SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

HUMULIN 30/70, biosynthetic human insulin (recombinant DNA origin), 100 I.U./ml, suspension for injection.

Read all of this leaflet carefully before you start taking HUMULIN 30/70.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- HUMULIN 30/70 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 HUMULIN 30/70 CONTAINS

- The active substance is biosynthetic human insulin (recombinant DNA origin) 100 I.U./ml.
- The other ingredients are dibasic sodium phosphate (crystals), glycerin, hydrochloric acid (solution, 10 %) and/or sodium hydroxide (solution, 10 %), protamine sulphate, water for injection, zinc oxide.
- The preservatives included are m-cresol 0,16 % m/v and phenol 0,06 m/v.

WHAT HUMULIN 30/70 IS USED FOR

- Humulin 30/70 is a premixed suspension of rapid and long acting insulin.
- HUMULIN 30/70, is used to treat diabetes mellitus. You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood (blood sugar).

BEFORE YOU USE HUMULIN 30/70

Do not use HUMULIN 30/70:

- If you are hypersensitive (allergic) to biosynthetic human insulin (recombinant DNA origin) or any of the other ingredients of HUMULIN 30/70, listed in this leaflet.
- If you are experiencing hypoglycaemia (low blood sugar).
- You should never administer HUMULIN 30/70 intravenously (into your vein).

Take special care with HUMULIN 30/70:

- Any change of insulin should be made cautiously and only under medical supervision.
- If you change insulin from an animal-source insulin to HUMULIN 30/70 the early warning symptoms of hypoglycaemia (low blood sugar) are less obvious or different.
- You may use more insulin during illness or emotional disturbances, or if you are taking other medicines at the same time that have a hyperglycaemic (high blood sugar) activity, e.g. oral contraceptives, corticosteroids such as prednisone or thyroid replacement therapy.
- You may use less insulin if you have kidney or liver disorders, or if you are taking other medicines at the same time that have a hypoglycaemic (low blood sugar) activity, e.g. monoamine oxidase and beta adrenergic blockers.
- Beta-blockers (such as atenolol and propanolol) therapy may mask the symptoms of insulin related hypoglycaemia (low blood sugar). A diabetic person might not realise that he/she has low blood sugar.
- If you exercise more or change your usual diet, please consult your doctor as your insulin dosage might require adjustment.
- If you are taking thiazolidinediones such as pioglitazone together with HUMULIN 30/70 it may increase the risk of oedema (e.g. swelling in arms, ankles; fluid retention) and heart failure, especially in patients with existing heart disease.
- HUMULIN 30/70 suspensions should look uniformly cloudy or milky. If the insulin substance (the cloudy material) settles at the bottom of the cartridge in the pen injector, it must be rotated or carefully shaken before injection so that the contents are uniformly mixed. Do not use if a deposit of solid particles remains on the bottom or wall of the cartridge, giving it a frosted appearance, or if there are clumps floating in the insulin after the pen injector has been rotated or carefully shaken. Also, an insulin suspension should not be used if it is clear and remains clear after it is rotated or shaken.
- After you prepare your dose, you should administer it promptly to avoid clogging of the needle.
- Do not change your insulin unless your doctor tells you to. Be very careful if you do change your insulin. Each type of insulin has a different colour and symbol on the pack and pen so that you can easily tell the difference.

Taking HUMULIN 30/70 with food and drink:

- Carefully follow your doctor's instructions regarding food intake and the use of HUMULIN 30/70.

Pregnancy and breastfeeding:

Pregnancy: If you are considering pregnancy, you should seek medical advice and you should be monitored medically with particular regard to adjustment of insulin dosage throughout your pregnancy. Your blood glucose should be as normal as possible from the time of conception until delivery. Insulin requirements are usually less during the first trimester and more during the second and third trimesters.

Breastfeeding: If you are nursing, you may require adjustments in insulin and/or in your diet.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking HUMULIN 30/70.

Driving and using machinery:

- Your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). Please remember this in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery).

Taking other medicines with HUMULIN 30/70

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

- Your insulin requirements may be more when using other medicines at the same time that have hyperglycaemic (high blood sugar) activity, e.g. oral contraceptives, corticosteroids such as prednisone or thyroid replacement therapy.
- Your insulin requirements may be less in the presence of, agents such as oral antidiabetic agents, salicylates, sulpha antibiotics, and certain antidepressants (monoamine oxidase inhibitors), beta-adrenergic blockers, angiotensin converting enzyme inhibitors and angiotensin II receptor blockers.

