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Mycophenolate: updated recommendations for contraception for men and women

Recommendations updated to reflect level of risk to unborn babies following organ transplantation

The European Medicines Agency (EMA) has updated recommendations for contraception in men and women taking mycophenolate medicines which are used to prevent rejection of transplanted organs.

Mycophenolate medicines are known to increase the risk of malformations and miscarriages during pregnancy if the fetus is exposed to them in the womb.

EMA has now concluded that current evidence does not indicate a risk of malformations or miscarriages when the father has taken mycophenolate, although the risk of genotoxicity cannot be completely ruled out.

For male patients, EMA now recommends that either the male patient or his female partner use reliable contraception during mycophenolate treatment and for at least 90 days after stopping treatment.

The previous recommendation that male patients should use condoms in addition to their female partners using a highly effective method of contraception has now been removed as this does not reflect the level of risk.

For female patients, the risk is unchanged. These medicines 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 contraception before, during and for 6 weeks after stopping treatment. Two forms of contraception are preferred but no longer mandatory.

The updated recommendations follow a periodic review of mycophenolate medicines by EMA's Pharmacovigilance Risk Assessment Committee (PRAC), which considered the available clinical and non-clinical data.

The recommendations have now been adopted by the Committee for Medicinal Products for Human Use (CHMP). A letter will be sent out to healthcare professionals in the EU to inform them of the outcome of the review and the updated recommendations.

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Information for patients and healthcare professionals

- Recommendations to manage the risk of malformations or miscarriages following treatment with mycophenolate have been updated.
- Male patients or their untreated female partner must use reliable contraception during mycophenolate treatment and for at least 90 days after stopping treatment. (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.
- Patients and healthcare professionals are reminded that mycophenolate medicines must never be used in pregnant women except in those instances where there are no suitable alternatives to prevent organ rejection.
- Patients who have any questions should speak to their doctor. Patients will also receive updated educational material with advice on contraception.

More about the medicines

Mycophenolate (mycophenolate mofetil or mycophenolic acid) is an immunosuppressant (a medicine that suppresses the action of the immune system, the body's natural defences). It is approved for use with other medicines to prevent rejection of the 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, and mycophenolic acid has been authorised through various national procedures.

More about the procedure

The review of mycophenolate medicines was first carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, as part of a periodic review known as a PSUR.

The PRAC recommendations were sent to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which 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.