

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/pqweb/sites/default/files/documents/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA753 trade name][†]
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 questions about the medicine, ask your health care provider.
- 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 seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HA753 trade name] is and what it is used for
2. What you need to know before you take [HA753 trade name]
3. How to take [HA753 trade name]
4. Possible side effects
5. How to store [HA753 trade name]
6. Contents of the pack and other information

1. What [HA753 trade name] is and what it is used for

[HA753 trade name] is one of a group of medicines called antifungals and contains the active substance flucytosine.

[HA753 trade name] is used to treat certain serious systemic fungal infections, such as candidiasis, cryptococcosis, chromoblastomycosis and certain forms of aspergillus. It is usually used in combination with other medicines as an alternative to, or when switching from injectable medicines.

2. What you need to know before you take [HA753 trade name]

Do not take [HA753 trade name]:

- if you are allergic to flucytosine or any of the ingredients of this medicine (see Section 6)
- 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 (medicines that inhibit dihydropyrimidine dehydrogenase (DPD)) or with uracil.
- If you are breastfeeding.

Warnings and precautions

- Tell your health care provider if you have kidney disease or poor kidney function.
- If you are a woman and you can have children, you must use effective contraception during treatment and up to one 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 three months after the end of treatment.
- Do not miss laboratory blood tests that your health care provider may ask you to have done.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

- Tell your health care provider before you start treatment with [HA753 trade name] if you are on herpes treatment with antiviral nucleoside analogues or if you have been on this treatment within the last four weeks.
- **If in doubt, please ask your health care provider for advice.**

Taking other medicines and [HA753 trade name]

[HA753 trade name] must not be used with some antiviral nucleoside analogues that inhibit dihydropyrimidine dehydrogenase (DPD) or with uracil.

Tell your health care provider if you are using, have recently used, or might use any other medications.

[HA753 trade name] with food or drink

[HA753 trade name] can be taken with or without food.

Pregnancy and breastfeeding

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

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

If you find out that you are pregnant during treatment, consult your health care provider as soon as possible. He or she can adjust the treatment to your condition and will implement close monitoring of your pregnancy and child.

If your health care provider has prescribed this medicine for you, you must not breastfeed.

3. How to take [HA753 trade name]

Always take your medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

[HA753 trade name] should be taken by mouth with a glass of water.

Frequency of administration

The daily dose should be divided into 3 or 4 doses.

Duration of treatment

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

Use in children

Although clinical data are available in children, these are not sufficient to support precise dosing recommendations for this age group. If [HA753 trade name] is prescribed to your child, your health care provider 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.

If you take more [HA753 trade name] than you should

If you accidentally take more [HA753 trade name] tablets than your health care provider recommended, contact your health care provider at once or contact the nearest hospital for advice.

If you forget to take [HA753 trade name]

It is important not to miss a dose of this medicine.

If you do miss a dose, you should take the next tablet at the usual time. Do not take a double dose (two doses close together).

If you stop taking [HA753 trade name]

It is important that you continue to take [HA753 trade name] during the whole treatment period. Otherwise, the medicine may not be effective in treating your infection. Do not stop taking [HA753 trade name] unless your health care provider tells you to.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

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

Common side effects (which may affect up to 1 in 10 people) include:

- nausea
- vomiting
- diarrhoea
- abdominal pain

Other side effects (of unknown frequency) include:

- allergic reactions, fever
- skin rash that may be serious and lead to skin detachment
- skin reactions on exposure to sunlight or ultraviolet light
- reduction in red blood cells, white blood cells or platelets
- increase in liver function tests or rarely, inflammation of the liver, which can be serious or fatal
- headache, drowsiness, convulsions, or damage to nerves causing loss of sensation or pins and needles sensation
- confusion, hallucinations (seeing or hearing things that are not there)
- difficulty breathing
- changes in kidney function and low levels of potassium in the blood

If any side effects become serious, or if you notice any side effects that are 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 improve understanding about the safety of this medicine.

5. How to store [HA753 trade name]

Do not store above 30°C. Store in the original container.

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

Do not use this medicine after the expiry date stated on the bottle after “EXP”. The expiry date refers to the last day of that month.

After first opening the bottle, tablets to be used within 100 days.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [HA753 trade name] contains

- The active ingredient is flucytosine. Each tablet contains 250 mg flucytosine.
- The other ingredients of [HA753 trade name] are: corn starch (maize starch), povidone, partially pregelatinized maize starch, silicon dioxide, microcrystalline cellulose, magnesium stearate.

What [HA753 trade name] looks like and contents of the pack

[HA753 trade name] is a white to off-white, round, flat-faced, round edge tablet debossed with 'M' on one side and 'FU1' on the other side.

The tablets are packed in a white, round HDPE bottle, closed with white opaque polypropylene screw cap with aluminium induction seal liner wad and white absorbent cotton fibre. Pack size: 100 tablets.

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
Plot No. 564/A/22
Road No. 92, Jubilee Hills
Hyderabad – 500096
Telangana
India
e-mail: Imtiyaz.basade@viatris.com

Manufacturer

Mylan Laboratories Limited
Plot No. 11, 12 & 13 Indore Special Economic Zone
Pharma Zone, Phase – II, Sector – III
Pithampur – 454775, Dist. Dhar
Madhya Pradesh
India

For any information about this medicine, contact the supplier.

This leaflet was last revised in November 2021

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/pqweb/medicines>