# Front Side

335 mm

260 mm

Grain Direction

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS** S4

**FLUCYTOSINE 500 mg MACLEODS tablets**
Flucytosine
Sugar Free

**Read all of this leaflet carefully before you start taking FLUCYTOSINE 500 mg MACLEODS**
- 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 500 mg MACLEODS** 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 500 mg MACLEODS** is and what it is used for
2. What you need to know before you take **FLUCYTOSINE 500 mg MACLEODS**
3. How to take **FLUCYTOSINE 500 mg MACLEODS**
4. Possible side effects
5. How to store **FLUCYTOSINE 500 mg MACLEODS**
6. Contents of the pack and other information


## 1. What FLUCYTOSINE 500 mg MACLEODS is and what it is used for

**FLUCYTOSINE 500 mg MACLEODS** contains flucytosine which is an antifungal medicine for oral use.

**FLUCYTOSINE 500 mg MACLEODS** is indicated for the treatment of certain fungal infections (microscopic fungi).

## 2. What you need to know before you take FLUCYTOSINE 500 mg MACLEODS

**Do not take FLUCYTOSINE 500 mg MACLEODS**:
- if you are allergic (hypersensitive) to flucytosine or any other ingredients of **FLUCYTOSINE 500 mg MACLEODS** (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) such as cancer treatments that include eniluracil, tegafur ;
- if you are breastfeeding.

**FLUCYTOSINE 500 mg MACLEODS**
PM04342854

**Warnings and precautions**
**Take special care with FLUCYTOSINE 500 mg MACLEODS.**
- 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.
Your doctor will reduce the starting dose to limit the risk of severe toxicity if you have been diagnosed with partial DPD deficiency (as you are at an increased risk of severe and potentially life-threatening toxicity) (see **section 3 'How to take FLUCYTOSINE 500 mg MACLEODS'**)

**Other medicines and FLUCYTOSINE 500 mg MACLEODS**
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
**FLUCYTOSINE 500 mg MACLEODS** must not be used with certain antiviral treatments that inhibit dihydropyrimidine dehydrogenase (DPD) such as brivudine, soriudine).
**FLUCYTOSINE 500 mg MACLEODS** must be used with caution with the antifungal amphotericin B.
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **FLUCYTOSINE 500 mg MACLEODS**.

**FLUCYTOSINE 500 mg MACLEODS** 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.

**Breastfeeding**
If your doctor has prescribed **FLUCYTOSINE 500 mg MACLEODS** for you, you must not breastfeed (breastfeeding 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 500 mg MACLEODS** should not affect your ability to drive or to use machines.
It is not always possible to predict to what extent **FLUCYTOSINE 500 mg MACLEODS** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **FLUCYTOSINE 500 mg MACLEODS** affects them.

## 3. How to take FLUCYTOSINE 500 mg MACLEODS

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

Always take **FLUCYTOSINE 500 mg MACLEODS** exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are not sure.
**The recommended dose is:**
The dose of **FLUCYTOSINE 500 mg MACLEODS** depends on your body weight. Your doctor will work out the dose for you.
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 will be considered to limit the risk of severe toxicity to you if you have partial DPD deficiency (as you are at an increased risk of severe and potentially life-threatening toxicity).

To be effective, **FLUCYTOSINE 500 mg MACLEODS** 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 500 mg MACLEODS** is too strong or too weak, talk to your doctor or pharmacist.

**If you take more FLUCYTOSINE 500 mg MACLEODS than you should**

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

**If you forget to take FLUCYTOSINE 500 mg MACLEODS**
If you forget to take a dose of **FLUCYTOSINE 500 mg MACLEODS**, 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 500 mg MACLEODS** can have side effects.
Not all side effects reported for **FLUCYTOSINE 500 mg MACLEODS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **FLUCYTOSINE 500 mg MACLEODS**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **FLUCYTOSINE 500 mg MACLEODS** 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 500 mg MACLEODS**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
*Less frequent*
- Feeling sick (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
- Increasing liver enzyme levels
- Inflammation of the liver
- Heart disease

*Frequency unknown*
- Urticaria
- Low level potassium in the blood (hypokalaemia)
- Confusion
- Hallucinations (seeing or hearing things that are not there)
- Headache
- Drowsiness
- Convulsion
- Skin sensitivity disorder (paraesthesia)
- Peripheral neuropathy - Symptoms include pain, numbness, tingling, swelling, or muscle weakness in the hands, feet, legs, or arms. Symptoms usually start in the hands or feet and worsen over time
- Vertigo - feels like you or your surroundings are moving or spinning, even though there's no actual movement
- 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.
Should your general health worsen or if you experience any untoward effects while taking **FLUCYTOSINE 500 mg MACLEODS**, please consult your healthcare provider for advice.

