

- Do not use this medicine after the expiry date which is stated on the carton and blister strip after "Exp". The expiry date refers to the last day of that month.
- Shelf life: 36 months
- Store in a dry place below 30°C. Protect from light.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

Pharmacodynamic properties

Pharmaco-therapeutic group: Oral antidiabetic agent, ATC code: A10BA02
Metformin is a biguanide with anti-hyperglycemic effects, lowering both basal and postprandial plasma glucose. It does not stimulate insulin secretion and therefore does not produce hypoglycemia.

Metformin may act via 3 mechanisms:

- Reduction of hepatic glucose production by inhibiting gluconeogenesis and glycogenolysis.
- In muscle, by increasing insulin sensitivity, improving peripheral glucose uptake and utilisation.
- Delay of intestinal glucose absorption.

Metformin stimulates intracellular glycogen synthesis by acting on glycogen synthase.

Metformin increases the transport capacity of all known types of membrane glucose transporters.

In humans, independently of its action on glycemia, metformin has favourable effects on lipid metabolism. This has been shown at therapeutic doses in controlled, medium-term or long-term clinical studies. Metformin reduces total cholesterol, LDL cholesterol and triglyceride levels.

Pharmacokinetic properties

After an oral dose of metformin hydrochloride, the maximum concentration is reached in 2.5 hours. Absolute bioavailability of a 500 mg or 850 mg metformin hydrochloride film-coated tablet is approximately 50–60% in healthy subjects.

After an oral dose, the non-absorbed fraction recovered in faeces was 20–30%.

After oral administration, metformin hydrochloride absorption is incomplete and saturable. It is assumed that the pharmacokinetics of metformin absorption are non-linear.

At the recommended metformin doses and dosing schedules, steady state plasma concentrations are reached within 24 to 48 hours. The latter is generally less than 1 µg/ml.

Food decreases the extent and slightly delays the absorption of metformin. Plasma protein binding is negligible. Metformin passes into erythrocytes. The blood peak is lower than the plasma peak and appears at approximately the same time. The red blood cells most likely represent a secondary compartment of distribution. The mean distribution volume (Vd) ranges between 63 and 276 L.

Metformin is excreted unchanged in the urine. No metabolites have been identified in humans to date.

Renal clearance of metformin is > 400 ml/min, indicating that metformin is eliminated by glomerular filtration and tubular secretion. Following an oral dose, the apparent terminal elimination half-life is approximately 6.5 hours. When renal function is impaired, renal clearance is decreased in proportion to that of creatinine and thus the elimination half-life is prolonged, leading to increased levels of metformin in plasma.

- Do not use this medicine after the expiry date which is stated on the carton and blister strip after "Exp". The expiry date refers to the last day of that month.
- Shelf life: 36 months
- Store in a dry place below 30°C. Protect from light.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Denk Pharma

Metformin Denk 1000

Comprimé pelliculé – voie orale
Antidiabétique oral
Substance active: Metformine

Notice : information de l'utilisateur

What Metformin Denk 1000 contains

The active substance is metformin. Each film-coated tablet contains 1000 mg metformin hydrochloride corresponding to 780 mg metformin.

The other ingredients are:

Tablet core: hypromellose, povidone K25, magnesium stearate.

Film coating: hypromellose, macrogol 6000, titanium dioxide.

General classification for supply

Medicinal product subject to medical prescription

What Metformin Denk 1000 looks like and contents of the pack

Metformin Denk 1000 are white, oblong film-coated tablets with a deep snap-tab break mark on one side and break mark on the other side.

The film-coated tablets can be divided into equal doses.

Metformin Denk 1000 is available in PVC/aluminum blisters.

Pack size: 30 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

DENK PHARMA GmbH & Co. KG
Prinzregentenstr. 79
81675 München
Germany

Production site

Göllstr. 1
84529 Tittmoning
Germany

This leaflet was last revised in 07/2017.

- Do not use this medicine after the expiry date which is stated on the carton and blister strip after "Exp". The expiry date refers to the last day of that month.
- Shelf life: 36 months
- Store in a dry place below 30°C. Protect from light.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Denk Pharma

Metformin Denk 1000

Comprimé pelliculé – voie orale

Antidiabétique oral

Substance active: Metformine

Notice : information de l'utilisateur

Quelles sont les informations à connaître avant de prendre Metformin Denk 1000 ?

Ne prenez jamais Metformin Denk 1000

Si vous êtes allergique à la metformine ou à l'un des autres composants contenus dans ce médicament (mentionnés dans la rubrique 6).

Si vous avez d'autres questions, interrogez votre médecin ou votre pharmacien.

Risque d'acidose lactique

Metformin Denk 1000 peut provoquer un effet indésirable rare, mais très grave, appelé « acidose lactique », en particulier si vos reins ne fonctionnent pas correctement. Le risque de développer une acidose lactique augmente également en cas de diabète mal contrôlé, d'infections graves, de jeûne prolongé ou de consommation d'alcool, de déshydratation (voir les informations complémentaires ci-dessous), de problèmes au foie et de toute autre affection médicale en présence de laquelle une partie du corps reçoit un apport réduit en oxygène (les maladies cardiaques aiguës sévères, par exemple).

Si vous ressentez un quelconque effet indésirable, parlez-en à votre médecin ou votre pharmacien. Ceci s'applique aussi à tout effet indésirable qui ne seraient pas mentionnés dans cette notice. Voir rubrique 4.

Effets indésirables fréquents (observés chez moins d'une personne sur 10)

• Modification du goût.

Effets indésirables très rares (observés chez moins d'une personne sur 1000)

• Acidose lactique. Cette complication est très rare mais elle est grave, en particulier si vos reins ne fonctionnent pas correctement. Les symptômes de l'acidose lactique sont : faiblesse, vertiges, augmentation de la transpiration, battements de cœur rapides, troubles de la vision ou difficultés à se concentrer. Ne conduisez pas ou n'utilisez pas de machines si vous commencez à ressentir ces symptômes.

3. Comment prendre Metformin Denk 1000 ?

Metformin Denk 1000 et contenu de l'emballage et autres informations

Le que contient Metformin Denk 1000

Le que contient Metformin Den