ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ANCOTIL 500 mg, tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Flucytosine..... 500 mg

Per tablet.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Severe systemic fungal infections with susceptible pathogens, as an alternative to or when switching from parenteral use, particularly: candidiasis, cryptococcosis, chromoblastomycosis and certain forms of aspergillosis.

Combination with another antifungal agent:

Flucytosine must be used in combination, in order to avoid the selection of resistant mutations as far as possible, especially in the treatment of candidiasis and cryptococcosis.

Combination with amphotericin B is often synergistic and never antagonistic.

4.2 Posology and method of administration

Oral use.

Posology

Dosages range from 100 to 200 mg/kg per day, depending on the nature of the infection, its site and the sensitivity of the causative agent.

The daily dosage must be divided into 3 or 4 oral doses.

Use in patients with renal impairment

Doses are administered at longer intervals, using the following dosage regimen:

CREATININE CLEARANCE	INDIVIDUAL DOSE	INTERVAL
≥ 40 mL/min	25 to 50 mg/kg	6 hours
20≤Cl<40 mL/min	25 to 50 mg/kg	12 hours
10≤Cl<20 mL/min	25 to 50 mg/kg	24 hours
Cl < 10 mL/min	Single dose of 25 mg/kg, then plasma monitoring 12 hours after the initial dose, before repeating the dose.	

Patients on dialysis

Since flucytosine is dialysable, the dose of this medicinal product must be repeated after each renal replacement session.

In anuric or nephrectomised patients on haemodialysis, the initial dose must not be repeated before the next dialysis session under any circumstances.

Hepatic impairment

The use of flucytosine has not been studied in patients with hepatic impairment.

Although hepatic impairment is not expected to have a significant effect on the pharmacokinetics of flucytosine, strict monitoring is necessary when treating patients with hepatic impairment with Ancotil. (See section 4.4 and section 5.2.)

Combinations with other antifungals

The flucytosine/amphotericin B combination is synergistic: in some cases, it allows the dose to be reduced and reduces the risk of secondary resistance to flucytosine.

Strict monitoring of renal function is necessary with this combination (see section 4.4).

There does not seem to be antagonism with imidazole derivatives.

Elderly patients

Since clinical data on the use of flucytosine in elderly patients are limited, this medicinal product may only be used in these patients if the expected benefit outweighs the potential risks.

Particular attention must be paid to renal function in this population.

Paediatric population

The available data are not sufficient to support evidence-based dosing recommendations in paediatric patients, including term and preterm neonates.

Flucytosine must not be used as first-line therapy or as monotherapy in paediatric patients. Flucytosine must be used in combination with other adequate antifungal agents when other appropriate medicinal products are not available or are unlikely to be effective.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Breastfeeding (see section 4.6).

Confirmed complete dihydropyrimidine dehydrogenase (DPD) deficiency.

Combination with irreversible inhibitors of dihydropyrimidine dehydrogenase (DPD), such as brivudine, sorivudine and their analogues, or uracil, a reversible DPD inhibitor, is contraindicated (see section 4.4).

Concomitant use of flucytosine and the tegafur/gimeracil/oteracil combination (where tegafur is a prodrug of 5-FU and gimeracil is a reversible inhibitor of DPD) (see sections 4.4 and 4.5).

4.4 Special warnings and precautions for use

Treatment with this medicinal product should be started after identification of the strain and evaluation of its susceptibility to flucytosine, due to the possibility of primary resistance. Treatment should be continued under regular medical surveillance.

Special monitoring

It is recommended that a blood count and liver function tests (ALT, AST, alkaline phosphatase) be performed prior to initiation of treatment, then regularly throughout it, especially during the initiation phase.

Patients with hepatic impairment may be treated with flucytosine but strict clinical and laboratory monitoring of liver function (AST, ALT, alkaline phosphatase) is required in conjunction with monitoring of plasma flucytosine levels.

This medicinal product must be used with caution in patients with bone marrow suppression or blood dyscrasia, as well as in patients treated with immunosuppressive or cytostatic agents; due to a high risk of haematological damage, strict clinical and laboratory (blood count) monitoring must be instituted, together with monitoring of plasma flucytosine levels.