**Reporting of side effects**
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com
By reporting side effects, you can help provide more information on the safety of **FLUCYTOSINE 500 mg MACLEODS**.

## 5. How to store FLUCYTOSINE 500 mg MACLEODS

Store at or below 30 °C.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Protect from moisture.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Contents of pack and other information

**What FLUCYTOSINE 500 mg MACLEODS contains**
The active ingredient is flucytosine.
The other ingredients are:
Microcrystalline cellulose
Corn starch/ Maize starch
Povidone K29/32
Crospovidone
Colloidal silicon dioxide
Magnesium stearate

**What FLUCYTOSINE 500 mg MACLEODS looks like and contents of the pack**
White to off white, round, biconvex, beveled edge, uncoated tablets debossed with "K" and "24" separated by break-line on one side and plain on other side.

**Contents of the pack:**
Tablets are packed in plain aluminium foil laminated with polyethylene film on both sides. Pack sizes include 6's tablets.
Round, white, HDPE container with neck finish, containing tablets silica, gel sachets and Polyester coil closed with white polypropylene closure with pulp and heat seal liner and packed in a pre-printed unit carton.
Pack sizes include 100's tablets.
Not all pack sizes may be marketed.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

**MACLEODS PHARMACEUTICALS SA (PTY) LTD**
Ground Floor, Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive,
Bassonia Rock Ext 12
Alberton
Gauteng

**This leaflet was last revised on**
20 August 2025

**Registration numbers**
**FLUCYTOSINE 500 mg MACLEODS:** 58/20.2.2/0028

**Access to the corresponding Professional Information**
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or email macleodsrsa@macleodspharma.com or contact 011 682 1169

# Back Side

335 mm

260 mm

**PASIËNTINLIGTINGSTUK**

**SKEDULERINGSTATUS:** S4

**FLUCYTOSINE 500 mg MACLEODS tablette**
**Flusitosien**
**Suikervry**

**Lees hierdie hele voubiljet sorgvuldig deur voordat u FLUCYTOSINE 500 mg MACLEODS begin gebruik.**
- Bêre hierdie voubiljet. Dit mag nodig wees om dit weer te lees.
- Vra die dokter, apteker, verpleegster of ander gesondheidsorgverskaffer indien u nog vrae het.
- **FLUCYTOSINE 500 mg MACLEODS** is vir u persoonlik voorgeskryf. Moenie die medisyne met ander mense deel nie. Dit kan skadelik wees vir ander persone, selfs as die persone se simptome dieselfde is as u simptome.

**Wat is in hierdie inligtingsblad**

1. Wat **FLUCYTOSINE 500 mg MACLEODS** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **FLUCYTOSINE 500 mg MACLEODS** gebruik
3. Hoe om **FLUCYTOSINE 500 mg MACLEODS** te gebruik
4. Moontlike newe-effekte
5. Hoe om **FLUCYTOSINE 500 mg MACLEODS** te bêre
6. Inhoud van die pak en ander inligting


## 1. Wat FLUCYTOSINE 500 mg MACLEODS is en waarvoor dit gebruik word

**FLUCYTOSINE 500 mg MACLEODS** bevat flusitosien, wat 'n antifungale medisyne vir mondelikse gebruik is.
**FLUCYTOSINE 500 mg MACLEODS** word aangedui vir die behandeling van sekere swaminfeksies (mikroskopiese swamme).

