



# Flucona-Denk 100

Hard capsule – oral use  
Antimycotic  
Active substance: fluconazole

## Package leaflet: Information for the user

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

1. What Flucona-Denk 100 is and what it is used for
2. What you need to know before you take Flucona-Denk 100
3. How to take Flucona-Denk 100
4. Possible side effects
5. How to store Flucona-Denk 100
6. Contents of the pack and other information

## 1. What Flucona-Denk 100 is and what it is used for

Flucona-Denk 100 is one of a group of medicines called "antifungals". The active substance is fluconazole. Flucona-Denk 100 is used to treat infections caused by fungi and may also be used to stop you from getting a candidal infection. The most common cause of fungal infections is a yeast called *Candida*.

### Adults

You might be given this medicine by your doctor to treat the following types of fungal infections:

- Cryptococcal meningitis – a fungal infection in the brain
- Coccidioidomycosis – a disease of the bronchopulmonary system
- Infections caused by *Candida* and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Mucosal thrush – infection affecting the lining of the mouth, throat and denture sore mouth
- Genital thrush – infection of the vagina or penis
- Skin infections – e.g. athlete's foot, ring-worm, jock itch, nail infection

You might also be given Flucona-Denk 100 to:

- stop cryptococcal meningitis from coming back
- stop mucosal thrush from coming back
- reduce recurrence of vaginal thrush
- stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly)

### Children and adolescents (0 to 17 years old)

You might be given this medicine by your doctor to treat the following types of fungal infections:

- Mucosal thrush – infection affecting the lining of the mouth, throat
- Infections caused by *Candida* and found in the blood stream, body organs (e.g. heart, lungs) or urinary tract
- Cryptococcal meningitis – a fungal infection in the brain

You might also be given Flucona-Denk 100 to:

- stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly).
- stop cryptococcal meningitis from coming back

## 2. What you need to know before you take Flucona-Denk 100 if you do not take Flucona-Denk 100

Do not take Flucona-Denk 100 if you:

- are allergic to fluconazole, other medicines or any of the other ingredients of this medicine (listed in section 6). The symptoms may include itching, reddening of the skin or difficulty in breathing

- are taking astemizole, terfenadine (antihistamine medicines for allergies)
- are taking cisapride (used for stomach upsets)
- are taking pimozide (used for treating mental illness)
- are taking quinidine (used for treating heart arrhythmia)
- are taking erythromycin (an antibiotic for treating infections)

### Warnings and precautions

Talk to your doctor or pharmacist before taking Flucona-Denk 100.

Tell your doctor if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozide (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Flucona-Denk 100 (see section: "Do not take Flucona-Denk 100 if you").

There are some medicines that may interact with Flucona-Denk 100. Make sure your doctor knows if you are taking any of the following medicines:

- rifampicin or rifabutin (antibiotics for infections)
- alfentanil, fentanyl (used as anaesthetic)
- amitriptyline, nortriptyline (used as antidepressant)
- amphotericin B, voriconazole (anti-fungal)
- medicines that thin the blood to prevent blood clots (warfarin or similar medicines)
- benzodiazepines (midazolam, triazolam or similar medicines) used to help you sleep or for anxiety

Other medicines and Flucona-Denk 100 Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you have liver or kidney problems

- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood
- develop severe skin reactions (itching, reddening of the skin or difficulty in breathing)

Tell your doctor immediately if you are taking astemizole, terfenadine (an antihistamine for treating allergies) or cisapride (used for stomach upsets) or pimozide (used for treating mental illness) or quinidine (used for treating heart arrhythmia) or erythromycin (an antibiotic for treating infections) as these should not be taken with Flucona-Denk 100 (see section: "Do not take Flucona-Denk 100 if you").

### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Flucona-Denk 100 while you are pregnant or breast-feeding unless your doctor has told you to.

Ask your doctor or pharmacist for advice before taking any medicines.

### Driving and using machines

When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur.

