

## Glimepiride Denk 3

Tablet – oral use  
Antidiabetic agent  
Active substance: glimepiride

### Package leaflet: Information for the patient

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

- What Glimepiride Denk 3 is and what it is used for
- What you need to know before you take Glimepiride Denk 3
- How to take Glimepiride Denk 3
- Possible side effects
- How to store Glimepiride Denk 3
- Contents of the pack and other information

**1. What Glimepiride Denk 3 is and what it is used for**  
Glimepiride Denk 3 is an orally active blood sugar lowering drug. This drug belongs to a blood sugar lowering group of medicines called sulfonylureas. Glimepiride Denk 3 works by increasing the amount of insulin released from your pancreas. The insulin then lowers your blood sugar levels.

#### 2. What you need to know before you take Glimepiride Denk 3

##### Do not take Glimepiride Denk 3 and tell your doctor if

- you are allergic to glimepiride or certain other sulfonylureas (medicines used to lower your blood sugar such as glibenclamide) or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of this medicine (listed in section 6)
- you have insulin dependent diabetes (type 1 diabetes mellitus)
- you have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness)
- you lose consciousness as a consequence of severely increased blood sugar (diabetic coma)
- you have severe kidney disease
- you have severe liver disease.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Glimepiride Denk 3.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Glimepiride Denk 3 if you are recovering from an injury, operation, infections with fever, or from other forms of stress, inform your doctor as temporary change of treatment may be necessary;

- if you have severe liver or kidney disorder.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Glimepiride Denk 3.

Particular caution must be taken if you have a particular disease of the red blood cells, so-called glucose-6-phosphate dehydrogenase deficiency, as treatment with glimepiride may cause damage to the red blood cells and a drop in the haemoglobin level (haemolytic anaemia).

Only limited information is available on the use of glimepiride in children under 18 years of age.

Therefore, use in this particular age-group is not recommended.

#### Important information about hypoglycaemia (low blood sugar)

When you take Glimepiride Denk 3, you may get hypoglycaemia (low blood sugar). Please see below for additional information about hypoglycaemia, its signs and treatment.

##### Following factors could increase the risk of you getting hypoglycaemia:

- Undernourishment, irregular meal time, missed or delayed meal or period of fasting
- Changes to your diet
- Taking more Glimepiride Denk 3 than needed
- Having kidneys that do not work properly
- Having severe liver disease

If you suffer from particular hormone-induced disorders (disorders of the thyroid glands, of the pituitary gland or adrenal cortex)

Drinking alcohol (especially when you skip a meal)

Taking certain other medicines (see section "Other medicines and Glimepiride Denk 3" below)

If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.

##### Signs of hypoglycaemia include:

Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, perception and sensory disorders, dizziness, helplessness.

Glimepiride Denk 3 is used to treat a certain form of diabetes (type 2 diabetes mellitus) when diet, physical exercise and weight reduction alone have not been able to control your blood sugar levels.

#### 2. What you need to know before you take Glimepiride Denk 3

##### Do not take Glimepiride Denk 3 and tell your doctor if

- Medicines used to lower your blood sugar such as glibenclamide or sulfonamides (medicines for bacterial infections such as sulfamethoxazole) or any of the other ingredients of this medicine (listed in section 6)
- you have insulin dependent diabetes (type 1 diabetes mellitus)
- you have diabetic ketoacidosis (a complication of diabetes when your acid level is raised in your body and you may have some of the following signs: fatigue, feeling sick (nausea), frequent urination and muscular stiffness)
- you lose consciousness as a consequence of severely increased blood sugar (diabetic coma)
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- you have severe liver disease.

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##### Treating hypoglycaemia:

In most cases the signs of reduced blood sugar vanish very quickly when you consume some form of sugar, e.g. sugar cubes, sweet juice, and sweetened tea. You should therefore always take some form of sugar with you (e.g. dextrose, sugar cubes). Remember that artificial sweeteners are not effective. Please contact your doctor or go to the hospital if taking sugar does not help or if the symptoms recur.

##### Laboratory Tests

The level of sugar in your blood or urine must be checked regularly. Your doctor may also take blood tests to monitor your blood cell levels and liver function.

##### Children and adolescents

Glimepiride Denk 3 is not recommended for use in children under 18 years of age.

### Other medicines and Glimepiride Denk 3

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to change your dose of Glimepiride Denk 3 if you are taking other medicines, which may weaken or strengthen the effect of treatment may be necessary;

- if you have severe liver or kidney disorder.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Glimepiride Denk 3.