## 2. Wat u moet weet voordat u FLUCYTOSINE 500 mg MACLEODS gebruik

**Moenie FLUCYTOSINE 500 mg MACLEODS neem:**
- indien u allergies (hipersensitief) is vir flusitosien of enige ander bestanddele van **FLUCYTOSINE 500 mg MACLEODS** (gelys in **afdeling 6**);
- indien u weet dat u geen dihidropirimidiendehidrogenase (DPD) ensiemaktiwiteit het nie (volledige DPD-tekort);
- indien u sekere antivirale behandelings ondergaan wat dihidropirimidiendehidrogenase (DPD) inhibeer, soos kankerbehandelings wat enilurasiel, tegafur insluit;
- indien u borsvoed.

**Waarskuwings en voorsorgmaatreëls**
**Wees veral versigtig met FLUCYTOSINE 500 mg MACLEODS**
- indien u nierversaking (swak nierfunksie) het;
- indien u 'n vrou van vrugbare ouderdom is, aangesien u effektiewe voorbehoeding tydens behandeling en tot 1 maand na die einde van behandeling moet gebruik;
- indien u 'n man is, aangesien u of u lewensmaat van vrugbare ouderdom effektiewe voorbehoeding tydens behandeling en tot 3 maande na die einde van behandeling moet gebruik;

Moenie die laboratoriumbloedtoetse mis wat u dokter u mag vra om te laat doen nie. Vertel u dokter voordat u met behandeling begin as u herpesbehandeling met antivirale nukleosiedanaloë ontvang of as u hierdie behandeling binne die afgelope 4 weke ontvang het.

U dokter sal die aanvangsdosis verminder om die risiko van ernstige toksisiteit te beperk as u gedeeltelike DPD-tekort het (aangesien u 'n verhoogde risiko het van ernstige en potensieel lewensgevaarlike toksisiteit) (sien **afdeling 3 'Hoe om FLUCYTOSINE 500 mg MACLEODS te neem'**).

**Ander medisyne en FLUCYTOSINE 500 mg MACLEODS**
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
**FLUCYTOSINE 500 mg MACLEODS** moet nie saam met sekere antivirale behandelings soos brivudine of soriudien, wat dihidropirimidiendehidrogenase (DPD) inhibeer, gebruik word nie.
**FLUCYTOSINE 500 mg MACLEODS** moet met omsigtigheid saam met die antifungale middel amfoterisien B gebruik word.
Vertel u dokter of apteker as u enige ander medisyne gebruik, onlangs gebruik het of dalk sal gebruik.

**Swangerskap, borsvoeding en vrugbaarheid**
Indien u swanger is of borsvoed, dink u mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer om advies voor u **FLUCYTOSINE 500 mg MACLEODS** gebruik.

**FLUCYTOSINE 500 mg MACLEODS** moet nie tydens swangerskap gebruik word nie, tensy dit absoluut noodsaaklik is, aangesien dit waarskynlik 'n skadelike (teratogene) effek op die ongebore kind kan hê. As u tydens behandeling uitvind dat u swanger is, raadpleeg u dokter so gou as moontlik: slegs hy/sy kan die behandeling by u toestand aanpas en sal u swangerskap en baba noukeurig monitor.

**Borsvoeding**
As u dokter **FLUCYTOSINE 500 mg MACLEODS** vir u voorgeskryf het, moet u nie borsvoed nie (borsvoeding is teenaangedui).

**Kontrasepsie**
As u 'n vrou van vrugbare ouderdom is, moet u effektiewe voorbehoeding gebruik tydens behandeling en tot 1 maand na die einde van die behandeling.
As u 'n man is, moet u of u lewensmaat van vrugbare ouderdom effektiewe voorbehoeding gebruik tydens behandeling en tot 3 maande na die einde van die behandeling.

**Bestuur en die gebruik van masjiene**
Dit is onwaarskynlik dat **FLUCYTOSINE 500 mg MACLEODS** u vermoë om te bestuur of enige gereedskap of masjiene te gebruik sal beïnvloed.
Dit is nie altyd moontlik om te voorspel tot watter mate **FLUCYTOSINE 500 mg MACLEODS** die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem nie totdat hulle bewus is tot watter mate **FLUCYTOSINE 500 mg MACLEODS** hulle beïnvloed.

## 3. Hoe om FLUCYTOSINE 500 mg MACLEODS te gebruik

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.

Neem altyd **FLUCYTOSINE 500 mg MACLEODS** presies soos deur die dokter of apteker voorgeskryf. Vra die dokter of apteker as u nie seker is nie.