### Flucona-Denk 100 contains lactose

Flucona-Denk 100 contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Dependent on the site of the infection 50 mg once daily, 150 mg once weekly, 300 to 400 mg once weekly for 1 to 4 weeks (Athlete's foot may be up to 6 weeks, for nail infection treatment until infected nail is replaced)

To stop you from getting an infection caused by *Candida* (if your immune system is weak and not working properly)

200 mg to 400 mg once daily while you are at risk of getting an infection

200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg

800 mg on the first day then 400 mg daily until you are told to stop

200 mg to 400 mg on the first day then 100 mg to 200 mg until you are told to stop

50 mg to 400 mg once daily for 7 to 30 days until you are told to stop

100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection

150 mg as a single dose

To reduce recurrence of vaginal thrush

To treat genital thrush

400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg

200 mg once daily until you are told to stop

200 mg to 400 mg once daily from 11 months for up to 24 months or longer if needed. Sometimes doses are increased up to 800 mg

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200 mg to 400 mg on the first day then 100 mg to 200 mg until you are told to stop

50 mg to 400 mg once daily for 7 to 30 days until you are told to stop

100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection

150 mg as a single dose

### Adults

To treat cryptococcal meningitis

To stop cryptococcal meningitis from coming back

To treat coccidioidomycosis

To treat internal fungal infections caused by *Candida*

To treat mucosal infections affecting the lining of mouth, throat and denture sore mouth

To reduce recurrence of vaginal thrush

400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg

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100 mg to 200 mg once daily, or 200 mg 3 times a week, while you are at risk of getting an infection

150 mg as a single dose

150 mg every third day for a total of 3 doses (day 1, 4 and 7) and then once a week for 6 months while you are at risk of getting an infection

400 mg on the first day then 200 mg to 400 mg once daily for 6 to 8 weeks or longer if needed. Sometimes doses are increased up to 800 mg

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150 mg as a single dose

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### Elderly

The usual adult dose should be given unless you have kidney problems.

### Patients with kidney problems

Your doctor may change your dose, depending on your kidney function.

### If you take more Flucona-Denk 100 than you should

Taking too many capsules at once may make you unwell. Contact your doctor or your nearest hospital casualty department at once. The symptoms of a possible overdose may include hearing, seeing, feeling and thinking things that are not real (hallucination and paranoid behaviour). Symptomatic treatment (with supportive measures and gastric lavage if necessary) may be adequate.

### If you forget to take Flucona-Denk 100

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A few people develop allergic reactions although serious allergic reactions are rare. If you get any of the following symptoms, tell your doctor immediately.

Lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding

red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes

severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue)

tiredness

loss of appetite

vomiting

yellowing of your skin or the whites of your eyes (jaundice)

Common side effects which affect 1 to 10 users in 100 are listed below:

headache

stomach discomfort, diarrhoea, feeling sick, vomiting

increases in blood tests of liver function

rash

uncommon side effects which affect 1 to 10 users in 1,000 are listed below:

reduction in red blood cells which can make skin pale and cause weakness or breathlessness

decreased appetite

inability to sleep, feeling drowsy

fit, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste

constipation, difficult digestion, wind, dry mouth

muscle pain

liver damage and yellowing of the skin and eyes (jaundice)

wheals, blistering (hives), itching, increased sweating

tiredness, general feeling of being unwell, fever

Rare side effects which affect 1 to 10 users in 10,000 are listed below:

lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding

red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes

severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue)

tiredness

loss of appetite

vomiting

yellowing of your skin or the whites of your eyes (jaundice)

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fit, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste

constipation, difficult digestion, wind, dry mouth

muscle pain

liver damage and yellowing of the skin and eyes (jaundice)

wheals, blistering (hives), itching, increased sweating

tiredness, general feeling of being unwell, fever

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wheals, blistering (hives), itching, increased sweating

tiredness, general feeling of being unwell, fever

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Common side effects which affect 1 to 10 users in 100 are listed below:

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stomach discomfort, diarrhoea, feeling sick, vomiting

increases in blood tests of liver function

rash

Pour éviter de développer une infection à *Candida* (si votre système immunitaire est affaibli et ne fonctionne pas correctement)

#### Adolescents âgés de 12 à 17 ans

Respectez la posologie indiquée par votre médecin (soit la posologie de l'adulte soit la posologie de l'enfant).