The following medicines can increase the blood sugar lowering effect of Glimepiride Denk 3. This can lead to a risk of hypoglycaemia (low blood sugar):

- Other medicines to treat diabetes mellitus (such as insulin or metformin)
- Medicines to treat pain and inflammation (phenylbutazone, azopropazone, oxphenbutazone, medicines with the active substance acetylsalicylic acid and similar medicines)
- Medicines to treat urinary infections (such as some long acting sulfonamides)
- Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, flucconazole, miconazole, quinolones, clarithromycin)
- Medicines to inhibit blood clotting (coumarin derivatives such as warfarin)

Medicines supporting muscle build up (anabolic)

Medicines used for male sex hormone replacement therapy

Medicines to treat depression (fluoxetine, MAO inhibitors)

Medicines lowering high cholesterol level (fibrates)

Medicines lowering high blood pressure (ACE inhibitors)

Medicines called anti-arrhythmic agents used to control abnormal heart beat (disopyramide)

Medicines to treat gout (allopurinol, probenecid, sulfapyrazone)

Medicines to treat cancer (cyclophosphamide, ifosfamide, trofosfamide)

Drinking alcohol (especially when you skip a meal)

Taking certain other medicines (see section "Other medicines and Glimepiride Denk 3" below)

If you increase the amount of exercise you do and you don't eat enough food or eat food containing less carbohydrate than usual.

##### What Glimepiride Denk 3 contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

##### Glimepiride Denk 3 contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

##### Signs of hypoglycaemia include:

Hunger pangs, headache, nausea, vomiting, sluggishness, sleepiness, problems sleeping, restlessness, aggression, problems with concentration, reduced alertness and reaction time, depression, confusion, problems with your speech and sight, slurred speech, shakiness, partial paralysis, perception and sensory disorders, dizziness, helplessness.

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### Warnings and precautions

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Medicines used for male sex hormone replacement therapy

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Medicines to treat urinary infections (such as some long acting sulfonamides)

Medicines to treat bacterial and fungal infections (tetracyclines, chloramphenicol, flucconazole, miconazole, quinolones, clarithromycin)

**Glimepiride Denk 3 contient du lactose**  
Si votre médecin vous a informé d'une intolérance à certains sucres, contactez-le avant de prendre ce médicament.

**Glimepiride Denk 3 contient du sodium**  
Ce médicament contient moins de 1 mmol/(23 mg) de sodium par comprimé, c.-à-d. qu'il est essentiellement « sans sodium ».

### 3. Comment prendre Glimepiride Denk 3

Veuillez à toujours prendre ce médicament en suivant exactement les indications de votre médecin. Vérifiez auprès de votre médecin ou pharmacien en cas de doute.

#### Mode d'administration

- Prenez ce médicament par voie orale juste avant ou pendant le premier repas de la journée (en général, le petit-déjeuner). Si vous ne prenez pas de petit-déjeuner, vous devez prendre le médicament à l'heure prescrite par votre médecin. Il est important de ne sauter aucun repas lorsque vous prenez Glimepiride Denk 3.
- Les comprimés doivent être avalés avec au moins un demi-verre d'eau. Les comprimés ne doivent pas être écrasés ni mâchés.
- Le comprimé peut être divisé en doses égales.

#### Posologie

La dose de Glimepiride Denk 3 dépend de vos besoins, de votre état de santé et des résultats des analyses du taux de sucre sanguin et urinaire, et elle sera déterminée par votre médecin.

Ne prenez pas plus de comprimés que le nombre prescrit par votre médecin.

- La dose initiale est habituellement de 1 mg de glimepiride une fois par jour.

Si nécessaire, votre médecin pourra augmenter la dose toutes les 1 à 2 semaines de traitement.

La dose maximale recommandée est de 6 mg de glimepiride par jour.

- Un traitement combiné par glimepiride et metformine ou par glimepiride et insulinine peut être instauré. Dans ce cas, votre médecin déterminera les doses adéquées de glimepiride, de metformine ou d'insuline pour vous.

Votre dose de glimepiride devra peut-être être ajustée si votre poids change, si vous modifiez votre mode de vie ou si vous faites face à une période de stress important. Adressez-vous à votre médecin si vous vous trouvez dans l'une de ces situations.

- Si vous pensez que les effets de votre médicament sont trop faibles ou trop forts, ne modifiez pas la dose vous-même, mais demandez conseil à votre médecin.

