SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

HUMULIN R, biosynthetic human insulin (recombinant DNA origin), 100 I.U./ml, solution for injection.

Read all of this leaflet carefully before you start taking HUMULIN R.

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

- The active substance is biosynthetic human insulin (recombinant DNA origin) 100 I.U./ml.
- The other ingredients are glycerol, hydrochloric acid (solution, 10 %) and/or sodium hydroxide (solution, 10 %), water for injection.
- The preservative included is m-cresol 0, 25 % m/v.

WHAT HUMULIN R IS USED FOR

- Humulin R is a rapidly acting insulin preparation.
- HUMULIN R, 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 R

Do not use HUMULIN R:

- If you are hypersensitive (allergic) to biosynthetic human insulin (recombinant DNA origin) or any of the other ingredients of HUMULIN R, listed in this leaflet.
- If you are experiencing hypoglycaemia (low blood sugar).

Take special care with HUMULIN R:

- Any change of insulin should be made cautiously and only under medical supervision.
- If you change insulin from an animal-source insulin to HUMULIN R 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-blocker (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 R 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 R solutions should be clear and colourless. Do not use the insulin if it appears cloudy, thickened, slightly coloured or if solid particles are visible.
- 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 R with food and drink:

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

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 R.

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 R:

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 R

Do not share medicines prescribed for you with any other person. Always take HUMULIN R 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 R will last. Do not stop treatment early. If you have the impression that the effect of HUMULIN R is too strong or too weak, tell your doctor or pharmacist.

- Your doctor may tell you to use HUMULIN R alone or together with a longer acting insulin such as HUMULIN N.
- HUMULIN R may be administered subcutaneously (under the skin), intramuscularly (into the muscle) or intravenously (into the vein).
- You should administer HUMULIN R 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:** You may administer HUMULIN R from vials together with HUMULIN N from vials as required. This is usually a twice daily regimen.
- 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 R 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 R:

- If you take less HUMULIN R than you need, your blood sugar levelsmay 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 R is stopped:

- If you take less HUMULIN R 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 R can have side effects.
- Not all side effects reported for HUMULIN R are included in this leaflet.
- Should your general health worsen while taking HUMULIN R or if you experience any untoward effects while taking HUMULIN R, 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.
- 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 R

- 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 R

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

IDENTIFICATION OF HUMULIN R

The vials, cartridges and disposable pens contain a sterile, clear, colourless solution for injection.

- Vials (HI 0210): a 10 ml size flint-glass vial sealed with a rubber stopper and an aluminium seal.

- Cartridges (HI 0219): 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.
- Disposable pens (HP 8720 & HP 8804) are supplied as prefilled, disposable pen injectors containing 3,0 ml size cartridges.

REGISTRATION NUMBER/ REFERENCE NUMBER:

R/21.1/2 for HUMULIN R

NAME AND ADDRESS OF REGISTRATION HOLDER:

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SKEDULERINGSTATUS S3

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM

HUMULIN R, biosintetiese menslike insulien (rekombinante DNS-oorsprong), 100 I.E./ml, oplossing vir inspuiting.

Lees hierdie hele brosjure versigtig voordat jy begin om HUMULIN R 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 R 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 R BEVAT

- Die aktiewe bestanddeel is biosintetiese menslike insulien (rekombinante DNS-oorsprong), 100 I.E./ml**.**
- Die ander bestanddele is gliserol, soutsuur (oplossing, 10%) en/of natriumhidroksied (oplossing, 10%), water vir inspuiting.
- Die preserveermiddel wat ingesluit word, is m-kresol 0,25% m/v.

WAARVOOR HUMULIN R GEBRUIK WORD

- HUMULIN R is ‘n vinnig-werkende insulienpreparaat.
- HUMULIN R, 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 R GEBRUIK

Moenie HUMULIN R gebruik nie:

- Indien jy hipersensitief (allergies) is vir biosintetiese menslike insulien (rekombinante DNS-oorsprong), of enige van die ander bestanddele van HUMULIN R, wat in hierdie brosjure gelys word.
- Indien jy hipoglisemie (lae bloedsuiker) ondervind.

Neem spesiale sorg met HUMULIN R:

- 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 R, 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 R neem, mag dit die risiko van edeem (bv. swelling in die arms, enkels; vloeistofretensie) en hartversaking verhoog, veral by pasiënte met bestaande hartsiekte.
- HUMULIN R oplossings behoort helder en kleurloos te wees. Moenie die insulien gebruik nie as it wolkerig, verdik, of effens gekleur voorkom, of as soliede partikels sigbaar 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 R saam met kos en drank:

- Jy moet jou dokter se instruksies oor voedselinname en die gebruik van HUMULIN R 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 R 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 R

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 R TE GEBRUIK

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Neem HUMULIN R 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 R sal duur. Moenie

behandeling vroeg staak nie. Indien jy onder die indruk verkeer dat die effek van HUMULIN R te sterk of te swak is, moet jy jou dokter of apteker daarvan vertel.

- Jou dokter mag jou vertel om HUMULIN R alleen, of saam met ‘n langerwerkende insulien soos HUMULIN N, te gebruik.
- HUMULIN R mag onderhuids (onder die vel), binnespiers (in die spier), of intraveneus (in ‘n vene), toegedien word.
- Jy behoort HUMULIN R 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:** Jy mag HUMULIN R van flessies saam met HUMULIN N van flessies soos nodig toedien. Dit is gewoonlik ‘n twee-keer-daaglikse regimen.
- 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 R 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 R te gebruik:

- Indien jy minder HUMULIN R 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 behandeling met HUMULIN R gestaak word:

- Indien jy minder HUMULIN R 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 R kan newe-effekte veroorsaak.
- Nie alle newe-effekte wat vir HUMULIN R aangemeld is, word in hierdie brosjure ingesluit nie.
- Indien jou algemene gesondheid sou vererger terwyl jy HUMULIN R neem of as jy enige nadelige effekte ondervind terwyl jy HUMULIN R 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.

- 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 R

- 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 enige oorblywende medisyne 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 R

- HUMULIN R (Oplossing vir Inspuiting), 10 ml flessies word as enkelinge verpak.
- HUMULIN R (Oplossing 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 R

Die flessies, patrone en wegdoenbare penne bevat ‘n steriele, helder, kleurlose oplossing vir inspuiting.

- Flessies (HI 0210): ‘n 10 ml grootte flintglasflessie verseël met ‘n rubber prop en ‘n aluminium seël.
- Patrone (HI 0219): ‘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.
- Wegdoenbare penne (HP 8720 & HP 8804), word verskaf as voorafgevulde, wegdoenbare inspuitingspenne wat 3,0 ml grootte patrone bevat.

REGISTRASIENOMMER/ VERWYSINGSNOMMER:

R/21.1/2 vir HUMULIN R

NAAM EN ADRES VAN DIE REGISTRASIEHOUER:

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