#### Enfants jusqu'à 11 ans

La posologie maximale chez l'enfant est de 400 mg par jour.

La posologie sera basée sur le poids de l'enfant en kilogrammes.

Affection	Dose quotidienne
Mycose de la muqueuse et infections de la gorge dues à <i>Candida</i> – la dose et la durée dépendent de la sévérité de l'infection et de sa localisation	3 mg par kg de poids corporel (une dose de 6 mg par kg de poids corporel peut être utilisée le premier jour)

Méningite à cryptocoques ou infections fongiques internes dues à <i>Candida</i>	6 mg à 12 mg par kg de poids corporel
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Pour empêcher les enfants de développer une infection à <i>Candida</i> (si leur système immunitaire ne fonctionne pas correctement)	3 mg à 12 mg par kg de poids corporel
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#### Enfants âgés de 3 à 4 semaines

Même posologie que ci-dessus mais à une fréquence de tous les 2 jours seulement. La posologie maximale est de 12 mg par kg de poids corporel toutes les 48 heures.

#### Enfants âgés de moins de 2 semaines

Même posologie que ci-dessus mais à une fréquence de tous les 2 jours seulement. La posologie maximale est de 12 mg par kg de poids corporel toutes les 72 heures.

Il arrive parfois que les médecins prescrivent d'autres doses que celle-ci.

#### Patients âgés

La dose usuelle adulte devrait être administrée sauf si vous souffrez de problèmes rénaux.

#### Patients avec des problèmes rénaux

Votre médecin pourra modifier votre dose en fonction de l'état de votre fonction rénale.

#### Si vous avez pris plus de Flucona-Denk 100 que vous n'auriez dû

Si vous prenez trop de gélules en une seule fois, vous pourriez vous sentir mal. Contactez immédiatement votre médecin ou le service des urgences de l'hôpital le plus proche. Les symptômes d'un éventuel surdosage peuvent être d'entendre, de voir, de ressentir ou de penser des choses qui ne sont pas réelles (hallucinations et comportement paranoïaque). Une prise en charge (avec un traitement symptomatique et un lavage d'estomac, si nécessaire) peut être nécessaire.

#### Si vous oubliez de prendre Flucona-Denk 100

Ne prenez pas de dose double pour compenser la dose que vous avez oublié de prendre. Si vous oubliez de prendre une dose, prenez-la dès que vous vous en rappelez. S'il est presque l'heure de votre dose suivante, ne prenez pas la dose que vous avez oublié.

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.

Quelques personnes développent des **réactions allergiques** mais les réactions allergiques graves sont rares. Si vous présentez les symptômes suivants, **prévenez immédiatement votre médecin**.

- sifflement respiratoire soudain, difficultés à respirer ou oppression dans la poitrine
- gonflement des paupières, du visage ou des lèvres
- rougeur de la peau avec démangeaisons sur tout le corps ou démangeaisons au niveau de taches rouges
- éruption cutanée
- réactions cutanées sévères telles qu'une éruption entraînant la formation de bulles (pouvant toucher la bouche et la langue).

Flucona-Denk 100 peut affecter votre foie. Les signes de problèmes hépatiques comprennent :

- de la fatigue
- une perte d'appétit
- des vomissements
- un jaunissement de la peau ou du blanc des yeux (jaunisse)

Si l'un de ces signes survient, arrêtez de prendre Flucona-Denk 100 et **prévenez immédiatement votre médecin**.

**Autres effets indésirables :**

Par ailleurs, si vous ressentez un des effets mentionnés comme graves ou si vous présentez des effets indésirables non mentionnés dans cette notice, veuillez en informer votre médecin ou votre pharmacien.

