction or any undiagnosed abdominal conditions.
- Galactosaemia, including patients on galactose-free diets.
- Undiagnosed rectal bleeding.
- Hypersensitivity to ANLAC SYRUP and any of the other ingredients.

4.4 Special warnings and precautions for use
Special warnings
ANLAC SYRUP should be use with caution in patients with lactulose intolerance. Because of the physiological mode of action of ANLAC SYRUP, it may take up to 48 hours before effects are obtained. In addition, there is a carry-over effect which may enable the patient to reduce the effective dose gradually over a period of time.
As ANLAC SYRUP is not absorbed to any significant degree, it may be to diabetics. It should however be noted that ANLAC SYRUP contains small amount of lactose and galactose.
ANLAC SYRUP should be given with care to children up to 6 years of age after consultation with a medical practitioner. Children are not able to describe their symptoms precisely. Proper diagnosis should precede the use of a laxative. This will avoid the complication of an existing condition (e.g. appendicitis) or the appearance of more severe side effects. Chronic use or overuse of ANLAC SYRUP may reduce serum potassium concentrations by promoting excessive potassium loss from the intestinal tract and may interfere with potassium-retaining effects of potassium-sparing diuretics.

Precautions for use
ANLAC SYRUP should not be given to patients with intestinal obstruction. ANLAC SYRUP should not be used by patients on low-galactose diet. Care should be taken in patients with lactose intolerance or in diabetes because of the presence of some free galactose and lactose. Hypernatraemia has also been reported.

4.5 Interaction with other medicines and other forms of interaction
Overuse of ANLAC SYRUP may interfere with potassium-retaining effects of potassium-sparing diuretics.

4.6 Fertility, pregnancy and lactation
Reports on the clinical experience of lactulose and data from animal reproduction studies have not revealed any increase in embryotoxic hazard to the foetus if the recommended dose is used during pregnancy.

4.7 Effects of ability to drive and use machines
Not applicable

4.8 Undesirable effects
Cases of mild abdominal distention, cramps, flatulence, diarrhoea, nausea, and vomiting have been reported following use of ANLAC SYRUP.

4.9 Overdose
Symptoms of overdosage included diarrhoea. There is no specific antidote; treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category A, 8.5.2 Laxatives and Purgatives.
Lactulose is a synthetic disaccharide osmotic laxative. Lactulose is broken down by colonic bacteria mainly into lactic acid which exerts a local osmotic effect in the colon resulting in increased faecal bulk and stimulation of peristalsis. When larger doses are given for hepatic encephalopathy the pH in the colon is reduced significantly by this acid production and absorption of ammonium ions and other toxic nitrogenous compounds is decreased leading to a drop in blood-ammonia concentration.

5.2 Pharmacokinetic properties
Following oral administration, a negligible amount of lactulose is absorbed in the gastro-intestinal tract. It passes essentially unchanged into the large intestine where it is metabolised by saccharolytic bacteria, forming simple organic acids such as lactic and acetic acid. Urinary excretion has been reported to be 3 % or less.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at or below 25 °C.
Do not refrigerate or freeze.
Keep out of reach of children.

6.5 Nature and contents of container
Amber glass bottles containing 150 ml and 500 ml.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal <and other handling>
No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION
BGM Pharmaceuticals (Pty) Ltd
Unit 19, 20, 25 & 26
Bergzicht Office Park,
5 Rooibok street,
Allen's Nek, 1724

8. REGISTRATION NUMBER(S)
41/11.5/0764

9. DATE OF FIRST AUTHORISATION
04 March 2011

10. DATE OF REVISION OF THE TEXT
04 September 2020

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SCHEDULING STATUS S0

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM:
ANLAC SYRUP
Each 5 ml contains 3,3 g lactulose

Read all of this leaflet carefully because it contains important information for you
ANLAC SYRUP is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ANLAC SYRUP carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share ANLAC SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet
1. What ANLAC SYRUP is and what it is used for
Category A, 8.5.2 Laxatives and Purgatives.
ANLAC SYRUP can help your bowels to move and pass a stool if you are constipated. ANLAC SYRUP does not enter the bloodstream but acts by drawing water into the bowel by osmosis and so softening the stool or motion. In this way, ANLAC SYRUP can encourage a normal bowel motion.
ANLAC SYRUP is also used to treat hepatic encephalopathy. This is an uncommon condition which sometimes occur in patients with severe liver disease. Lactulose is broken down by the normal bacteria in the bowel to form lactic acid which prevents the formation and absorption of ammonia from the bowel into the blood stream. In this way lactulose helps to treat hepatic encephalopathy.