**Die aanbevole dosis is:**
Die dosis van **FLUCYTOSINE 500 mg MACLEODS** hang af van u liggaamsgewig. U dokter sal die dosis vir u uitwerk.
Die daaglikse dosis moet in 3 tot 4 dosisse tydens maaltye verdeel word. Die tablette moet met 'n glas water geneem word.
'n Verlaagde aanvangsdosis sal oorweeg word om die risiko van ernstige toksisiteit te beperk as u gedeeltelike DPD-tekort het (aangesien u 'n verhoogde risiko van ernstige en potensieel lewensbedreigende toksisiteit het).

Om effektief te wees, moet **FLUCYTOSINE 500 mg MACLEODS** gebruik word teen die voorgeskrewe dosisse en vir so lank as wat u dokter voorgestel het.

As u die indruk het dat die effek van **FLUCYTOSINE 500 mg MACLEODS** te sterk of te swak is, praat met u dokter of apteker.

**Indien u meer FLUCYTOSINE 500 mg MACLEODS gebruik het as wat u moes**
In geval van oordosering, raadpleeg u dokter of apteker. Indien een nie beskikbaar is nie, kry hulp by die naaste hospitaal of gifbeheersentrum.

**Indien u vergeet om FLUCYTOSINE 500 mg MACLEODS te neem**
Indien u vergeet om 'n dosis **FLUCYTOSINE 500 mg MACLEODS** te neem, neem dit so gou as moontlik. As dit egter amper tyd vir u volgende dosis is, slaan die gemiste dosis oor en gaan terug na u gereelde doseringskedule. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

## 4. Moontlike newe-effekte

**FLUCYTOSINE 500 mg MACLEODS** kan newe-effekte hê.
Nie alle newe-effekte wat vir **FLUCYTOSINE 500 mg MACLEODS** aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid agteruitgaan of u enige ongewenste reaksies ervaar terwyl u **FLUCYTOSINE 500 mg MACLEODS** gebruik, raadpleeg asseblief u dokter, apteker of gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om **FLUCYTOSINE 500 mg MACLEODS** te neem en vertel u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, tong en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak;
- ernstige veluitslag wat tot velloslating kan lei.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u moontlik 'n ernstige reaksie op **FLUCYTOSINE 500 mg MACLEODS** gehad. U benodig moontlik dringende mediese aandag of hospitalisasie.

Vertel u dokter as u enige van die volgende opmerk:
*Newe-effekte wat minder dikwels aangemeld is:*
- Siek gevoel (naarheid)
- Diarree
- Braking
- Veluitslag
- Jeuk
- Erge velreaksies op blootstelling aan sonlig of UV (fotosensitiwiteit)
- Bloedafwykings wat die rooibloedselle, witbloedselle en bloedplaatjies aantas
- Verhoogde lewerensiemvlakke
- Inflammasie van die lewer
- Hartsiekte

*Newe-effekte waarvan die voorkoms onbekend is*
- Urtikarie
- Lae vlak kalium in die bloed (hipokalemie)
- Verwarring
- Hallusinasies (sien of hoor dinge wat nie daar is nie)
- Hoofpyn
- Lomerigheid
- Stuiptrekkings
- Velsensitiwiteitsversteuring (parestesie)
- Perifere neuropatie - Simptome sluit in pyn, gevoelloosheid, tinteling, swelling of spierswakheid in die hande, voete, bene of arms. Simptome begin gewoonlik in die hande of voete en vererger met verloop van tyd.
- Vertigo - dit voel asof jy of jou omgewing beweeg of draai, al is daar geen werklike beweging nie.
- Moeilike asemhaling
- Borspyn
- Asemhalingsarres en onvermoë van die asemhalingstelsel om behoorlik te funksioneer (respiratoriese ontoereikendheid)
- Verandering in nierfunksie (nierversaking) en gepaardgaande biologiese veranderinge
- Koors

Indien u enige newe-effekte waarneem wat nie in hierdie voubiljet genoem word nie, stel asseblief u dokter of apteker in kennis.
Indien u algemene gesondheid agteruitgaan of u enige ongewenste reaksies ervaar terwyl u **FLUCYTOSINE 500 mg MACLEODS** gebruik, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

**Rapportering van newe-effekte**
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegster. Dit sluit enige moontlike newe-effekte in wat nie in hierdie voubiljet gelys word nie. U kan ook newe-effekte aan SAHPRA rapporteer via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op die SAHPRA-webwerf gevind kan word, of aan Macleods Pharmaceuticals SA (Pty) Ltd. by safety@macleodspharma.com
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **FLUCYTOSINE 500 mg MACLEODS**.

