ACNE, ROSACEA, AND RELATED DISORDERS (INCLUDING HIDRADENITIS SUPPURATIVA)

PREGNANCY PREVENTION MEASURES FOR ISOTRETINOIN THERAPY

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Background: Isotretinoin has been the only treatment to date that targets all the main pathophysiological factors of acne vulgaris. While isotretinoin is an effective treatment, it is a potent human teratogen. Due to teratogenic risk that isotretinoin imposes on consumers, many regulatory programs have been implemented across the world to prevent its use in pregnancy.

Objective: To evaluate the effectiveness of the current isotretinoin risk management programs.

Methods: A comprehensive review of the regulatory programs for isotretinoin across the world was conducted. The main outcomes of interest included concomitant use of contraception and isotretinoin, rates of pre-therapy pregnancy tests and the effects of regulatory programs on the number of isotretinoin fetal exposures.

Results: Despite being the most stringent risk management programs, the iPLEDGE program in the United States and Pregnancy Prevention Program (PPP) in Europe may not be effective in significantly reducing isotretinoin use in pregnancy. More stringent programs led to a decrease in the overall number of prescriptions, which may negatively impact on isotretinoin access, while not producing a real-world benefit in reducing teratogenic risks. A successful program should have an emphasis on counselling regarding effective contraception, while minimising any inessential administrative requirements that have been shown to lack efficacy, such as monthly pregnancy tests.

Conclusions: The overall benefits to society from isotretinoin therapy in the management of severe acne vulgaris significantly outweigh the risks. Importantly, a prudent regulatory measure for isotretinoin is required to minimise its teratogenic risks while ensuring that acne in women is not inadvertently undertreated. Although these risks may never be completely eliminated, experience and evidence from the various regulatory programs used across the world can inform an appropriate approach.