

Guidance

Informed consent should be based on any known pertinent information related to reproduction toxicity, such as a general assessment of potential toxicity of pharmaceuticals with related structures or pharmacological effects. If no relevant reproductive information is available, the potential for unidentified risks to the embryo or foetus should be communicated. The following clauses or their equivalent are required to be included in the PICF where relevant.

Reproductive risks and pregnancy testing: wording for children and adolescents

For children: The study drug could cause bad birth defects in babies. If you are a girl and have started your periods, pregnancy testing will be done. You must not become pregnant during the study. If you think you may be pregnant you must tell your study doctor straight away. You must not take part in this study if you become pregnant.

For adolescents: The effects of the study drug are unknown. Therefore, there are unknown risks to the unborn child if you become pregnant during this study. You must not participate if you are pregnant, plan to become pregnant or are breastfeeding a child during the study. The study doctor must discuss effective methods of avoiding pregnancy during the study with you. Regular pregnancy testing will be done during the study.

Pregnancy, breastfeeding and reproductive wording for participants and partners of participants

The effect of [name of investigational product] on your fertility, including future fertility, may not be known.

The effects of [name of investigational product] on the unborn child and on the newborn baby are not known. Because of this, participants must not participate in the study if pregnant, trying to become pregnant, breastfeeding, or planning ovum donation.

If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the study. If you are male, you should not father a child or donate sperm for at least [number] months after the last dose of study drug.

Both male and female participants must avoid pregnancy during the course of the research and for a period of [number] months after completion of the research project, as there is potential risk for an abnormal child being born. It is highly recommended that you inform a sexual partner of your participation in the study and the need to avoid pregnancy. The study doctor must discuss effective methods of avoiding pregnancy with you.

[For female participants, depending on the study] If you do become pregnant whilst participating in the study, you should advise your study doctor immediately. Your study doctor will withdraw you from the study and advise on further medical attention should this be necessary. You must not continue in the study if you become pregnant.

or

If you do become pregnant whilst participating in the study, you should advise your study doctor immediately. Your study doctor will cease the study drug, but you may remain on the study. This will be for safety follow up only. The study doctor will advise on further medical attention should this be necessary.

[For male participants] You should advise your study doctor if you father a child while participating in the study. Your study doctor will advise on medical attention for your partner should this be necessary.

Public

Pregnancy & Sexual Health Standard Clauses

[For male participants, where appropriate] The study drug may cause harm to a sexual partner through the absorption of the study drug from seminal fluid. The study drug may also affect your sperm risking the potential for an abnormal child being born. You should discuss with your study doctor effective methods of avoiding this.

[Where appropriate] It is recommended that a condom be worn for all sexual intercourse.

In the event you do become pregnant the sponsor will request that you sign a separate consent form to allow monitoring of your pregnancy and the birth and the health of your child up to [number] years of age.

Discussions with participants

The following contraception information is provided as a guide for Investigators when discussing with participants fertility risks, mutagenic risks and avoiding pregnancy.

For women

The effect the study drug has on your fertility, including future fertility, may not be known.

Because the experimental agents in this study may affect an unborn baby, and there is potential risk for an abnormal child being born, you should not be pregnant or become pregnant while on this study and for months following the end of the study.

You must confirm to the investigator that, to the best of your knowledge, you are not pregnant now, and that you do not intend to become pregnant during the study.

You must use a highly effective method of contraception/birth control (methods which result in low failure rate, i.e. less than 1% per year, when used consistently and correctly) and if currently lactating, you should not breast feed your baby while on this study and for 3 months after the last dose of study drug has been taken.

Examples of acceptable forms of highly effective contraception include:

- Established use of oral, injected or implanted hormonal methods of contraception.
- Placement of an intrauterine device (IUD) or intrauterine system (IUS).
- Sterilised male partner (with the appropriate post-vasectomy documentation of the absence of sperm in the ejaculate).
- True abstinence: When this is in line with your preferred and usual lifestyle

Examples of non-acceptable methods of contraception include:

- Condoms alone or double barrier
- Periodic abstinence (e.g., calendar, ovulation, symphothermal, post ovulation)
- Withdrawal
- Spermicide (as it is not approved as a method of contraception in Australia)

If you are uncertain of what form of contraception is acceptable for use during the study, then please ask your study doctor.

If you suspect that you have become pregnant during the study, you must notify your study doctor immediately. You will not be able to continue participation in the study if you become pregnant. In the event you do become pregnant the Sponsor will request that you sign a separate consent form to allow monitoring of your pregnancy and the birth and the health of your child up to [number] years of age.

For men

The effect the study drug has on your fertility, including future fertility, may not be known.

Because the experimental agents in this study may affect an unborn baby, you should not father a baby while on this study and for **[number]** months following the end of the study.

The study drug may also affect your sperm, risking the potential for an abnormal child being born.

It is also highly recommended that you inform your partner of your participation in the study and that highly effective methods of contraception (as detailed above) are strongly advised.

Further, you must agree that if your sexual partner becomes pregnant while you are on the study, you will advise the study doctor who will then provide you with an authorisation form to present to that person. If they provide authorisation, that will function as consent to approve the study doctor's access to medical information to allow monitoring of the pregnancy, and the birth and the health of the child up to **[number]** years of age.

References

BA G5 Participant Information and Consent Form Development

BA G14 Pregnancy and Sexual Health Guidance