## 5. Hoe om FLUCYTOSINE 500 mg MACLEODS te bêre

Berg by of benede 30 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bêre in die oorspronklike verpakking/houer.
Beskerm teen vog.
Moenie in 'n badkamer bêre nie.
Moenie gebruik na die vervaldatum wat op die blisterverpakking/etiket/karton/bottel aangedui word nie.
Stuur alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

## 6. Inhoud van die pak en ander inligting

**Wat FLUCYTOSINE 500 mg MACLEODS bevat**
Die aktiewe bestanddeel is flusitosien.
Die ander bestanddele is:
Mikrokristallyne sellulose,
Mieliestysel,
Povidoon K29/32,
Krospovidoon,
Kolloïdale silikondioksied,
Magnesiumstearaat.

**Hoe FLUCYTOSINE 500 mg MACLEODS lyk en inhoud van die pak**
Wit tot naaswit, ronde, bikonvekse, skuins rand, onbedekte tablette met "K" en "24" gegraveer, geskei deur 'n breeklyn aan die een kant en glad aan die ander kant.

Inhoud van die pak:
- Tablette word verpak in gewone aluminiumfoelie gelamineer met poliëtileenfilm aan beide kante. Pakgroottes sluit 6 tablette in.
- Ronde, wit, HDPE houer met nekafwerking, wat tablette silica, gelle sachets en poliësterspiraal bevat, gesluit met wit polipropileen sluiting met pulp en hitte-seël voering en verpak in 'n vooraf-gedrukte eenheidskarton.
  Pakgroottes sluit 100 tablette in.

Nie alle pakgroottes word noodwendig bemark nie.

**Houer van die Registrasiesertifikaat**
**MACLEODS PHARMACEUTICALS SA (EDMS) BPK**
Grondvloer, Blok 1,
Bassonia Estate Office Park (Oos),
Cussonia-rylaan 1,
Bassonia Rock Uitbreiding 12
Alberton
Gauteng

**Hierdie inligtingsblad was laas hersien op**
20 Augustus 2025

**Registrasienommer**
**FLUCYTOSINE 500 mg MACLEODS :** 58/20.2.2/0028

**Toegang tot die ooreenstemmende professionele inligting**
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

PACKAGING RESEARCH & DEVELOPMENT

*Restricted Circulation*

(Front Page)

# ARTWORK / PRINTPROOF APPROVAL FORM

| | |
|---|---|
| **1. Product: FLUCYTOSINE 500 mg MACLEODS (Flucytosine Tablets 500 mg)** | |
| **2. Country: South Africa (Private Market )** | **3. Packaging component: Patient Information Leaflet** |
| **4. No. of Colours: 1 Colour** | **5. Pantone Shade No.: Black** |
| **6. Specification: 40 gsm bible paper** | |
| **7. Machine Layout No.: NA** | **8. Dimensions: 335 (L) x 260 (W) mm** |
| **9. Design / Style: Booklet** | **10. Item code No.: PM04342854** |
| **11. Artwork has been made: Actual Size** | **12. Pharma code No.: 41359 mini** |
| **13. Barcode/NDC No: NA** | **14. Supersedes Item code No: NA** |
| **15. Revision no: 00** | **16. A/W File name:G:\Regulated_Artwork\SOUTH AFRICA\Flucytosine Tablets\Flucytosine 500 mg Macleods Leaflet - PM04342854.cdr** |
| **Approved By:** | **17. Location: Pithampur** |

| PRD | M.A. HOLDER | RAD | QC | PRODN | QA |
|---|---|---|---|---|---|
| | 08/06/2026 | | | | |

**Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.**

**Instructions to Vendor** :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.



| Reason for revision : | Item code | Artwork Send for Printing Date | Artwork Implementation Date |
|---|---|---|---|
| 1) New Artwork for South Africa (Private Market) | PM04342854 | | |