**Si vous avez pris plus de Glimepiride Denk 3 que vous n'auriez dû**  
Si vous avez pris trop de Glimepiride Denk 3 ou si vous avez pris une dose supplémentaire, il existe un risque d'hypoglycémie (pour les symptômes de l'hypoglycémie voir rubrique 2) et vous devez donc consommer tout de suite suffisamment de sucre (par exemple, quelques morceaux de sucre, du jus de fruits, du thé sucré) et en informer immédiatement un médecin. Lors du traitement d'une hypoglycémie due à une prise accidentelle chez l'enfant, la quantité de sucre administrée doit être soigneusement contrôlée pour éviter de provoquer une hypoglycémie dangereuse. Ne pas donner d'aliments ou de boissons aux personnes qui ont perdu connaissance.

L'état hypoglycémique pouvant durer un certain temps, il est très important de surveiller attentivement le patient jusqu'à ce que tout danger soit écarté. Une hospitalisation peut être nécessaire, même par mesure de précaution. Montrez l'emballage ou les comprimés restants au médecin pour qu'il sache ce qui a été pris.

Les cas sévères d'hypoglycémie accompagnés d'une perte de connaissance et de déficits neurologiques sévères sont des urgences médicales qui imposent un traitement médical immédiat et une hospitalisation. Assurez-vous que des personnes en ont été informées et qu'elles pourront avertir un médecin en cas d'urgence.

**Si vous oubliez de prendre Glimepiride Denk 3**

Si vous oubliez de prendre une dose, ne prenez pas de dose double pour compenser la dose que vous avez oublié de prendre. Continuez à prendre le médicament comme d'habitude.

### Si vous arrêtez de prendre Glimepiride Denk 3

Si vous suspendez ou arrêtez le traitement, vous devez savoir que l'effet hypoglycémiant souhaité ne sera plus obtenu et que la maladie s'aggraverait.

Continuez à prendre Glimepiride Denk 3 jusqu'à ce que votre médecin vous dise d'arrêter.

Si vous avez d'autres questions sur l'utilisation de ce médicament, demandez plus d'informations à votre médecin ou à votre pharmacien.

### 4. Quels sont les effets indésirables éventuels

Comme tous les médicaments, ce médicament peut provoquer des effets indésirables, mais ils ne surviennent pas systématiquement chez tout le monde.

En signalant les effets indésirables, vous contribuez à fournir davantage d'informations sur la sécurité du médicament.

### 5. Comment conserver Glimepiride Denk 3

Tenir ce médicament hors de la vue et de la portée des enfants. N'utilisez pas ce médicament après la date de péremption indiquée sur la boîte ou la plaquette après « Exp. ». La date de péremption fait référence au dernier jour de ce mois.

Durée de conservation : 4 ans.

A conserver dans un endroit sec, à une température inférieure à 30°C.

Conserver dans l'emballage original afin d'en protéger le contenu de l'humidité.

Ne jetez aucun médicament au tout-à-l'égoût. Demandez à votre pharmacien d'éliminer les médicaments que vous n'utilisez plus. Ces mesures contribueront à protéger l'environnement.

### 6. Contenu de l'emballage et autres informations

#### Ce que contient Glimepiride Denk 3

- La substance active est le glimepiride. Chaque comprimé contient 3 mg de glimepiride.
- Diminution du nombre de cellules sanguines :
  - Plaquettes sanguines (ce qui augmente le risque de saignement ou d'écchymoses)
  - Globules blancs (ce qui rend plus sensible aux infections)
  - Globules rouges (ce qui peut rendre la peau pâle et entraîner une faiblesse ou un essoufflement)

Ces problèmes s'atténuent généralement après l'arrêt du traitement.

#### Autres effets indésirables éventuels :

- Chute sévère du taux de sucre dans le sang (hypoglycémie ; voir rubrique 2)
- Une autre composante est : lactose mono-hydraté, amidon de maïs, glycolate d'amidon sodique, povidone, polysorbate 80, oxyde de fer jaune, talc, stéarate de magnésium [végétal].

#### Condition de livraison

Médicament soumis à prescription médicale

#### Comment se présente Glimepiride Denk 3 et contenu de l'emballage extérieur

Glimepiride Denk 3 se présente sous la forme de comprimés non pelliculés de couleur jaune, oblongs, plats, à facettes et avec barre de cassure d'un côté.

Glimepiride Denk 3 est disponible sous forme de plaquettes thermoformées en PVC/PVDC/aluminium.

Présentation : 30 comprimés

#### Titulaire de l'Autorisation de Mise sur le Marché et Fabricant

DENK PHARMA GmbH & Co. KG

Prinzregentenstr. 79

81675 München

Allemagne

#### Site de production :

DENK PHARMA GmbH & Co. KG

Göllstr. 1

84529 Tittmoning

Allemagne

La dernière date à laquelle cette notice a été révisée est 02/2020.