2. What you need to know before you take ANLAC SYRUP
Do not use ANLAC SYRUP
- If you are hypersensitive (allergic) to lactulose or any of the other ingredients of ANLAC SYRUP.
- If you are unable to metabolise galactose and/or are on a galactose-free diet.
- If you suffer from bleeding from your rectum which your doctor has not diagnosed yet.
- If you suffer from cramps, nausea, vomiting; pains in your stomach which starts and stops suddenly; have an obstruction in your intestines; or if you have an abdominal condition which your doctor has not diagnosed yet.

You must tell your doctor or pharmacist before taking ANLAC SYRUP if:
- You are allergic to lactulose or galactose or any sugars.
- You have taken ANLAC SYRUP before and have suffered an unpleasant allergic reaction.
- You are suffering from a blockage in your intestine.

Warnings and precautions:
The effect of ANLAC SYRUP may not be seen for up to 48 hours; therefore, it is important to continue taking your medicine regularly.

Remember, this medicine was prescribed by your doctor for you, do not give it to others, it may harm them.

Other medicines and ANLAC SYRUP
Always tell your health care provider if you are taking any other medicine.

Pregnancy and breastfeeding:
Tell your doctor or pharmacist if you are pregnant or breastfeeding.

3. How to take ANLAC SYRUP
Do not share medicines prescribed for you with any other person.
Always take ANLAC SYRUP exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is
Adults:
Starting dose: 30 ml (6 x 5 ml medicine measures)
Maintenance dose: 15 – 30 ml (3 - 6 x 5 ml medicine measures)
Children (6 – 14 years):
Starting dose: 15 ml (3 x 5 ml medicine measures)
Maintenance dose: 10 – 15 ml (2 - 3 x 5 ml medicine measures)
Children (1 – 5 years):
Starting dose: 10 ml (2 x 5 ml medicine measures)
Maintenance dose: 5 – 10 ml (1 - 2 x 5 ml medicine measures)
Children (<1 year):
Starting dose: 5 ml (1 x 5 ml medicine measures)
Maintenance dose: 2,5 – 5 ml (0,5 - 1 x 5 ml medicine measure)

If you take more ANLAC SYRUP 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 ANLAC SYRUP
If you forget to take a dose of ANLAC SYRUP take it as soon as you remember. If it is almost time for your next dose though, do not double the dose just carry on as before.

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

Cases of mild abdominal distention, cramps, flatulence, diarrhoea, nausea and vomiting have been reported following use of ANLAC SYRUP.
If you are taking large doses of ANLAC SYRUP to treat hepatic encephalopathy you may also suffer from nausea, vomiting and abdominal pain. If this is the case, tell your doctor as he/she can adjust your dose to obtain just two or three soft stools a day.

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 ANLAC SYRUP.

5. How to store ANLAC SYRUP
- Store at or below 25 °C.
- Do not refrigerate or freeze.
- Keep out of reach of children.
- Protect from light / moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the 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 the pack and other information
What ANLAC SYRUP contains
The active substance is lactulose.
The other ingredient is water.

What ANLAC SYRUP looks like and contents of the pack
A clear, viscous liquid, colourless or pale brownish yellow. It may be a supersaturated solution or may contain crystals which disappear on heating.

