IRISH MEDICINES BOARD

Notice Information: Human Medicines - 3rd Party Publications 04 March 2008

Part 1. Product Information

a)	Title:	Isotretinoin - Pregnancy Prevention Programme
b)	Product Name/Type:	Isotretinoin-containing medicinal products
c)	Reference:	MIMS publication - March 2008

Part 2. Problem/Issue

a)	Problem/Issue:	Isotretinoin is a medicinal substance approved for oral use in the treatment of severe forms of acne resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy. Isotretinoin should only be prescribed by or under the supervision of physicians with expertise in the use of systemic retinoids for the treatment of severe acne. The conditions of use for all isotretinoin-containing medicines for oral use were harmonised in the European Union in 2003 and a Risk Management Programme to prevent pregnancy in women of child-bearing potential treated with isotretinoin was introduced. The IMB would like to take this opportunity to remind healthcare professionals that isotretinoin should only be used in women of child-bearing potential when all of the conditions of the Pregnancy Prevention Programme are met as follows: The patient has severe acne resistant to adequate courses of standard therapy with systemic antibacterials and topical therapy. The patient understands the teratogenic risk. The patient understands the need for rigorous follow-up on a monthly basis. The patient understands and accepts the need for effective contraception, without interruption, 1 month before starting treatment, throughout the duration of treatment and 1 month after the end of treatment. At least one and preferably two complementary forms of contraception including a barrier method should be used. The patient understands that even if she has amenorrhoea she must follow all of the advice on effective contraception. The patient is capable of complying with effective contraceptive measures. The patient is informed and understands the potential consequences of pregnancy and the need to rapidly consult if there is a risk of pregnancy. The patient understands the need and accepts to undergo pregnancy testing before, during and 5 weeks after the end of treatment. The patient has acknowledged that she has understood the hazards and necessary precautions associated with the use of isotretinoin. The prescriber must ensure that the the patient complies with the conditions for pregnancy prevention, including confirmation that she has an adequate level of understanding of the aforementioned conditions and that she has used and continues to use at least one and preferably two methods of effective contraception including a barrier method for at least 1 month prior to starting treatment and is continuing to use effective contraception throughout the treatment period and for at least 1 month after cessation of treatment. Finally the presciber must ensure that negative pregnancy test results have been obtained before, during and 5 weeks after the end of treatment and the dates and results of such pregnancy tests are documented. Medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL are recommended to be performed in the first 3 days of the menstrual cycle prior to starting therapy, at follow-up visits at 28 day intervals and five weeks after stopping treatment to exclude pregnancy. Finally healthcare professionals are reminded that prescriptions for isotretinoinfor oral use are limited to 30 days treatment for women of childbearing potential. Continuation of treatment requires a new prescription and each prescription is only valid for seven days. Healthcare professionals are reminded that sus

suspected adverse reactions, including those associated with use of isotretinoin, should be reported to the IMB either on-line on the IMB website at www.imb.ie or using the downloadable version of the adverse reaction report form also available from the IMB's website. Downloaded forms should be completed and sent by freepost to the IMB at "Freepost", Pharmacovigilance Section, Irish Medicines Board, The Earlsfort Centre, Earlsfort Terrace, Dublin 2. Alternatively, completed forms may be submitted by fax to (01) 6762517. Finally, post-paid report cards can be obtained directly from the Pharmacovigilance Section of the IMB at (01) 6764971.