- Beta-blockers (such as atenolol and propanolol) therapy may mask your symptoms of insulin-related hypoglycaemia (low blood sugar). A diabetic person might not realise that he/she has low blood sugar.
- Please consult your doctor when using other medication in addition to human insulin.

HOW TO USE HUMULIN 30/70

Do not share medicines prescribed for you with any other person. Always take HUMULIN 30/70 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with HUMULIN 30/70 will last. Do not stop treatment early. If you have the impression that the effect of HUMULIN 30/70 is too strong or too weak, tell your doctor or pharmacist.

- HUMULIN 30/70 is a ready-made mixture designed to avoid the need for mixing of insulins. Its action is prolonged by the inclusion of protamine sulfate in the suspension. It should normally be administered twice daily, usually with two-thirds of the daily requirement being given in the morning and the remainder in the evening.
- Your doctor may tell you to use Humulin 30/70 as well as a longer acting insulin.
- The dose of one injection should not exceed 50 I.U.
- HUMULIN 30/70 may be administered subcutaneously (under the skin) or intramuscularly (into the muscle) only.
- You should never administer HUMULIN 30/70 intravenously (into the vein).
- You should administer HUMULIN 30/70 subcutaneously (under the skin) in the upper arms, thighs, buttocks or abdomen.
- You should rotate the injection sites so that the same exact site is not used more than once a month.
- You should use proper injection techniques.
- Care should be taken to ensure that you have not injected into a blood vessel. The injection site should not be massaged.

Mixing of insulin:

- **Vials**: If you are mixing insulins, the short acting insulin HUMULIN R should be drawn into the syringe first to prevent contamination of the vial by the longer-acting preparation (i.e. HUMULIN N). You should inject immediately after mixing. Such mixtures should not be administered intravenously (into the vein).
- **Cartridges:** HUMULIN cartridges are not designed to allow any other insulin to be mixed in the cartridges and disposable pen injectors.

Before starting therapy, you should read the "User Manual" that accompanies the delivery device, to ensure the correct use thereof. Before using Lilly cartridges in any other manufacturer's insulin delivery device, the user must check the device manufacturer's literature to verify that Lilly cartridges are compatible with that device.

If you use more HUMULIN 30/70 than you should:

- Overdosage causes hypoglycaemia (low blood sugar) with accompanying symptoms that include confusion, palpitations (rapid irregular action of the heart), sweating and vomiting.
- Treatment: Mild hypoglycaemic (low blood sugar) episodes can be treated with glucose or sugar and rest.
- In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.

If you forget to use HUMULIN 30/70:

- If you take less HUMULIN 30/70 than you need, your blood sugar levels may increase. Check your blood sugar and please consult your doctor, pharmacist or other healthcare professional. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with HUMULIN 30/70 is stopped:

- If you take less HUMULIN 30/70 than you need, your blood sugar levels may increase. Check your blood sugar and please consult your doctor, pharmacist or other healthcare professional.

POSSIBLE SIDE EFFECTS

- HUMULIN 30/70 can have side effects.

- Not all side effects reported for HUMULIN 30/70 are included in this leaflet.
- Should your general health worsen while taking this medicine or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
- Tell your doctor if you notice any of the following:
- Hypoglycaemia (low blood sugar).
- Allergic reaction occurs.
- Lipodystrophy (thickening or pitting of the skin).
- Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORING AND DISPOSING OF HUMULIN 30/70

- Store all medicines out of reach of children.
- Store at (2-8 °C) in a refrigerator.
- Do not freeze or expose to excessive heat or sunlight.
- Please return left over medicine to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste.
- Ask your pharmacist how to dispose of medicines no longer required.

Vials, cartridges or pens in use:

- Vials: If refrigeration is not possible, the vial in use can be stored at or below 25 °C for 28 days. Do not expose to excessive heat or sunlight.
- Cartridges and disposable pens: The cartridge of insulin currently in use should not be refrigerated but should be kept cool (at or below 25 °C) and away from heat and sunlight.
- Unrefrigerated cartridges and disposable pens containing 3,0 ml cartridges should be discarded after 28 days, even if they still contain product.
- Do not use after the expiration date stamped on the label.