Amber glass bottles containing 150 ml and 500 ml.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
BGM Pharmaceuticals (Pty) Ltd
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Allen's Nek, 1724

This leaflet was last revised on
04 September 2020

Registration number
41/11.5/0764

SKEDULERINGSTATUS S0

1. NAAM VAN MEDISYNE
ANLAC SYRUP

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
Elke 5 ml bevat laktulose 3,3 g

3. FARMASEUTIESE VORM
Stroop.
'n Helder dikvloeiende vloeistof, kleurloos of ligte bruinerige geel. Dit kan 'n superversadigde oplossing wees of kan kristalle bevat wat na verhitting verdwyn.

4. KLINIESE BESONDERHEDE
4.1 Terapeutiese indikasies
Vir die behandeling van hardlywigheid.
Vir die behandeling van hepatiese ensefalopatie (hepatiese koma).

4.2 Posologie en metode van toediening
Hardlywigheid:
Volwassenes:
Aanvangsdosis: 30 ml (6 x 5 ml medisynemaat)
Instandhoudingsdosis: 15 – 30 ml (3 - 6 x 5 ml medisynemaat)
Kinders (6 – 14 jaar):
Aanvangsdosis: 15 ml (3 x 5 ml medisynemaat)
Instandhoudingsdosis: 10 – 15 ml (2 - 3 x 5 ml medisynemaat)
Kinders (1 – 5 jaar):
Aanvangsdosis: 10 ml (2 x 5 ml medisynemaat)
Instandhoudingsdosis: 5 – 10 ml (1 - 2 x 5 ml medisynemaat)
Kinders (<1 jaar):
Aanvangsdosis: 5 ml (1 x 5 ml medisynemaat)
Instandhoudingsdosis: 2,5 – 5 ml (0,5 - 1 x 5 ml medisynemaat)

Portale sistemiese ensefalopatie:
Die aanvanklike dosis van 30 – 50 ml, 3 maal daagliks; daarna aangepas om 2 – 3 sagte stoelgange elke dag te produseer.

4.3 Kontra-indikasies
- Pasiënte met krampe, koliek, naarheid, braking, intestinale obstruksie of enige ongediagnoseerde abdominale toestande.
- Galaktosemie, insluitend pasiënte op 'n galaktosevrye dieet.
- Ongediagnoseerde rektale bloeding.
- Hipersensitiwiteit vir ANLAC SYRUP en enige van die ander bestanddele.

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik
Spesiale waarskuwings
ANLAC SYRUP moet met waaksaamheid gebruik word in pasiënte met laktulose-intoleransie. Weens die fisiologiese werkingsmetode van ANLAC SYRUP, kan dit tot 48 uur neem voordat uitwerking bewerkstellig word. Verder is daar 'n omrol-effek wat die pasiënt in staat kan stel om die doeltreffende dosis mettertyd geleidelik te verminder.
Indien ANLAC SYRUP nie tot 'n noemenswaardige mate geabsorbeer word nie, kan dit as gevolg van diabetes wees. Daar moet egter opgelet word dat ANLAC SYRUP 'n klein hoeveelheid laktose en galaktose bevat.
ANLAC SYRUP moet met sorgsaamheid aan kinders tot 6 jaar oud toegedien word, na konsultasie met 'n mediese praktisyn. Kinders is nie in staat om hulle simptome presies te beskryf nie. Behoorlike diagnose moet die gebruik van 'n lakseermiddel voorafgaan. Dit sal die komplikasie van 'n bestaande toestand (bv. blindederm-ontsteking) of die verskyning van erger newe-effekte vermy. Chroniese gebruik of teveel gebruik van ANLAC SYRUP kan kaliumkonsentrasies in die serum verminder, deur uitermatige kaliumverlies van die intestinale weg te verhoog, en mag met die kalium-behoudende effekte van kalium-besparende diuretikas inmeng.

Voorsorgmaatreëls vir gebruik
ANLAC SYRUP moet nie vir pasiënte met intestinale obstruksie gegee word nie. ANLAC SYRUP moet ook nie gebruik word deur pasiënte op 'n lae-galaktosedieet nie. Sorg moet gedra word in pasiënte met laktose-intoleransie of diabetes, weens die aanwesigheid van 'n mate van vrye galaktose en laktose. Hipernatremie is ook al aangemeld.

