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 ANCOTIL 500 mg, tablet is and what it is used for
2. What you need to know before you take ANCOTIL 500 mg, tablet
3. How to take ANCOTIL 500 mg, tablet
4. Possible side effects
5. How to store ANCOTIL 500 mg, tablet
6. Contents of the pack and other information.

1. WHAT ANCOTIL 500 mg, TABLET IS AND WHAT IT IS USED FOR

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 are undergoing certain antiviral treatments that inhibit dihydropyrimidine dehydrogenase (DPD),
- if you are breast-feeding.

Take special care with ANCOTIL 500 mg, tablet:

Special warnings and precautions for use
- Tell your doctor if you have kidney failure.
- 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.
• Do not miss the laboratory blood tests that your doctor may ask you to have done.

For children who cannot swallow, the tablets should be crushed and mixed for administration.

IF IN DOUBT, DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

ANCOTIL 500 mg, tablet must not be used with certain antiviral treatments that inhibit dihydropyrimidine dehydrogenase (DPD).
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
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.

Athletes
Not applicable.

Driving and using machines
Not applicable.

3. HOW TO TAKE ANCOTIL 500 mg, TABLET
Dosage
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.

**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 gastrointestinal disorders: nausea, diarrhoea, more rarely vomiting,
- Allergic skin conditions,
- Biological disorders affecting the red blood cells, white blood cells, platelets and liver enzymes,
- In exceptional cases, heart disorders.

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: *Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance (French National Agency for the Safety of Medicinal and Health Products (ANSM) and the network of French Regional Pharmacovigilance Centres)* - website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

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.

Store below 25°C and protected from moisture.

Do not throw away any medicines via 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.

Marketing Authorisation Holder
MEDA PHARMA
40-44 RUE WASHINGTON
75008 PARIS

Marketing Authorisation Distributor
MEDA PHARMA
40-44 RUE WASHINGTON
75008 PARIS

Manufacturer
ICN POLFA RZESZOW SPOLKA AKCYJNA
UL. PRZEMYSLOWA 2
35-959 RZESZWO
POLAND

This medicinal product is authorised in the Member States of the EEA under the following names:
Not applicable.

This leaflet was last revised in:
April 2017

Other
Detailed information on this medicine is available on the website of ANSM (France).