PRESENTATION OF HUMULIN 30/70

- HUMULIN 30/70 (Suspension for Injection), 10 ml vials are packed as singles.
- HUMULIN 30/70 (Suspension for Injection), 3,0 ml cartridges and disposable pen injectors containing 3,0 ml cartridges are packed in cartons containing 5.

IDENTIFICATION OF HUMULIN 30/70

HUMULIN 30/70 (Suspension for Injection) cartridges and disposable pens contain a sterile, white suspension.

- Vials (HI 0710): a 10 ml size flint-glass vial sealed with a rubber stopper and an aluminium seal.
- Cartridges (HI 0719): a 3,0 ml size flint-glass cartridge sealed with a rubber plunger head at the bottom of the cartridge and a rubber disc and outer aluminium seal at the top of the cartridge. The cartridges should be used in reusable pen injectors. Each suspension-containing cartridge contains a small flint glass bead to assist in mixing.
- Disposable pens (HP 8770 & HP 8803): Prefilled, disposable pen injectors containing 3,0 ml size cartridges.

REGISTRATION NUMBER/ REFERENCE NUMBER:

W/21.1/397 for HUMULIN 30/70

NAME AND ADDRESS OF REGISTRATION HOLDER:

Eli Lilly (S.A.) (Pty) Limited

Private Bag X119, 2021

Building E, Ballyoaks Office Park,

35 Ballyclare Drive

Bryanston, 2191

DATE OF PUBLICATION:

Date of registration: 17 January 1990

Date of most recently revised approved package insert: 02 June 2017

SKEDULERINGSTATUS S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

HUMULIN 30/70, **biosintetiese menslike insulien** (rekombinante DNS-oorsprong), 100 I.E./ml, suspensie vir inspuiting.

Lees hierdie hele brosjure versigtig voordat jy begin om HUMULIN 30/70 te neem.

- Hou hierdie brosjure. Jy mag dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter of jou apteker daaroor.
- HUMULIN 30/70 is vir jou persoonlik voorgeskryf en jy behoort nie jou medisyne met ander persone te deel nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

WAT HUMULIN 30/70 BEVAT

- Die aktiewe bestanddeel is biosintetiese menslike insulien (rekombinante DNS-oorsprong), 100 I.E./ml**.**
- Die ander bestanddele is dibasiese natriumfosfaat (kristalle), gliserien, soutsuur (oplossing, 10%) en/of natriumhidroksied (oplossing, 10%), protamiensulfaat,
  - water vir inspuiting, sinkoksied.
- Die preserveermiddels wat ingesluit word, is m-kresol 0,16% m/v en fenol 0,06 m/v.

WAARVOOR HUMULIN 30/70 GEBRUIK WORD

- HUMULIN 30/70 is ‘n voorafgemengde suspensie van vinnige en langwerkende insulien.
- HUMULIN 30/70 word gebruik om diabetes mellitus te behandel. Jy ontwikkel diabetes indien jou pankreas nie genoeg insulien maak om die vlak van glukose in jou bloed (bloedsuiker) te beheer nie.

VOORDAT JY HUMULIN 30/70 GEBRUIK

Moenie HUMULIN 30/70 gebruik nie:

- Indien jy hipersensitief (allergies) is vir biosintetiese menslike insulien (rekombinante DNS-oorsprong), of enige van die ander bestanddele van HUMULIN 30/70, wat in hierdie brosjure gelys word.
- Indien jy hipoglisemie (lae bloedsuiker) ondervind.
- Jy behoort nooit HUMULIN 30/70 intraveneus (in jou vene) toe te dien nie.

Neem spesiale sorg met HUMULIN 30/70:

- Enige verandering in insulien behoort omsigtig gemaak te word en alleenlik as dit onder mediese toesig plaasvind
- Indien jy insulien van ‘n diere-bron insulien verander na HUMULIN 30/70, sal die vroeë waarskuwingssimptome van hipoglisemie (lae bloedsuiker) minder ooglopend of anders wees.
- Jy mag meer insulien tydens siekte of emosionele versteurings gebruik, of as jy ander medisynes gelyktydig neem wat ‘n hiperglisemiese (hoë bloedsuiker) aktiwiteit het, bv. orale kontraseptiewe, kortikosteroïede soos prednisoon of tiroïedvervangingsterapie.
- Jy mag minder insulien gebruik indien jy nier- of lewerversteurings het, of as jy ander medisynes gelyktydig neem wat ‘n hipoglisemiese (lae bloedsuiker) aktiwiteit het, bv. monoamienoksidase en beta-adrenergiese blokkeerders.
- Terapie met betablokkeerders (soos atenolol en propanolol) mag jou simptome van insulien-verwante hipoglisemie (lae bloedsuiker) versluier. ‘n Diabetiese persoon mag nie besef dat hy/sy lae bloedsuiker het nie.
- Indien jy meer oefen of jou gebruiklike dieet verander, moet jy asseblief jou dokter raadpleeg omdat jou insuliendosis moontlik aangepas sal moet word.
- Indien jy tiasoliediendione soos pioglitasoon saam met HUMULIN 30/70 neem, mag dit die risiko van edeem (bv. swelling in die arms, enkels; vloeistofretensie) en hartversaking verhoog, veral by pasiënte met bestaande hartsiekte.
- HUMULIN 30/70 suspensies behoort eenvormig wolkerig of melkerig te lyk. Indien die insulien substans (die wolkerige materiaal) op die bodem van die patroon in die inspuitingspen afsak,

moet dit gedraai of versigtig geskud word voor inspuiting om te verseker dat die inhoud uniform gemeng is. Moenie dit gebruik nie indien ‘n neerslag van soliede partikels op die bodem of die wand van die patroon bly lê, wat dit ‘n bevrore voorkoms gee, of as klonte in die insulien dryf nadat die inspuitingspen gedraai of versigtig geskud is. ‘n Insuliensuspensie behoort ook nie gebruik te word nie indien dit helder is en helder bly nadat dit gedraai of geskud is.

- Nadat jy jou dosis voorberei het, behoort jy dit dadelik toe te dien om verstopping van die naald te verhoed.
- Moenie jou insulien verander nie, tensy jou dokter vir jou sê om dit te doen. Wees baie versigtig indien jy wel jou insulien verander. Elke soort insulien het ‘n verskillende kleur en simbool op die verpakking en pen sodat jy maklik die verskil kan raak sien.

Neem van HUMULIN 30/70 saam met kos en drank:

- Jy moet jou dokter se instruksies oor voedselinname en die gebruik van HUMULIN 30/70 versigtig volg.

Swangerskap en borsvoeding:

Swangerskap: Indien jy swangerskap oorweeg, behoort jy mediese advies te kry en jy behoort medies gemoniteer te word veral ten opsigte van die aanpassing van insuliendosis dwarsdeur jou swangerskap. Jou bloedglukose behoort so normaal as moontlik te wees vanaf die tyd van konsepsie tot geboorteskenking. Insulienbehoeftes is gewoonlik laer tydens die eerste trimester en hoër gedurende die tweede en derde trimesters.

Borsvoeding: Indien jy jou baba borsvoed, mag jy aanpassings van insulien en/of jou dieet nodig hê.

Indien jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige raadpleeg vir advies voordat jy HUMULIN 30/70 neem.

Bestuur en gebruik van masjiene:

- Jou vermoë om te konsentreer en te reageer, mag verminder wees indien jy hipoglisemie (lae bloedsuiker) het. Onthou dit asseblief in alle situasies waar jy jouself en ander persone aan risiko mag blootstel (bv. bestuur van ‘n motor of gebruik van masjiene).

Neem van ander medisyne saam met HUMULIN 30/70

Jy moet altyd jou gesondheidsorgdeskundige daarvan vertel indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

- Jou insulienbehoeftes mag verhoog wees wanneer jy ander medisynes gelyktydig gebruik wat hiperglisemiese (hoë bloedsuiker) aktiwiteit het, bv. orale kontraseptiewe, kortikosteroïede soos prednisoon of tiroïedvervangingsterapie.
- Jou insulienbehoeftes mag verlaag wees in die teenwoordigheid van middels soos orale antidiabetiese middels, salisilate, sulfa-antibiotika, en sekere antidepressante (monoamienoksidase-inhibeerders), beta-adrenergiese blokkeerders, angiotensienomsettingsensiem-inhibeerders en angiotensien-II-reseptorblokkeerders.
- Terapie met betablokkeerders (soos atenolol en propanolol) mag jou simptome van insulien-verwante hipoglisemie (lae bloedsuiker) versluier. ‘n Diabetiese persoon mag nie besef dat hy/sy lae bloedsuiker het nie.
- Raadpleeg asseblief jou dokter wanneer jy ander medikasies bykomstig tot menslike insulien gebruik.

