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Revision of Precautions

Azathioprine

July 10, 2018

Non-proprietary name

Azathioprine

Safety measure

Precautions should be revised in the package insert.

"Pregnant women or women who may be pregnant" should be deleted from the Contraindications section.

The following language should be deleted from the Important Precaution section:

Cases of neonates born with chromosomal anomalies in lymphocytes to women who received azathioprine during pregnancy have been reported. Teratogenic effects have been reported in animal studies (rabbits, rats, mice). Both men and women receiving this drug should be instructed to use contraception.

Language concerning pregnant women or women who may be pregnant in the Use during Pregnancy, Delivery, or Breastfeeding section should be revised as follows (revised language is underlined):

Pregnant women or women who may be pregnant <u>should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks.</u> <u>Women with reproductive potential should be informed of the risks associated with this drug.</u> <u>Women should be counseled to avoid pregnancy whenever possible while receiving</u>

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this drug. [Placental transfer in humans has been reported. Cases of neonates born with chromosomal anomalies in lymphocytes, and congenital anomalies, decrease in blood cell count or immunocompetent cell counts observed in the neonates have been reported. Cases of premature birth or low birth weight baby have been reported in women who received this drug during pregnancy (particularly in women who concomitantly received adrenocorticosteroids.) Miscarriage subsequent to administration of this drug to either parent has also been reported. Teratogenic effects have been reported as a result of animal studies (rabbits, rats, mice.)]

And the following language should be added to the Use during Pregnancy, Delivery, or Breastfeeding section (revised language is underlined):

Men having partners with reproductive potential should be informed of the risks associated with this drug if they are to be administered this drug and should be counseled to avoid pregnancy of their partners whenever possible while they are receiving this drug. [Genotoxicity has been reported in bacterial reverse mutation studies and micronucleus studies in mice and rats.]

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