4.5 Interaksie met ander medisynes en ander vorms van interaksie
Teveel gebruik van ANLAC SYRUP kan inmeng met die kalium-behoudende effekte van kalium-besparende diuretikas.

4.6 Vrugbaarheid, swangerskap en borsvoeding
Aanmeldings van die kliniese ervaring van laktulose en data afkomstig van diere-voortplantingstudies het nie gedui op enige verhoging in embriotoksiese gevaar waar die aanbevole dosis tydens dragtigheid gebruik word nie.

4.7 Uitwerking op vermoë om motor bestuur en masjinerie gebruik
Nie van toepassing nie.

4.8 Ongewenste effekte
Gevalle van ligte abdominale opgeblasenheid, krampe, winderigheid, diarree, naarheid en braking is al ná gebruik van ANLAC SYRUP aangemeld.

4.9 Oordosering
Simptome van oordosering het diarree ingesluit. Daar is geen spesifieke teenmiddel nie; behandeling is simptomaties en ondersteunend.

5. FARMAKOLOGIESE EIENSKAPPE
5.1 Farmakodinamiese eienskappe
Kategorie A, 8.5.2 Lakseermiddels en purgeermiddels
Laktulose is 'n sintetiese disaccharied-osmotiese lakseermiddel. Laktulose word afgebreek deur bakterieë in die kolon, hoofsaaklik in melksuur, wat 'n plaaslike osmotiese effek in die kolon uitoefen, met 'n gevolglike verhoging in fekale massa en stimulasie van peristalse. Waar groter dosisse vir hepatiese ensefalopatie toegedien word, word die pH in die kolon aansienlik verminder deur hierdie suurproduksie en word absorpsie van ammonia-ione en ander toksiese nitrogeen-samestellings verminder, wat aanleiding gee tot 'n daling in die konsentrasie van ammonia in die bloed.

5.2 Farmakokinetiese eienskappe
Na orale toediening word 'n nietige hoeveelheid laktulose in die gastroïntestinale weg geabsorbeer. Dit beweeg in wese onveranderd in die dikderm, waar dit deur saccharolitiese bakterieë gemetaboliseer word en eenvoudige organiese sure vorm, soos melksuur en asynsuur. Urinêre uitskeiding is aangemeld as 3 % of minder.

6. FARMASEUTIESE BESONDERHEDE
6.1 Lys van mengmiddels
Water

6.2 Onverenigbaarhede
Nie van toepassing nie.

6.3 Raklewe
24 maande

6.4 Spesiale voorsorgmaatreëls vir bewaring
Bêre by of benede 25 °C.
Moenie verkoel of bevries nie.
Hou buite die bereik van kinders.

6.5 Aard en inhoud van houer
Amberkleurige glas bottels wat 150 ml en 500 ml bevat.
Alle pakgroottes word nie noodwendig bemark nie.

6.6 Spesiale voorsorgmaatreëls vir wegdoening <en ander hantering>
Geen spesiale vereistes nie.

7. HOUER VAN REGISTRASIESERTIFIKAAT
BGM Pharmaceuticals (Edms.) Bpk.
Eenheid 19, 20, 25 & 26
Bergzicht Office Park,
Rooibokstraat 5,
Allen's Nek, 1724

8. REGISTRASIENOMMER(S)
41/11.5/0764

9. DATUM VAN EERSTE MAGTIGING
04 Maart 2011

10. DATUM VAN TEKSHERSIENING
04 September 2020

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SKEDULERINGSTATUS S0

PRODUKNAAM, STERKTE EN FARMASEUTIESE VORM:
ANLAC SYRUP
Elke 5 ml bevat laktulose 3,3 g

Lees hierdie hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou.
ANLAC SYRUP (stroop) is sonder 'n dokter se voorskrif beskikbaar vir jou om 'n ligte siekte te behandel. Nietemin moet jy steeds ANLAC SYRUP versigtig gebruik om die beste resultate daarvan te kry.
- Bêre hierdie pamflet. Dit mag vir jou nodig wees om dit weer deur te lees.
- Moenie ANLAC SYRUP met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy verdere inligting of advies nodig het.
- As jou simptome erger word of nie verbeter nie, moet jy 'n dokter spreek.