Les effets indésirables fréquents qui touchent 1 à 10 utilisateurs sur 100 sont énumérés ci-dessous :

- maux de tête
- maux d'estomac, diarrhée, nausées, vomissements
- augmentations des tests sanguins liés au fonctionnement du foie
- éruption

Les effets indésirables peu fréquents qui touchent 1 à 10 utilisateurs sur 1000 sont énumérés ci-dessous :

- réduction du nombre de globules rouges pouvant entraîner une pâleur de la peau et ils ne surviennent pas systématiquement chez tout le monde.

– sifflement respiratoire soudain, difficultés à respirer ou oppression dans la poitrine

– gonflement des paupières, du visage ou des lèvres

– rougeur de la peau avec démangeaisons sur tout le corps ou démangeaisons au niveau de taches rouges

– éruption cutanée

– réactions cutanées sévères telles qu'une éruption entraînant la formation de bulles (pouvant toucher la bouche et la langue).

– réaction cutanée sévère telle qu'une éruption entraînant la formation de bulles (pouvant toucher la bouche et la langue).

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Les effets indésirables rares qui touchent 1 à 10 utilisateurs sur 10.000 sont énumérés ci-dessous :

- diminution du nombre de globules blancs (cellules sanguines qui contribuent à combattre les infections) et des plaquettes (cellules sanguines qui contribuent à arrêter les saignements)
- coloration rouge ou violette de la peau pouvant être due à un faible nombre de plaquettes ou à d'autres modifications des cellules sanguines
- modifications biochimiques sanguines (taux élevés de cholestérol, de graisses dans le sang)
- faible taux de potassium dans le sang
- tremblements
- anomalies à l'électrocardiogramme (ECG), modification de la fréquence ou du rythme cardiaque
- insuffisance hépatique
- réactions allergiques (parfois sévères), y compris éruption bulleuse généralisée et desquamation de la peau, réactions cutanées sévères, gonflement des lèvres ou du visage
- perte de cheveux

– réaction cutanée sévère telle qu'une éruption entraînant la formation de bulles (pouvant toucher la bouche et la langue).

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

**Ce que contient Flucona-Denk 100**

La substance active est le fluconazole. Chaque gélule contient 100 mg de fluconazole.

Les autres composants sont : Lactose monohydraté, cellulose microcristalline, amidon de maïs, dioxyde de silicium, haute dispersion, stéarate de magnésium, laurylsulfate de sodium, gélatine, dioxyde de titane, oxyde ferrique jaune.

**Conditions de délivrance**

Médicament soumis à prescription médicale

**Aspect de Flucona-Denk 100 et contenu de l'emballage extérieur**

Gélules beiges.

Flucona-Denk 100 est disponible sous forme de plaquettes thermoformées en PVC/PVDC et aluminium.

Présentation : boîte de 10 gélules

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

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

**Site de production**

Göllstr. 1  
84529 Tittmoning  
Allemagne

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**Ce que contient Flucona-Denk 100**

La substance active est le fluconazole. Chaque gélule contient 100 mg de fluconazole.

Les autres composants sont : Lactose monohydraté, cellulose microcristalline, amidon de maïs, dioxyde de silicium, haute dispersion, stéarate de magnésium, laurylsulfate de sodium, gélatine, dioxyde de titane, oxyde ferrique jaune.

**Conditions de délivrance**

Médicament soumis à prescription médicale

**Aspect de Flucona-Denk 100 et contenu de l'emballage extérieur**

Gélules beiges.

Flucona-Denk 100 est disponible sous forme de plaquettes thermoformées en PVC/PVDC et aluminium.

Présentation : boîte de 10 gélules

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

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

**Site de production**

Göllstr. 1  
84529 Tittmoning  
Allemagne

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uma candidíase. A causa comum mais frequente das infecções fúngicas é o fungo denominado *Candida*.