HOE OM HUMULIN 30/70 TE GEBRUIK

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem HUMULIN 30/70 altyd presies volgens jou dokter se instruksies. Jy behoort met jou dokter of apteker te gesels indien jy onseker is. Jou dokter sal vir jou vertel hoe lank jou behandeling met HUMULIN 30/70 sal duur. Moenie behandeling vroeg staak nie. Indien jy onder die indruk verkeer dat die effek van HUMULIN 30/70 te sterk of te swak is, moet jy jou dokter of apteker daarvan vertel.

- HUMULIN 30/70 is ‘n vooraf voorbereide mengsel wat ontwerp is om die noodsaaklikheid van vermenging van insuliene te vermy. Sy aksie is verleng deur die insluiting van protamiensulfaat in die suspensie. Onder normale omstandighede behoort dit twee keer

daagliks toegedien te word, gewoonlik met twee derdes van die daaglikse behoefte wat in die oggend gegee word en die res in die aand.

- Jou dokter mag vir jou vertel om HUMULIN 30/70 asook ‘n langerwerkende insulien te gebruik.
- Die dosis van een inspuiting behoort nie 50 I.E. te oorskry nie.
- HUMULIN 30/70 mag alleenlik onderhuids (onder die vel) of binnespiers (in die spier), toegedien word.
- Jy moet nooit HUMULIN 30/70 intraveneus (in ‘n vene) toedien nie.
- Jy behoort HUMULIN 30/70 onderhuids (onder die vel) in die boarms, dye, boude of buik toe te dien.
- Jy behoort die inspuitingsplekke te roteer sodat presies dieselfde plek nie meer as een keer per maand gebruik word nie.
- Jy behoort korrekte inspuitingstegnieke te gebruik.
- Sorg moet toegepas word om seker te maak dat jy nie in ‘n bloedvat ingespuit het nie. Die inspuitingsplek behoort nie gemasseer te word nie.

Meng van insulien:

- **Flessies:** Indien jy insuliene meng, behoort die kortwerkende HUMULIN R eerste in die spuit opgetrek te word om besmetting van die flessie deur die langerwerkende preparaat (bv. HUMULIN N) te vermy. Jy behoort die inspuiting onmiddellik na vermenging toe te dien. Sulke mengsels behoort nie intraveneus (in die vene) toegedien te word nie.
- **Patrone:** HUMULIN patrone is nie ontwerp om toe te laat dat enige ander insulien in die patrone en wegdoenbare inspuitingspenne gemeng kan word nie.

Voordat terapie begin word, moet jy die “Gebruikershandleiding” lees wat saam met die afleweringstoestel voorsien word, om die korrekte gebruik daarvan te verseker. Voordat Lilly patrone in enige ander vervaardiger se afleweringstoestel gebruik word, moet die gebruiker die toestelvervaardiger se leesstof nagaan om seker te maak dat Lilly patrone met daardie toestel verenigbaar is,

Indien jy meer HUMULIN 30/70 gebruik, as wat jy behoort te gebruik:

- Oordosering veroorsaak hipoglisemie (lae bloedsuiker) met begeleidende simptome wat verwarring, hartkloppings (vinnige onreëlmatige werking van die hart), sweet en braking insluit.
- Behandeling: Ligte hipoglisemie (lae bloedsuiker) episodes kan met glukose of suiker en rus behandel word.
- In ‘n geval van oordosis, moet jy jou dokter of apteker raadpleeg. Indien beide nie beskikbaar is nie, moet jy hulp gaan soek by die naaste hospitaal of gifsentrum.

Indien jy vergeet om HUMULIN 30/70 te gebruik:

- Indien jy minder HUMULIN 30/70 neem as wat jy nodig het, mag jou bloedsuikervlakke toeneem. Toets jou bloedsuiker en raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige. Moenie ‘n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Effekte wanneer HUMULIN 30/70 gestaak word:

- Indien jy minder HUMULIN 30/70 neem as wat jy nodig het, mag jou bloedsuikervlakke toeneem. Toets jou bloedsuiker en raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige.