Wat bevat hierdie pamflet
1. Waarvoor ANLAC SYRUP is en waarvoor dit gebruik word
Kategorie A, 8.5.2 Lakseermiddels en purgeermiddels
ANLAC SYRUP kan jou help met ontlasting en opelyf as jy hardlywig is. ANLAC SYRUP gaan nie die bloedsomloop binne nie, maar werk deur water deur middel van osmose in die ingewande in te trek en sodoende die stoelgang of ontlasting te versag. Op hierdie manier kan ANLAC SYRUP 'n normale opelyf aanmoedig.
ANLAC SYRUP word ook gebruik om hepatiese ensefalopatie te behandel. Dit is 'n ongewone toestand wat partykeer in pasiënte met erge lewersiekte voorkom. Laktulose word deur die normale bakterieë in die ingewande afgebreek om melksuur te vorm, wat die vorming en absorpsie van ammonia vanuit die ingewande in die bloedstroom verhoed. Op hierdie manier help laktulose om hepatiese ensefalopatie te behandel.

2. Wat jy behoort te weet voordat jy ANLAC SYRUP neem
Moenie ANLAC SYRUP neem
- As jy hipersensitief (allergies) is vir laktulose of enige van die ander bestanddele van ANLAC SYRUP nie.
- As jy nie in staat is om galaktose te metaboliseer nie en/of op 'n galaktosevrye dieet is nie.
- As jy aan bloeding van jou rektum ly wat jou dokter nog nie gediagnoseer het nie.
- As jy aan krampe, naarheid, braking; pyne op die maag wat skielik begin en weer weggaan; of 'n obstruksie in jou ingewande het nie; of as jy 'n abdominale toestand het wat jou dokter nog nie gediagnoseer het nie.

Voordat jy ANLAC SYRUP neem, moet jy jou dokter of apteker vertel as:
- jy allergies is vir laktulose of galaktose of enige tipes suiker.
- jy voorheen ANLAC SYRUP geneem het en 'n onaangename allergiese reaksie opgedoen het.
- jy 'n blokkasie in jou ingewande het.

Waarskuwings en voorsorgmaatreëls:
Die uitwerking van ANLAC SYRUP kan dalk tot 48 uur vat om te voorskyn te tree, daarom is dit belangrik om jou medisyne aanhoudend gereeld te neem.

Onthou dat hierdie medisyne deur jou dokter vir jou voorgeskryf is. Moenie dit vir enige iemand anders gee nie; dit kan vir hulle skadelik wees.

Ander medisynes saam met ANLAC SYRUP
Vertel altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik.

Swangerskap en vorsvoeding:
Vertel jou dokter of apteker as jy swanger is of 'n baba borsvoed.

3. Hoe om ANLAC SYRUP te neem
Moenie medisynes wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem ANLAC SYRUP altyd presies soos in hierdie pamflet beskryf word of volgens jou dokter of apteker se opdrag. Praat met jou dokter of apteker as jy nie seker is nie.

Die gewone dosis is
Volwassenes:
Aanvangsdosis: 30 ml (6 x 5 ml medisynemaat)
Instandhoudingsdosis: 15 – 30 ml (3 - 6 x 5 ml medisynemaat)
Kinders (6 – 14 jaar):
Aanvangsdosis: 15 ml (3 x 5 ml medisynemaat)
Instandhoudingsdosis: 10 – 15 ml (2 - 3 x 5 ml medisynemaat)
Kinders (1 – 5 jaar):
Aanvangsdosis: 10 ml (2 x 5 ml medisynemaat)
Instandhoudingsdosis: 5 – 10 ml (1 - 2 x 5 ml medisynemaat)
Kinders (<1 jaar):
Aanvangsdosis: 5 ml (1 x 5 ml medisynemaat)
Instandhoudingsdosis: 2,5 – 5 ml (0,5 - 1 x 5 ml medisynemaat)

As jy meer ANLAC SYRUP neem as wat jy moes
In die geval van oordosering, raadpleeg jou dokter of apteker. As nie een van hulle beskikbaar is nie, kom in aanraking met die naaste hospitaal of gifbeheersentrum.

