

**PACKAGE LEAFLET: INFORMATION FOR THE USER****Read this entire leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**In this leaflet:**

1. What Flucytosine 500mg Tablet is and what it is used for
2. What you need to know before you take Flucytosine 500mg Tablet
3. How to take Flucytosine 500mg Tablet
4. Possible side effects
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6. Contents of the pack and other information

**1. WHAT FLUCYTOSINE 500mg TABLET IS AND WHAT IT IS USED FOR**

Pharmacotherapeutic group: antifungal for systemic use, ATC code: J: General anti-infectives for systemic use. This medicine is indicated for the treatment of certain fungal infections (microscopic fungi).

**2. What you need to know before you take FLUCYTOSINE 500mg TABLET****Do not take Flucytosine 500mg Tablet:**

- if you are allergic to any of the ingredients,
- if you know that you have no dihydropyrimidine dehydrogenase (DPD) enzyme activity (complete DPD deficiency).
- if you are being treated with antiviral nucleoside analogues (medicines that inhibit dihydropyrimidine dehydrogenase (DPD)) or with uracil.
- if you are breast feeding

**Warnings and precautions**

Take special care with Flucytosine 500mg Tablet,

**Special warnings and precautions for use**

- Tell your doctor if you have poor kidney function.
- If you are a woman of childbearing potential, you must use effective contraception during treatment and up to 1 month after the end of treatment.
- If you are a man, you or your partner of childbearing potential must use effective contraception during treatment and up to 3 months after the end of treatment.
- Do not miss the laboratory blood tests that your doctor may ask you to have done.
- Tell your doctor before you start treatment if you are on herpes treatment with antiviral nucleoside analogues or if you have been on this treatment within the last 4 weeks.
- IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

**Other medicines and Flucytosine 500mg Tablet**

Flucytosine 500mg Tablet must not be used with some antiviral nucleoside analogues that inhibit dihydropyrimidine dehydrogenase (DPD) or with uracil.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

**Flucytosine 500mg Tablet with food and drink**

Not applicable.

**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.

This medicine must not be used during pregnancy unless absolutely necessary, as it is likely to have a harmful (teratogenic) effect on the unborn child.

If you find out that you are pregnant during treatment, consult your doctor as soon as possible: only he/she can adjust the treatment to your condition and will implement close monitoring of your pregnancy and child.

If your doctor has prescribed this medicine for you, you must not breast-feed (breast-feeding is contraindicated).

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

If you are a woman of childbearing potential, you must use effective contraception during treatment and up to 1 month after the end of treatment.

If you are male, you or your partner of childbearing potential must use effective contraception during treatment and up to 3 months after the end of treatment.

**Driving and using machines**

Not applicable

**3. How to take Flucytosine 500mg Tablet****Posology**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Method of administration**

Oral use

**Frequency of administration**

The daily dose should be divided into 3 to 4 doses at mealtimes. The tablets must be swallowed with a glass of water.

**Use in children**

Although clinical data are available in children, these are not sufficient to support precise dosing recommendations for this age group. If this medicine is prescribed to your child, the doctor will choose the most appropriate dose. Due to the prolonged elimination of flucytosine in paediatric patients, particularly in very young children, administration of flucytosine may mean that optimal blood levels are exceeded. Therefore, your child will undergo routine blood monitoring throughout treatment to determine flucytosine levels.

**Duration of treatment**

To be effective, this medicine must be used at the prescribed doses and for as long as your doctor has advised you.

**If you take more Flucytosine 500mg Tablet than you should**

Not applicable

**If you forget to take Flucytosine 500mg Tablet**

Not applicable

**If you stop taking Flucytosine 500mg Tablet**

Not applicable.

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.

- Minor digestive disorders: diarrhoea, nausea, vomiting, stomachache, inflammatory bowel disease (ulcerative colitis)
- Allergic reactions, skin rash, severe skin rash that may lead to skin detachment, itching and skin reactions on exposure to sunlight or UV (photosensitivity)
- Biological disorders affecting the red blood cells, white blood cells, platelets and liver enzymes,
- Lesions (hepatitis), which may be fatal
- Exceptionally heart trouble
- Low level of potassium in the blood (hypokalaemia)
- Confusion, hallucinations (seeing or hearing things that are not there)
- Headache, drowsiness, convulsion, skin sensitivity disorder (paraesthesia), peripheral neuropathy
- Vertigo
- Difficulty breathing, chest pain, respiratory arrest and inability of the respiratory system to perform properly (respiratory insufficiency).
- Change in kidney function (renal impairment) and associated biological changes
- Fever

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

#### Reporting of side effects

If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

#### 5. How to store Flucytosine 500mg Tablet.

Keep out of the reach and sight of children.

For container pack: Do not store above 30°C, Protect from moisture, Store in the original bottle tightly closed.

Do not remove the desiccant.

Do not use Flucytosine tablets 500mg after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. FURTHER INFORMATION

##### What Flucytosine 500mg Tablet contains

- The active substance is Flucytosine.  
Each Flucytosine 500mg tablet contains Flucytosine 500mg

**The other ingredients are:** – Corn Starch /Maize starch, Povidone, Microcrystalline Cellulose, Crospovidone, Colloidal Silicon Dioxide and Magnesium Stearate.

**What Flucytosine 500mg Tablets looks like and contents of the pack:**

White to off white, round, biconvex, beveled edge, uncoated tablets debossed with “K” and “24” separated by break-line on one side and plain on other side

**Flucytosine tablets 500mg will be packed in:**

**Container pack: 100’s Tablet with silica gel**

100 tablets packed in 120cc white, round, HDPE Container with 38mm Screw neck finish with 38mm Closure child resistant 123 white printed with heat seal liner with 1g Silica gel sachet and Polyester coil 12g/yard along with pack insert.

**Supplier**

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**This leaflet was last approved on {MM/YYYY}:**

Detailed information on this medicinal product is available on PQTm’s website (see:

<http://www.who.int/prequal>.