### Denk Pharma

### Glimepiride Denk 3

#### Comprimido – via oral

#### Agente antidiabético

#### Substância ativa: glimepirida

#### Folheto informativo: Informação para o doente

#### Leia com atenção todo este folheto antes de começar a tomar este medicamento, pois contém informação importante para si.

#### – Conserve este folheto. Pode ser necessário de o ler novamente.

#### – Caso ainda tenha dúvidas, fale com o seu médico ou farmacêutico.

#### – Este medicamento foi receitado apenas para si. Não deve dá-lo a outros. O medicamento pode ser-lhes prejudicial mesmo que apresentem os mesmos sintomas de doença.

#### Os seguintes fatores podem aumentar o risco de ter hipoglicemia:

#### – Se tomar quaisquer efeitos indesejáveis, incluindo possíveis efeitos indesejáveis não indicados neste folheto, fale com o seu médico ou farmacêutico.

#### Se tomar mais Glimepiride Denk 3 do que deveria

#### – Subnutrição, refeições a horas irregulares, refeição omitida ou atrasada ou período de jejum

#### – Alterações na sua dieta

#### – Tomar mais Glimepiride Denk 3 do que o necessário

#### – Os seus rins não funcionarem bem

#### – Ter uma doença grave do fígado

#### – Se tiver determinadas doenças induzidas por hormonas (doenças da tireoide, da hipófise ou do córtex suprarrenal)

#### – Medicamentos para tratar a depressão (fluoxetina, inibidores da MAO)

#### – Medicamentos para reduzir níveis elevados de colesterol (fibrostatos)

#### – Medicamentos para reduzir a tensão arterial elevada (inibidores da ECA)

#### – Medicamentos chamados agentes antiarrítmicos utilizados para controlar o batimento cardíaco irregular (disopiramida)

#### – Beber álcool (especialmente se saltar uma refeição)

#### – Tomar determinados outros medicamentos (ver secção "Outros medicamentos e complementos" na página 16)

#### – Medicamentos para tratar a gota (allopurinol, probenecida, sulfinpirazona)

#### – Medicamentos para tratar cancos (ciclofosfamida, ifosfamida, trofosfamida)

#### – Medicamentos utilizados para reduzir o peso (fenfluramina)

#### – Outro medicamento que diminui a coagulação do sangue (derivados da cumarina, tais como a varfarina)

#### – Alterações do paladar

#### Muito raros (podem afetar até 1 em 10.000 pessoas)

#### – Reações alérgicas (incluindo inflamação dos vasos sanguíneos, frequentemente com erupção cutânea) que podem desenvolver-se em reações graves com dificuldade em respirar, queda da tensão arterial e, por vezes, progredir para choque. Se sentir algum destes sintomas.

#### – Aumento de peso

#### – Queda de cabelo

#### – Alterações do paladar

#### – Medicamentos sujeito a receita médica

#### Qual a composição de Glimepiride Denk 3

#### – A substância ativa é a glimepirida. Cada comprimido contém 3 mg de glimepirida.

#### – Outros componentes são lactose mono-hidratada, amido de milho, glicolato de amido sódico, povidona, polissorbato 80, óxido de ferro amarelo, talco, estearato de magnésio (vegetal).

#### – Comprimido pode ser dividido em doses iguais.

#### Posologia

#### Outros medicamentos e Glimepiride Denk 3

#### A dose de Glimepiride Denk 3 depende das suas necessidades, do seu estado e dos resultados das análises ao açúcar no sangue e na urina.

#### – Fale com o seu médico ou farmacêutico antes de tomar Glimepiride Denk 3.

#### – Medicamentos para tratar convulsões (fenitoína)

#### – Medicamentos para tratar o nervosismo e problemas em dormir (barbitúricos)

#### – Medicamentos para tratar a aumento da pressão no olho (acetazolamida)

#### – Medicamentos para tratar a tensão arterial elevada ou diminuir o açúcar no sangue (diáxido)

#### – Medicamentos para tratar determinadas infecções, tais como a tuberculose (rifampicina)

#### – Medicamentos para tratar níveis baixos graves de açúcar no sangue (glucagon)

#### – Medicamentos para tratar a insuficiência hepática (fenoacetonida)

#### – Medicamentos para tratar a diabetes mellitus (alginato de ferro)

#### – Medicamentos para tratar a hiperlipidemia (fenoacetonida)

#### – Medicamentos para tratar a artrite (fenoacetonida)

#### – Medicamentos para tratar a urticária, a angioedema e a reação de hipersensibilidade (fenoacetonida)

#### – Medicamentos para tratar a hiperpigmentação (fenoacetonida)

#### – Medicamentos para tratar a acne (fenoacetonida)

#### – Medicamentos para tratar a hiperplasia da próstata (fenoacetonida)

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