**Adultos**

O seu médico pode-lhe ter receitado este medicamento para tratar os seguintes tipos de infecção fúngica:

- Meningite criptocócica – uma infecção fúngica no cérebro
- Coccidioidomíose – uma doença no sistema broncopulmonar
- Infecções causadas por *Candida* presentes na circulação sanguínea, nos órgãos (por ex. coração, pulmões) ou tracto urinário
- Candidíase das mucosas – infecção ao redor da boca, garganta e lesão bucal provocada por prótese dentária
- Candidíase genital – infecção da vagina ou pênis
- Infecções da pele – por ex. pé de atleta, micose, infecção da virilha, infecção na unha

– candidíase das mucosas – infecção ao redor da boca, garganta e lesão bucal provocada por prótese dentária

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#### 2. O que precisa de saber antes de tomar Flucona-Denk 100

**Não tome Flucona-Denk 100**

– se tem alergia (hipersensibilidade) ao fluconazol, a outros medicamentos que tomou para tratar infecções fúngicas ou a qualquer outro componente deste medicamento (indicados na secção 6). Os sintomas podem incluir comichão, vermelhidão da pele ou dificuldade em respirar

- se está a tomar astemizol, terfenadina (medicamentos anti-histaminicos para alergias)
- se está a tomar cisaprida (utilizada para problemas de estômago)
- se está a tomar pimozida (utilizada para tatar doença mental)
- se está a tomar quinidina (utilizado para tratar arritmia cardíaca)
- se está a tomar eritromicina (um antibiótico para tratar infecções)

– se está a tomar cisaprida (utilizada para problemas de estômago)

– se está a tomar pimozida (utilizada para tatar doença mental)

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Assure-se que o seu médico tem conhecimento se está a tomar alguns dos seguintes medicamentos:

- rifampicina ou rifabutina (antibióticos anti-fúngicos)
- alfentanilo, fentanilo (utilizados como anestésicos)
- amitriptilina, nortriptilina (utilizados como anti-depressivos)
- anfetocina B, voriconazol (antifúngicos)
- medicamentos que tornam o sangue mais fluido para prevenir coágulos sanguíneos (varfarina ou medicamentos similares)
- benzodiazepinas (midazolam, triazolam ou medicamentos similares) utilizados para o ajudar a dormir ou para a ansiedade
- carbamazepina, fenitoína (utilizado no tratamento de convulsões)
- nifedipina, isradipina, amlodipina, felodipina e losartan (para a hipertensão – pressão arterial elevada)
- ciclosporina, everolimus, sirolimus ou tacrolimus (para prevenir a rejeição do transplante)
- ciclofosfamida, alcalóides da vinca (vincristina, vinblastina ou medicamentos similares) utilizados para reduzir os níveis de colesterol elevados
- metadona (utilizado na dor)
- celecoxib, flurbiprofeno, naproxeno, ibuprofeno, lornoxicam, meloxicam, diclofenac (Medicamentos anti-inflamatórios não esteróides [AINES])
- contraceptivos orais
- prednisona (esteróide)
- zidovudina, também conhecido como AZT; saquinavir (utilizados em doentes infectados com o VIH)
- medicamentos para a diabetes como a clorpropamida, glibenclamida, glizipida ou tolbutamida
- teofilina (utilizado para controlar a asma)
- vitamina A (suplemento nutricional)

– ciclofosfamida, alcalóides da vinca (vincristina, vinblastina ou medicamentos similares) utilizados para reduzir os níveis de colesterol elevados

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#### Gravidez e amamentação

Se está grávida ou a amamentar, se pensa estar grávida ou planeia engravidar, consulte o seu médico ou farmacêutico antes de tomar este medicamento. Não deve tomar Flucona-Denk 100 enquanto estiver grávida ou a amamentar a menos que o seu médico lhe tenha dito para o tomar.

Consulte o seu médico ou farmacêutico antes de tomar qualquer medicamento.

**Condução de veículos e utilização de máquinas**

Durante a condução de veículos ou utilização de máquinas, deve ter-se em consideração que podem ocorrer, ocasionalmente, vertigens ou convulsões.

**Flucona-Denk 100 contém lactose**

Flucona-Denk 100 contém lactose (açúcar do leite). Se foi informado pelo seu médico que tem intolerância a alguns açúcares, contacte-o antes de tomar este medicamento.

**3. Como tomar Flucona-Denk 100**

Tome este medicamento exatamente como indicado pelo seu médico. Fale com o seu médico ou farmacêutico se tiver dúvidas.

Engula a cápsula inteira com um cop