EMA updates recommendations on contraception for men and women on mycophenolate

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Information on Mycophenolate

- Mycophenolate (mycophenolate mofetil or mycophenolic acid) is an immunosuppressant. Immunosupressants are medicines that suppress the action of the immune system, the body's natural defences.
- Mycophenolate is used with other medicines to prevent rejection of a transplanted organ in patients given a kidney, heart, or liver transplant.
- In the EU, mycophenolate mofetil has been authorised centrally as CellCept and other names since 1996. Mycophenolic acid has been authorised through various national procedures in EU member states.

In Malta the following mycophenolate-containing products are authorised:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	Marketing Authorization Holder
Mycophenolate Mofetil 250mg	Mycophenolate Mofetil 250mg Capsules	Hard Capsules	POM	MA054/00102	Accord Healthcare Limited
Mycophenolate Mofetil 500mg	Mycophenolate Mofetil 500mg film-coated tablets	Film-coated tablets	POM	MA054/00101	Accord Healthcare Limited
Mycophenolate mofetil 500mg	Mycophenolate mofetil 500mg powder for concentrate for solution for infusion	Powder for concentrate for solution for infusion	POM	MA054/00103	Accord Healthcare Limited
Mycophenolic Acid 180mg	Myfortic	Gastro-resistant film-coated tablet	POM	MA088/04901	Novartis Pharmaceuticals UK Limited
Mycophenolic Acid 360mg	Myfortic	Gastro-resistant film-coated tablet	POM	MA088/04902	Novartis Pharmaceuticals UK Limited
Mycophenolic Acid 180mg	Axympa 180mg Gastro-resistant Tablets	Gastro-resistant tablet	POM	MA715/04501	Teva Pharma B.V. (utrecht)
Mycophenolic Acid 360mg	Axympa 360mg Gastro-resistant Tablets	Gastro-resistant tablet	POM	MA715/04502	Teva Pharma B.V. (utrecht)
Mycophenolate mofetil 250mg	Myclausen 250 mg hard capsules	Hard Capsules	POM	EU/1/10/647/003-004	Passauer Pharma GmbH

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Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	Marketing Authorization Holder
Mycophenolate Mofetil 500mg	Myclausen 500 mg film-coated tablets	Film-coated tablets	POM	EU/1/10/647/001-002	Passauer Pharma GmbH
Mycophenolate mofetil 250mg	Myfenax 250mg hard capsules	Hard Capsules	POM	EU/1/07/438/001-002 EU/1/07/438/006	Teva BV
Mycophenolate Mofetil 500mg	Myfenax 500mg film-coated tablets	Film-coated tablets	POM	EU/1/07/438/003-005	Teva BV
Mycophenolate mofetil 250mg	Mycophenolate mofetil Teva 250mg capsules	Hard Capsules	POM	EU/1/07/439/ 001-002 EU/1/07/439/ 006	Teva Pharma BV
Mycophenolate Mofetil 500mg	Mycophenolate mofetil Teva 500mg film-coated tablets	Film-coated tablets	POM	EU/1/07/003-005	Teva Pharma BV
Mycophenolate mofetil 250mg	CellCept 250 mg capsules	Hard Capsules	POM	EU/1/96/005/001, EU/1/96/005/003	Roche Registration Ltd.
Mycophenolate Mofetil 500mg	CellCept 500 mg powder for concentrate for solution for infusion	Powder for concentrate for solution for infusion	POM	EU/1/96/005/005	Roche Registration Ltd.
Mycophenolate Mofetil 1g/5ml	CellCept 1g/5 ml powder for oral suspension	Powder for oral suspension	POM	EU/1/96/005/006	Roche Registration Ltd.
Mycophenolate Mofetil 500mg	CellCept 500 mg film-coated tablets	Film-coated tablets	POM	EU/1/96/005/002 EU/1/96/005/004	Roche Registration Ltd.

The use of contraceptives to reflect level of risk to unborn babies following organ transplantation

The European Medicines Agency (EMA) has updated recommendation on contraception in men and women taking mycophenolate medicines. It has been concluded by EMA using current evidences that mycopehnolate medicine use by the father does not indicate risk of malformation or miscarriages, although the risk of genotoxicity cannot be completely ruled out.

The following are recommended by EMA:

- For male patients, either the male or his female partner must use a reliable and highly effective method of contraception during mycophenolate treatment and for at least 90 days after the last dose. It is no longer required that both use contraception.
- Use of condom by a male patient in addition to their female partner's use of a highly effective contraceptive method has now been removed as it does not reflect the level of risk.
- For female patients, the risk is unchanged. It must not be used in pregnant women unless there are no suitable alternatives to prevent transplant rejection. In addition, female patients who can become pregnant must use at least one reliable form of contraceptives before, during, and for 6 weeks after last dose. Use of two forms of contraception is preferred but no longer mandatory.

The Committee for Medicinal Products for Human Use (CHMP) has adopted the Agency's opinion. The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States in due course.

In Malta

For Healthcare Professionals

- Recommendations to manage the risk of malformations or miscarriages following treatment with mycophenolate have been updated.
- Healthcare professionals are reminded that mycophenolate medicines must never be prescribed in pregnant women except in those instances where there are no suitable alternatives to prevent organ rejection.

Healthcare professionals were sent a DHPC letter on the subject of contraception for patients on mycophenolate. Archived DHPC letter are available at http://www.medicinesauthority.gov.mt/dhpc

Advice for Patients

- Male patients or their untreated female partner must use reliable contraception during mycophenolate treatment and for at least 90 days after stopping treatment.
- Use of condom by male patients in addition to their female partner's use of highly effective contraception method has now been removed. It is no longer required that they both use contraception.
- Female patients who can get pregnant must use at least one reliable form of contraception before, during and for 6 weeks after stopping treatment. Two forms of contraception are preferred but no longer mandatory.
- Mycophenolate must not be used by pregnant women unless there is no suitable alternative treatment to prevent transplant rejection.

For more information refer to the EMA press release.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on mycophenolate containing products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form (available from: http://www.medicinesauthority.gov.mt/adrportal), fill and send by mail to Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or by email to postlicensing.medicinesauthority@gov.mt or to the marketing authorization holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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