PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

ANCOTIL 500 mg, tablet

Flucytosine

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. 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 the leaflet. See section 4.

What is in this leaflet

1. WHAT ANCOTIL 500 mg, 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 ANCOTIL 500 mg, TABLET

Do not take ANCOTIL 500 mg, 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 ANCOTIL 500 mg, 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 6 months 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. In case of reduced kidney function, the contraception period should be prolonged for additional two months.
- 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 ANCOTIL 500 mg, tablet

ANCOTIL 500 mg, 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.

ANCOTIL 500 mg, 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.

Contraception in men and women

If you are a woman of childbearing potential, you must use effective contraception during treatment and up to 6 months 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. If you have reduced kidney function, you should add two extra months to this contraception period.

Driving and using machines

Not applicable.

ANCOTIL 500 mg, tablet contains:

Not applicable.

3. HOW TO TAKE ANCOTIL 500 mg, 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 ANCOTIL 500 mg, tablet than you should:

Not applicable.

If you forget to take ANCOTIL 500 mg, tablet:

Not applicable.

If you stop taking ANCOTIL 500 mg, 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 ANCOTIL 500 mg, TABLET?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

Do not store above 25°C. Store in the original bottle. Keep the bottle tightly closed in order to protect from moisture. Do not remove the desiccant canister.

Do not throw away any medicines in wastewater or household waste. 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

What ANCOTIL 500 mg, tablet contains

- The active substance is:
  Flucytosine 500 mg per tablet.

- The other ingredients are maize starch, microcrystalline cellulose, precipitated hydrated silica, povidone, magnesium stearate.

What ANCOTIL 500 mg, tablet looks like and contents of the pack

This medicine is presented in tablet form. Bottle of 100.

Supplier and Manufacturer

Supplier	Manufacturer
Mylan Laboratories Limited Plot No.564/A/22, Road No.92, Jubilee Hills Hyderabad, Telangana – 500096, India Email: Imtiyaz.basade@viatris.com	**ICN POLFA RZESZOW SPOLKA AKCYJNA** UL. PRZEMYSLOWA 2 35-959 RZESZWO POLAND

For any information about this medicinal product, please contact the local representative of the supplier:

This leaflet was last revised on 26 April 2022.

Detailed information on this medicine is available on the World Health Organization (WHO) web site: https://extranet.who.int/prequal