Warnings with regard to renal function

As elimination of this medicinal product is exclusively renal, creatinine clearance must be regularly monitored in patients with renal impairment or in combination with a nephrotoxic agent likely to affect renal function, and the dosage must be adjusted according to creatinine clearance (see section 4.2).

65-75% of Ancotil present in the body is removed by haemodialysis. Therefore, in patients on dialysis, administration of this medicinal product must be repeated after each dialysis or renal replacement session.

Interference with laboratory test results

Measurement of creatinine: Flucytosine can have an effect on the two-step enzyme measuring method for creatinine levels and lead to false-positive diagnosis of azotaemia. Other methods are therefore recommended for measuring creatinine levels.

Dihydropyrimidine dehydrogenase (DPD) enzyme deficiency

5-fluorouracil is a metabolite of flucytosine. DPD is an enzyme that plays a key role in the metabolism and elimination of 5-fluorouracil.

The risk of severe adverse reactions associated with the medicinal product is therefore increased when Ancotil is used in individuals with dihydropyrimidine dehydrogenase (DPD) deficiency. Determination of DPD activity may be considered when drug toxicity is confirmed or suspected.

In the event of suspected drug toxicity, discontinuation of Ancotil treatment must be considered. A minimum interval of 4 weeks must be observed after treatment with sorivudine or other analogues that inhibit DPD, such as brivudine, prior to treatment with Ancotil.

A minimum interval of 7 days between treatment with the tegafur/gimeracil/oteracil combination and initiation of Ancotil treatment must be respected (see sections 4.3 and 4.5).

Monitoring plasma flucytosine levels during treatment

Flucytosine levels must be monitored in order to adjust the dosage accordingly.

The mean steady-state serum level should be 35 to 70 µg/mL. In most sensitive strains, *in vitro* sensitivity is characterised by a minimum inhibitory concentration of between 10 and 25 µg/mL. However, values below 25 µg/mL must be avoided due to an increased risk of developing resistance at low concentrations. Prolonged serum levels above 100 µg/mL must be avoided due to an increased risk of severe haematological toxicity.

Contraception in men and women

Flucytosine is partially metabolised to 5-fluorouracil, which is genotoxic and considered to be potentially teratogenic in humans. Women of childbearing potential must use effective contraception during treatment and for 6 months after discontinuation of treatment. In patients with renal impairment, this contraception period should be extended by a further 2 months. Male patients (or their female partners of childbearing potential) must use effective contraception during treatment and for 3 months after discontinuation of treatment (see section 4.6). In patients with renal impairment, this contraception period should be extended by a further 2 months.

Paediatric population

Flucytosine has a narrow therapeutic index and there is a risk of potential toxicity at high systemic concentrations.

Due to the prolonged elimination of flucytosine in paediatric patients, particularly in term and preterm neonates, administration of flucytosine may mean that optimal serum levels are exceeded. Plasma flucytosine levels must be monitored based on local (or national) guidelines for antifungal treatment and the dose adjusted as necessary to avoid excessive exposure to flucytosine.

Blood count and renal function must be checked regularly in paediatric patients during treatment in order to monitor creatinine concentrations and clearance.

The tablets are not suitable for children who are unable to swallow solid formulations.

4.5 Interaction with other medicinal products and other forms of interaction

Contraindicated combinations (see section 4.3)

+ Antiviral antiherpes nucleoside analogues (e.g. brivudine, sorivudine and their analogues)

+ Uracil

Antiviral antiherpes nucleoside analogues (e.g. brivudine, sorivudine and their analogues) and uracil are potent inhibitors of dihydropyrimidine dehydrogenase (DPD), an enzyme that metabolises fluorouracil (see sections 4.4 and 4.5).

Since fluorouracil is a metabolite of flucytosine, combining these medicinal products with Ancotil is contraindicated (see section 4.3).

