Information for healthcare professionals
Ancotil® 2.5 g/250 ml (1 g in 100 ml) Solution for Infusion
Flucytosine

This leaflet provides technical information about Ancotil for the healthcare professional. The tear-off portion attached is intended for the patient.

Presentation
Infusion bottles contain 2.5 g flucytosine in 250 ml isotonic sodium chloride solution.

Other excipients are sodium chloride, tromethamine, hydrochloric acid and water for injections. The solution is colourless to slightly yellow.

Uses
Ancotil is a fluorinated pyrimidine effective in the treatment of certain systemic fungal infections.

In female patients, the treatment is effective in the prevention of relapses due to resistant strains of Candida albicans. Flucytosine has demonstrated successful cure of fungemia, but at a lower rate than that observed with amphotericin B.

Dosage and administration
Adults and children
Ancotil for infusion should be administered using a set. It may be administered directly into a vein, through a central venous catheter, or by intra-peritoneal infusion. The recommended adult dose is 2.5 g (per 100 ml) flucytosine. Patients weighing more than 60 kg should receive 2.5 g flucytosine (240 mg/m2 or 0.043 times the human daily dose). The flucytosine metabolite 5-fluorouracil is genotoxic in mice and in vitro, embryotoxic and teratogenic in mice. 5-fluorouracil is genotoxic in mice and in vitro, embryotoxic and teratogenic in mice.

In children, the daily dose should be calculated according to body weight (see table). For children weighing more than 60 kg, the dose should be calculated according to body surface area (see table). Doses for premature infants are available in specific leaflets, but it is recommended that the dose is not increased above the recommended dose.

The duration of treatment should be determined on an individual basis. The duration of therapy will be affected by variations in the individual susceptibility of the infecting organism, its accessibility and its susceptibility to Ancotil, as well as by differences in the response of individual patients.

Contra-indications and warnings
Contra-indications
Ancotil is contra-indicated in patients with known hypersensitivity to flucytosine or any of the excipients and are being treated with antiviral nucleoside analogues.

Caution should be exercised in patients with bone marrow depression, patients who are pregnant or breast-feeding, and patients with renal or hepatic impairment.

Topical use
Flucytosine has been shown to be teratogenic and embryotoxic in rats when given in oral or parenteral doses of 40 mg/kg body weight per day onwards (240 mg/kg or 0.043 times the human daily dose). The flucytosine metabolite 5-fluorouracil is genotoxic in mice and in vitro, embryotoxic and teratogenic in mice.

Patients and pregnant women
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The treatment period with Ancotil will vary on a patient by patient basis, but treatment will not usually be longer than a few weeks. 

Ancotil can be given with a glucose and/or saline infusion. It should not be mixed in the same solution with other medicines.

4. POSSIBLE SIDE EFFECTS 

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

Your doctor will monitor your reaction to Ancotil. Possible side effects may include:

- Nausea, vomiting, diarrhoea and skin rashes may occur but these usually do not last long.

Less frequent side effects include:

- Allergic reaction. If you have an allergic reaction you may experience palpitations, swelling of eyes, face, lips, mouth or tongue, sudden wheeziness, chest tightness, lumpy skin etc.

- Skin inflammation that may lead to severe blistering.

- Effects on the heart muscle and its pumping.

- Confusion, effects on your senses (e.g. seeing or hearing things), fits, headache, sleepiness and dizziness.

- Tests on your blood may show changes to your liver or certain factors in your blood.

- Ancotil contains 34.5 mmol (or 0.8 g) sodium/250 ml solution for infusion. To be taken into consideration by patients on a controlled sodium diet.

5. HOW ANCOTIL SOLUTION FOR INFUSION IS STORED

- All medicines should be kept out of the reach and sight of children.

- Hospital staff should store Ancotil between 18°C and 25°C.

- This product should not be used after the expiry date shown on the bottle label after “EXP”. The expiry date refers to the last day of that month.

- Before administration, Ancotil should be visually inspected for any particulate matter and discolouration.

- Do not use Ancotil if you notice that there are any visible particles, precipitation or discolouration.

- For single use only. Discard any remaining contents after use.

- The product should only be handled by experienced healthcare professionals.

- Medicines should not be disposed of via wastewater or household waste. The pharmaceutical industry will provide instructions as to how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ancotil Solution for Infusion contains

Active substance: Flucytosine. Each infusion bottle contains 2.5 g in 250 ml (1 g in 100 ml) of flucytosine.

Other ingredients: Sodium chloride, tromethamine, hydrochloric acid, and water for injections.

What Ancotil Solution for Infusion looks like and contents of the pack

- Ancotil Solution for Infusion is a clear, colourless to slightly yellow solution.

- Ancotil Solution for Infusion is available in packs of 5 bottles of 250 ml.

Marketing Authorisation Holder

Mylan Products Ltd.

Station Close, Posters Bar, Hertfordshire, EN4 8TL, United Kingdom

Meda Health Sales Ireland Limited

Unit 34/35, Ballylumford Business Park, Dunboyne, Co. Meath, Ireland.

Manufacturer

Mylan Products Ltd & Co. KG

Benzstrasse 1, 6332 Bad Homburg, Germany.

For any information about this medicine, please contact the Marketing Authorisation Holder:

This leaflet was last revised in March 2018.

Information on the safety of this medicine.

You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

For the United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

For the Republic of Ireland:

HPRA Pharmacovigilance

Eirfort Terrace, Tull.

Email: info@hpра.ie

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