PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

FLUCYTOSINE MYLAN 250 mg Tablets

FLUCYTOSINE MYLAN 500 mg Tablets

Flucytosine

Sugar free

Read all of this leaflet carefully before you start taking FLUCYTOSINE MYLAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FLUCYTOSINE MYLAN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FLUCYTOSINE MYLAN is and what it is used for
2. What you need to know before you use FLUCYTOSINE MYLAN
3. How to use FLUCYTOSINE MYLAN
4. Possible side effects
5. How to store FLUCYTOSINE MYLAN
6. Contents of the pack and other information

1. What FLUCYTOSINE MYLAN is and what it is used for

FLUCYTOSINE MYLAN contains flucytosine which is an antifungal medicine for oral use.

FLUCYTOSINE MYLAN is indicated for the treatment of certain fungal infections (microscopic fungi).

2. What you need to know before you take FLUCYTOSINE MYLAN

You should not take FLUCYTOSINE MYLAN:

- if you are allergic (hypersensitive) to flucytosine or any other ingredients of FLUCYTOSINE MYLAN (listed in section 6);
- if you know that you have no dihydropyrimidine dehydrogenase (DPD) enzyme activity (complete DPD deficiency);
- if you are undergoing certain antiviral treatments that inhibit dihydropyrimidine dehydrogenase (DPD);
- if you are breastfeeding.

Warnings and precautions

Take special care with FLUCYTOSINE MYLAN:

- if you have kidney failure (poor kidney function);
- if you are a woman of childbearing potential, as you must use effective contraception during treatment and up to 1 month after the end of treatment;
- if you are male, as 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.

Tell your doctor before you start treatment if you are on herpes treatment with antiviral nucleoside analogues or if you have been on this treatment within the last 4 weeks.

A reduced starting dose should be considered to limit the risk of severe toxicity for patients with partial DPD deficiency (as they are at an increased risk of severe and potentially life-threatening toxicity) *(see section 3 'How to take FLUCYTOSINE MYLAN*')

Other medicines and FLUCYTOSINE MYLAN

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

FLUCYTOSINE MYLAN 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.

FLUCYTOSINE MYLAN with food and drink:

You should take FLUCYTOSINE MYLAN tablets with food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby while taking FLUCYTOSINE MYLAN, please consult your doctor, pharmacist or other healthcare professional for advice before taking FLUCYTOSINE MYLAN.

Pregnancy

FLUCYTOSINE MYLAN 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.

Breast-feeding

If your doctor has prescribed FLUCYTOSINE MYLAN for you, you must not breast-feed (breast-feeding is contraindicated).

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.

Driving and using machines

FLUCYTOSINE MYLAN should not affect your ability to drive or to use machines.

3. How to take FLUCYTOSINE MYLAN

Do not share medicines prescribed for you with any other person.

Always take FLUCYTOSINE MYLAN 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.

A reduced starting dose should be considered to limit the risk of severe toxicity for patients with partial DPD deficiency (as they are at an increased risk of severe and potentially life-threatening toxicity).

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

Duration of treatment

To be effective, FLUCYTOSINE MYLAN must be used at the prescribed doses and for as long as your doctor has advised you.

If you have the impression that the effect of FLUCYTOSINE MYLAN is too strong or too weak, tell your doctor or pharmacist.

If you take more FLUCYTOSINE MYLAN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of FLUCYTOSINE MYLAN:

If you forget to take a dose of FLUCYTOSINE MYLAN, take it as soon as possible. However if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

FLUCYTOSINE MYLAN can have side effects.

Not all side effects reported for FLUCYTOSINE MYLAN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLUCYTOSINE MYLAN, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking FLUCYTOSINE MYLAN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing;
- severe skin rash that may lead to skin detachment.

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUCYTOSINE MYLAN. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- nausea,
- diarrhoea,
- vomiting,
- skin rash,
- itching,
- severe skin reactions on exposure to sunlight or UV (photosensitivity)
- blood disorders affecting the red blood cells, white blood cells and platelets,
- increases in liver enzymes levels,
- inflammation of the liver,
- heart disease,
- low level of potassium in the blood (hypokalaemia) ,
- confusion,
- hallucinations (seeing or hearing things that are not there),
- headache,
- drowsiness,

- convulsion,
- skin sensitivity disorder (paraesthesia),
- peripheral neuropathy,
- vertigo,
- difficulty breathing,
- chest pain,
- respiratory arrest and inability of the respiratory system to perform properly (respiratory insufficiency),
- change in kidney function (renal impairment) and associated biological changes,
- fever.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of FLUCYTOSINE MYLAN.

5. How to store FLUCYTOSINE MYLAN

Store all medicines out of reach of children.

Store at or below 25 °C and protect from moisture.

Do not store in a bathroom.

Do not use after the expiry date stated on the bottle label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Keep the bottle tightly closed.

6. Contents of the pack and other information

What FLUCYTOSINE MYLAN contains

The active substance is flucytosine.

FLUCYTOSINE MYLAN 250 mg contains 250 mg flucytosine per tablet.

FLUCYTOSINE MYLAN 500 mg contains 500 mg flucytosine per tablet.

The other ingredients are corn starch, magnesium stearate, maize starch, microcrystalline cellulose, povidone and silicon dioxide.

What FLUCYTOSINE MYLAN looks like and contents of the pack

FLUCYTOSINE MYLAN 250 mg:

White to off white round, flat faced round edge tablet debossed with **M** on one side and **FU1** on the other side of the tablet.

FLUCYTOSINE MYLAN 500 mg:

White to off white round, flat faced round edge tablet debossed with **M** above the break line on one side and **FU2** on the other side of the tablet.

FLUCYTOSINE MYLAN 250 mg and 500 mg tablets are packed in a HDPE bottle.

The HDPE bottle pack comprises of a round, wide mouth white high density polyethylene bottle with a white opaque polypropylene screw cap closure with aluminium induction sealing liner wad with or without a desiccant.

Pack size: 100 tablets per bottle.

Holder of Certificate of Registration

MYLAN (PTY) LTD

4 Brewery Street

Isando, 1600

Gauteng

Republic of South Africa

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FLUCYTOSINE MYLAN 500 mg: 54/20.2.2/0749

Access to the corresponding Professional Information

Can be obtained from the SAHPRA website www.sahpra.org.za