Concomitant use of the tegafur/gimeracil/oteracil combination (where tegafur is a prodrug of 5-FU and gimeracil is a reversible inhibitor of DPD) and flucytosine is contraindicated (see section 4.3) as it may lead to additional toxicities.

Combinations requiring precautions for use

+ Zidovudine

Increased haematological toxicity (additive myelotoxic effects). More frequent monitoring of blood counts.

Combinations to be taken into account

+ Ganciclovir, valganciclovir

Increased haematological toxicity.

+ Cytotoxics

Increased haematological toxicity.

+ Immunosuppressants (ciclosporin, everolimus, sirolimus, tacrolimus, temsirolimus)

Increased haematological toxicity.

4.6 Fertility, pregnancy and lactation

Contraception in men and women

Flucytosine is partially metabolised to 5-fluorouracil, which is genotoxic and considered to be potentially teratogenic in humans (see section 5.3: Preclinical safety data).

Women of childbearing potential must use effective contraception during treatment and for 6 months after discontinuation of treatment. In patients with renal impairment, this contraception period should be extended by a further 2 months. Male patients (or their female partners of childbearing potential) must use effective contraception during treatment and for 3 months after discontinuation of treatment. In patients with renal impairment, this contraception period should be extended by a further 2 months.

Pregnancy

Studies in animals have shown reproductive toxicity for flucytosine and one of its metabolites (5-fluorouracil) (teratogenicity and embryotoxicity) (see section 5.3).

In humans, flucytosine crosses the placenta.

There are very limited data from the use of flucytosine in pregnant women.

Embryonic or foetal toxicity cannot be excluded, especially in the event of exposure during the first trimester. Therefore, Ancotil must not be used during pregnancy or in women of childbearing potential without effective contraception, unless absolutely necessary for life-threatening infections where there is no effective therapeutic alternative.

If Ancotil is administered during pregnancy, the patient must be advised of the teratogenic risk from Ancotil and careful prenatal and postnatal monitoring must be carried out. Furthermore, if administered up until delivery, in view of the safety profile of flucytosine, neonatal surveillance (haematological and hepatic) must be performed.

Breastfeeding

There are no data on the excretion of flucytosine in breast milk.

Breastfeeding is contraindicated during treatment with flucytosine (see section 4.3).

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Gastrointestinal disorders:

Common: nausea, diarrhoea, vomiting, abdominal pain

Frequency not known: ulcerative colitis

Blood disorders:

Haematological disorders (leukopenia, thrombocytopenia), which are usually moderate and transient and are more common in patients with renal impairment or when serum flucytosine levels exceed 100 µg/mL. More severe disorders (aplasia, agranulocytosis) that are potentially irreversible and may be fatal in exceptional cases have sometimes been observed, mainly in patients who are also undergoing myelotoxic treatment.

Frequency not known: eosinophilia

Hepatobiliary disorders:

Common: elevated transaminases (AST, ALT) and alkaline phosphatase, resolving upon discontinuation of treatment.

Frequency not known: acute hepatitis, cytolytic hepatitis sometimes with fatal outcome

Cardiac disorders:

Frequency not known: cardiac disorders usually of an ischaemic nature, myocardial toxicity, ventricular function disorders, cardiac arrest, tachycardia, arrhythmia

Immune system disorders:

Urticaria, hypersensitivity

Metabolism and nutrition disorders:

Frequency not known: hypokalaemia

Psychiatric disorders:

Frequency not known: confusion, hallucinations

Nervous system disorders:

Frequency not known: headache, sedation, convulsions, paraesthesia, peripheral neuropathy

Ear and labyrinth disorders:

Frequency not known: vertigo

Respiratory and thoracic disorders:

Frequency not known: dyspnoea, chest pain, respiratory arrest, acute respiratory failure

Skin and subcutaneous tissue disorders:

Frequency not known: pruritus, maculopapular erythema, photosensitivity reaction, Lyell's syndrome

Renal and urinary disorders:

Frequency not known: renal impairment, elevated serum creatinine and blood urea

General disorders and administration site conditions:

Frequency not known: fever

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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 Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centres) - website: www.signalement-sante.gouv.fr.