MOONTLIK NEWE-EFFEKTE

- HUMULIN 30/70 kan newe-effekte veroorsaak.
- Nie alle newe-effekte wat vir HUMULIN 30/70 aangemeld is, word in hierdie brosjure ingesluit nie.
- Indien jou algemene gesondheid sou vererger terwyl jy hierdie medisyne neem of as jy enige nadelige effekte ondervind terwyl jy hierdie medisyne neem, moet jy asseblief jou dokter, apteker of ander gesondheidsorgdeskundige vir advies raadpleeg.
- Vertel jou dokter indien jy enige van die volgende opmerk:
- Hipoglisemie (lae bloedsuiker).
- ‘n Allergiese reaksie ondervind.

- Lipodistrofie (verdikking of duiking van die vel).
- Edeem (bv. swelling van die arms, enkels; vloeistofretensie) is al aangemeld, veral aan die begin van insulienterapie of gedurende ‘n verandering in terapie.
- Indien enige van die newe-effekte ernstig word, of as jy bewus word van enige newe-effekte wat nie in hierdie brosjure gelys word nie, moet jy asseblief jou dokter of apteker daarvan vertel.

OPBERGING EN WEGDOENING VAN HUMULIN 30/70

- Bewaar alle medisyne buite bereik van kinders.
- Bewaar by (2-8^{o}C) in ‘n yskas.
- Moenie vries, of aan oormatige hitte of sonlig blootstel nie.
- Gee asseblief medisyne wat oortollig is terug aan jou apteker.
- Medisyne moet nie in dreine of huishoudelike afval weggooi word nie.
- Vra jou apteker hoe om van medisyne wat nie langer nodig is nie, ontslae te raak.

Flessies, patrone of penne wat in gebruik is:

- Flessies: Indien opberging in ‘n yskas nie moontlik is nie, kan die flessie by of onder 25^{o}C vir 28 dae bewaar word. Moenie aan oormatige hitte of sonlig blootstel nie.
- Patrone en wegdoenbare penne: Die insulien patroon wat tans gebruik word, behoort nie in die yskas gestoor te word nie, maar moet koel (by of onder 25^{o}C), en weg van hitte en sonlig bewaar word.
- Patrone wat nie in ‘n yskas bewaar word nie en wegdoenbare penne wat 3,0 ml patrone bevat, behoort na 28 dae weggedoen te word, selfs as dit nog produk bevat.
- Moenie na die vervaldatum wat op die etiket gestempel is, gebruik nie.

AANBIEDING VAN HUMULIN 30/70

- HUMULIN 30/70 (Suspensie vir Inspuiting), 10 ml flessies word as enkelinge verpak.
- HUMULIN 30/70 (Suspensie vir Inspuiting), 3,0 ml patrone en wegdoenbare inspuitingspenne wat 3,0 ml patrone bevat, word in kartondose wat 5 bevat, verpak.

IDENTIFIKASIE VAN HUMULIN 30/70

HUMULIN 30/70 (Suspensie vir Inspuiting) patrone en wegdoenbare penne bevat ‘n steriele, wit suspensie.

- Flessies (HI 0710): ‘n 10 ml grootte flintglasflessie verseël met ‘n rubber prop en ‘n aluminium seël.
- Patrone (HI 0719): ‘n 3,0 ml grootte flintglaspatroon verseël met ‘n rubber plonsprop aan die onderkant van die patroon en ‘n rubber skyf en buitenste aluminium seël aan die bokant van die patroon. Die patrone behoort in herbruikbare inspuitingspenne gebruik te word. Elke suspensie-bevattende patroon bevat ‘n klein flintglaskraaltjie om vermenging te bevorder.
- Wegdoenbare penne (HP 8770 & HP 8803): Voorafgevulde, wegdoenbare inspuitingspenne wat 3,0 ml grootte patrone bevat.

REGISTRASIENOMMER/ VERWYSINGSNOMMER:

W/21.1/397 vir HUMULIN 30/70

NAAM EN ADRES VAN DIE REGISTRASIEHOUER:

Eli Lilly (S.A) (Edms) Beperk

Privaatsak X119, 2021

Gebou E, Ballyoaks Kantoorpark,

35 Ballyclare Rylaan

Bryanston, 2191

DATUM VAN PUBLIKASIE:

Datum van registrasie: 17 Januarie 1990