As jy vergeet om ANLAC SYRUP te neem
As jy vergeet om 'n dosis van ANLAC SYRUP te drink, neem dit so gou as wat jy onthou. As dit egter reeds amper tyd is vir jou volgende dosis, moenie 'n dubbele dosis neem nie. Gaan net soos voorheen voort.

4. Moontlike newe-effekte
ANLAC SYRUP kan newe-effekte hê.
Nie alle newe-effekte wat al vir ANLAC SYRUP aangemeld is, word by hierdie pamflet ingesluit nie. As jou algemene gesondheid sou agteruitgaan of as jy enige ongewenste effekte ervaar terwyl jy ANLAC SYRUP neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Gevalle van ligte abdominale opgeblasenheid, krampe, winderigheid, diarree, naarheid en braking is al na gebruik van ANLAC SYRUP aangemeld.
As jy groot dosisse van ANLAC SYRUP neem om hepatiese ensefalopatie te behandel, kan jy ook dalk aan naarheid, braking en buikpyn ly. As dit die geval is, vertel jou dokter aangesien hy/sy jou dosis kan aanpas om net twee of drie sagte stoelgange per dag te bewerkstellig.

As jy enige newe-effekte opmerk wat nie in hierdie pamflet aangedui word nie, vertel asseblief vir jou dokter of apteker.

Aanmelding van newe-effekte
As jy newe-effekte opdoen, gesels met jou dokter of apteker. Jy kan ook newe-effekte by SAROG aanmeld d.m.v. die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn verskyn onder SAROG se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur rapportering van newe-effekte kan jy help om meer inligting oor die veiligheid van ANLAC SYRUP te voorsien.

5. Hoe om ANLAC SYRUP te bewaar
- Bêre by of benede 25 °C.
- Moenie verkoel of bevries nie.
- Hou buite die bereik van kinders.
- Beskerm teen lig / vogtigheid.
- Moenie in 'n badkamer hou nie.
- Moenie na die vervaldatum op die etiket / kartondosie / bottel gebruik nie.
- Besorg alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Inhoud van ANLAC SYRUP
Die aktiewe middel is laktulose.
Die ander bestanddeel is water

Hoe ANLAC SYRUP lyk en inhoud van die pakkie
'n Helder dikvloeiende vloeistof, kleurloos of ligte bruinerige geel. Dit kan 'n superversadigde oplossing wees of kan kristalle bevat wat na verhitting verdwyn.

Amberkleurige glas bottels wat 150 ml en 500 ml bevat.
Alle pakgroottes word nie noodwendig bemark nie.

Houer van Registrasiesertifikaat
BGM Pharmaceuticals (Edms.) Bpk.
Eenheid 19, 20, 25 & 26
Bergzicht Office Park,
Rooibokstraat 5,
Allen's Nek, 1724

Hierdie pamflet is laas hersien op
04 September 2020

Registrasienommer
41/11.5/0764

PRO-PRINT (PTY) LTD
THE PROFESSIONALS IN PRINT

REPRO

Date:	2nd November 2020
Operator:	Aaron Sudree
Customer:	BGM Pharmaceuticals
Product Name:	Anlac Syrup 150ml Pl/PIL
Product Code:	--
Dimensions:	100 mm x 650 mm
Fold Size:	100 mm x 28 mm
Colours: (1)	Black
	--
	--
Barcode:	--
Pharmacode:	(Ref.50) 01100
Stock:	--
Proof Status:	1st (First)

Proof read by: _____

Reset: ☐ **Alterations:** ☐ **Disk/Possie:** ☑

No alterations – proceed as soon as possible ☐

Note alterations – Further proof is required ☐

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature: .....**Date:** .....

PROOF NOT READ – NO COPY SUPPLIED ☐