4.9 Overdose

In the event of overdose, which may result from impaired renal function in particular, exaggerated adverse reactions, especially haematological effects, can be expected. Blood counts must therefore be very closely monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antifungal for systemic use, ATC code: J: General antiinfectives for systemic use.

Activity: fungistatic in humans, at therapeutic doses.

Natural spectrum: *Candida* serotype A, *Cryptococcus neoformans*, chromoblastomycosis agents, and to a lesser extent *Aspergillus*.

Mechanism of action

The cells of Ancotil-sensitive pathogens are able to absorb flucytosine (5-FC), which is subsequently metabolised to 5-fluorouracil (5-FU) via a specific cytosine deaminase. The amount of 5-FU incorporated into the ribonucleic acids of the pathogen is proportional to the pathogen's susceptibility.

Resistance is possible due to:

- Cases of primary resistance. Only an *in vitro* study of the strain in question can evaluate its susceptibility.
- The risk of acquired resistance during treatment. Combination with another antifungal is recommended.

Strains initially susceptible to Ancotil may acquire resistance during treatment. It is therefore recommended that the sensitivity of these strains be evaluated before and also during treatment. (The method described by Shadomy and Speller is well suited.) Use of 5-FC discs is recommended.

For some pathogen species, synergy has been demonstrated *in vitro* and *in vivo* with a combination of Ancotil and amphotericin B, which is particularly pronounced in the case of organisms with reduced susceptibility to Ancotil.

5.2 Pharmacokinetic properties

Absorption

When administered orally, 90% of this treatment is absorbed by the digestive tract and the same concentrations are obtained as those observed following short-term IV infusion with an identical dose. After single IV administration, peak serum concentrations are approximately equivalent, in micrograms/mL, to the dose administered in mg/kg.

Distribution

The volume of distribution is between 0.5 and 1 L/kg. This medicinal product is diffused throughout the body, including in the CSF, as a result of very low binding (< 5%) to plasma proteins.

Urinary concentrations of this medicinal product are always higher than plasma concentrations in patients with normal renal function.

Metabolism

More than 90% of the flucytosine dose is recovered in unchanged form in the urine. Flucytosine is metabolised (probably by intestinal bacteria) to 5-fluorouracil (5-FU). The 5-FU/5-FC plasma concentration ratio is low.

Elimination

The plasma half-life is 3 to 6 hours. Elimination is rapid via the kidneys, mainly by glomerular filtration, in unchanged form. In patients with renal impairment, the plasma half-life is prolonged; the dosage must therefore be adjusted to creatinine clearance (see section 4.2).

Flucytosine is dialysable.

Paediatric population

There are limited data available on the pharmacokinetic properties of flucytosine in paediatric patients. These suggest that the half-life of flucytosine is longer in children than in adults (7 vs 4 h), particularly in neonates. A pharmacokinetic study in neonates showed that the half-life of flucytosine was twice as long as in adults, even though peak concentrations were comparable. In addition, the volume of distribution of flucytosine is close to the total body water volume because of its high solubility. In a retrospective study of 391 paediatric patients, 65% of trough concentrations of flucytosine exceeded the normal reference range values.

5.3 Preclinical safety data

In vitro studies on the mutagenic potential of flucytosine are negative. No studies are available on the carcinogenic potential of Ancotil.

Flucytosine is teratogenic and embryotoxic in rats receiving oral or parenteral doses of at least 40 mg/kg per day (240 mg/m^2 or 0.043 times the daily human dose).

5-fluorouracil, a metabolite of flucytosine, is genotoxic in mice and, *in vitro*, embryotoxic and teratogenic in mice and rats; it is classified as potentially teratogenic in humans. Malformations (abnormalities of the nervous system, palate, skeleton, tail and limbs) have occurred in several species (including rats and Syrian hamsters).

Embryotoxic effects (small foetus, resorption) have also been observed in monkeys treated with 5-fluorouracil.

