

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/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HA754 trade name][†]
Flucytosine

*The warnings and instructions in this leaflet are intended for the person taking the medicine.
If you are a parent or carer responsible for giving the medicine to someone else such as a child,
you will need to apply the instructions accordingly.*

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 is for you only. Do not pass it on to others. It may harm them, even if their illness seems 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 [HA754 trade name] is and what it is used for
2. What you need to know before you take [HA754 trade name]
3. How to take [HA754 trade name]
4. Possible side effects
5. How to store [HA754 trade name]
6. Contents of the pack and other information

1. What [HA754 trade name] is and what it is used for

[HA754 trade name] is one of a group of medicines called antifungals and contains the active substance flucytosine.

[HA754 trade name] is used to treat some serious fungal infections that have spread to different parts of the body. These include conditions called candidiasis, cryptococcosis or cryptococcal meningitis, chromoblastomycosis and certain forms of aspergillosis.

[HA754 trade name] is used in combination with other medicines for fungal infection, and is usually given as an alternative to, or when switching from, injectable medicines.

2. What you need to know before you take [HA754 trade name]

Do not take [HA754 trade name]:

- if you are allergic to flucytosine or any of the ingredients of this medicine (see Section 6)
- if you have been told that you do not have an enzyme called dihydropyrimidine dehydrogenase (DPD) (complete DPD deficiency).
- if you are being treated with antiviral medicines for shingles called brivudine or sorivudine, which stop DPD from working, or with the medicine uracil which also affects the action of DPD.
- if you are being treated with the cancer medicines fluorouracil, capecitabine or the combination tegafur/gimeracil/oteracil.

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

Warnings and precautions

- Your health care provider will carry out blood tests before starting treatment and during treatment, to check for side effects on your blood, liver and kidneys and ensure the medicine is working. Blood tests are particularly important when the medicine is given to children. Tell your health care provider before starting treatment if you have kidney disease or poor kidney function, problems with your blood, bone marrow or liver.
- Also tell your health care provider if you are receiving treatment for cancer or if you have been treated for shingles in the last 4 weeks, as some medicines used for these conditions may increase the risk of side effects with [HA754 trade name].
- 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 any partner who can become pregnant must use effective contraception during treatment and for three months after the end of treatment.
- **If in doubt, please ask your health care provider for advice.**

Taking other medicines and [HA754 trade name]

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

[HA754 trade name] must not be used with some medicines to treat shingles or with some cancer medicines. Also, treatments that affect your blood and bone marrow or how well your kidneys work may increase the risk of side effects with [HA754 trade name].

Make sure to tell your health care provider if you are taking medicines for HIV, as the dose of [HA754 trade name] or of your HIV medicines may need to be adjusted.

If you take phenytoin for epilepsy, your doctor may carry out additional tests or adjust your phenytoin dose.

[HA754 trade name] with food or drink

[HA754 trade name] can be taken with or without food.

Pregnancy and breastfeeding

This medicine is used to treat very serious infections that may be life-threatening. However, if you are pregnant it may have a harmful effect on your 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.

You may need to use contraception during treatment and for a while afterwards (see ‘Warnings and precautions’, above).

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 [HA754 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.

Your health care provider will work out the right dose of [HA754 trade name] for you, based on your weight and condition. You will also be given other medicines that work with [HA754 trade name] to treat the fungal infection.

[HA754 trade name] should be taken by mouth with a glass of water.

You will take [HA754 trade name] 4 times a day, and each time you may have to take several tablets. If there is more than 1 tablet to take for a dose, you can spread them out over about 15 minutes with a short interval in between each tablet; this can help reduce stomach upsets and feeling sick.

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

If you take more [HA754 trade name] than you should

If you accidentally take more [HA754 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 [HA754 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 [HA754 trade name]

It is important that you continue to take [HA754 trade name] during the whole treatment period. Otherwise, the medicine may not be effective in treating your infection. Do not stop taking [HA754 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:

- feeling sick (nausea)
- being sick (vomiting)
- diarrhoea
- belly ache
- rash
- low levels of white blood cells and blood platelets

Other side effects (of unknown frequency) include:

- allergic reactions, fever
- inflammation of the bowel (ulcerative colitis)
- heart problems, abnormal heart rhythm
- skin rash that may be serious and lead to skin detachment
- itching, red patches on the skin
- skin reactions on exposure to sunlight or ultraviolet light
- effects on the bone marrow leading to very low levels of blood cells, abnormal levels of white blood cells called eosinophils
- 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
- dizziness (vertigo)
- confusion, hallucinations (seeing or hearing things that are not there)
- difficulty breathing
- pain in the chest
- 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 a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

For reporting of adverse events and PV related queries please write to Email: ProductSafety@viatris.com

5. How to store [HA754 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 use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

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 [HA754 trade name] contains

- The active ingredient is flucytosine. Each tablet contains 500 mg flucytosine.
- The other ingredient(s) of [HA754 trade name] are: corn starch (maize starch), povidone, partially pregelatinized maize starch, silicon dioxide, microcrystalline cellulose, magnesium stearate.

What [HA754 trade name] looks like and contents of the pack

[HA754 trade name] is a white to off-white, round, uncoated tablet. They are flat on the top and bottom with round edge. The tablet have 'M' debossed (stamped into the tablet) above the break-line on one side and 'FU2' debossed (stamped into the tablet) on the other side.

The break line can be used to divide [HA754 trade name] into equal doses

[HA754 trade name] is provided in a round white HDPE bottle containing 100 tablets. The bottle is closed with white opaque polypropylene screw cap with aluminium induction seal liner wad and white absorbent cotton fibre.

Supplier and Manufacturer

Supplier

Mylan Laboratories Limited
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For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>