Flucytosine and 5-fluorouracil cross the placental barrier.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch, microcrystalline cellulose, precipitated hydrated silica, polyvidone, magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Store below 25°C and protect from moisture.

6.5 Nature and contents of container

100 tablets in a tube (polyethylene) closed by a polyethylene stopper.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

VIATRIS MEDICAL
1 BIS PLACE DE LA DEFENSE
TOUR TRINITY

92400 COURBEVOIE 8. MARKETING AUTHORISATION NUMBER(S)

- 34009 317 964 3 5: 100 tablets in a tube (polyethylene).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[to be completed later by the holder]

10. DATE OF REVISION OF THE TEXT

05/02/2024

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

List I

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicine

ANCOTIL 500 mg, tablet

Flucytosine

Text box

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

Pharmacotherapeutic group: antifungal for systemic use, ATC code: J: General antiinfectives for systemic use.

This medicine is used to treat some 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 do not have an enzyme called dihydropyrimidine dehydrogenase (DPD) (complete DPD deficiency)
- if you are being treated with antiviral nucleoside analogues that inhibit dihydropyrimidine dehydrogenase (DPD) or with uracil
- if you are taking tegafur/gimeracil/oteracil (an anticancer medication) concurrently
- if you are breast-feeding.

Warnings and precautions

Take special care with ANCOTIL 500 mg, tablet:

<u>Special warnings and precautions for use</u>

- Tell your doctor if you have kidney failure.
- If you are a woman of childbearing age, you must use effective contraception during treatment and for 6 months fter stopping treatment.
- If you are a man, you (or your partner of childbearing age) must use effective contraception during treatment and for 3 months after stopping treatment.
- Do not miss the blood tests that your doctor may ask you to have done.
- Tell your doctor before you start treatment if you are on antiherpes 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.

If you have taken tegafur/gimeracil/oteracil (an anticancer medication), you must wait at least 7 days before starting Ancotil.

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 arrange close monitoring of your pregnancy and your 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 age, you must use effective contraception during treatment and for 6 months after stopping treatment.

If you are a man, you (or your partner of childbearing age) must use effective contraception during treatment and for 3 months after stopping 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

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 or 4 doses, taken 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.

Use in children

Although clinical data are available for children, these are not enough to give exact recommendations on the dose in this age group. If this medicine is prescribed to your child, your doctor will choose the most suitable dose. As flucytosine takes longer to be eliminated in paediatric patients, and especially in very young children, giving flucytosine may mean that serum levels are too high. Because of this, your child will have regular blood tests throughout their treatment to measure their flucytosine levels.

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 may cause side effects, although not everybody gets them.

- Digestive complaints: diarrhoea, nausea, vomiting, stomach ache, 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 light (photosensitivity)
- Abnormal test results affecting the red blood cells, white blood cells, platelets and liver enzymes
- Lesions (hepatitis), which can be fatal
- In exceptional cases, heart disorders
- Low levels of potassium in the blood (hypokalaemia)
- Confusion, hallucinations (seeing or hearing things that are not there)
- Headache, drowsiness, seizures, problems with skin sensitivity (paraesthesia), peripheral neuropathy
- Dizziness (vertigo)
- Difficulty breathing, chest pain, respiratory arrest, and inability of the respiratory system to work properly (respiratory failure)
- Change in kidney function (renal impairment) and related changes on laboratory test results
- Fever

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 Medicines and Health Products (ANSM) and network of French Regional Pharmacovigilance Centres) - website: www.signalementsante.gouv.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 protect 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 provided in tablet form. Box of 100.

Marketing Authorisation Holder

VIATRIS MEDICAL
1 BIS PLACE DE LA DEFENSE
TOUR TRINITY
92400 COURBEVOIE

Marketing Authorisation Distributor

VIATRIS SANTE
1 BIS PLACE DE LA DEFENSE
TOUR TRINITY
92400 COURBEVOIE

Manufacturer

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

This medicine is authorised in the Member States of the European Economic Area under the following names:

Not applicable.

This leaflet was last revised in

05/02/2024

Other sources of information

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