PHARMACIST CHECKLIST

Guidance for dispensing CONTRACNE

Contracné

Isotretinoin

CONTRACNE belongs to the retinoid class of drugs that cause severe birth defects. Foetal exposure to CONTRACNE, even for short periods of time, presents a high risk of congenital malformations and miscarriage.

CONTRACNE is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions in the CONTRACNE Pregnancy Prevention Programme are fulfilled.

A negative pregnancy test, issuing a prescription and dispensing CONTRACNE should ideally occur on the same day.

If you are aware that a pregnancy has occurred in a woman treated with CONTRACNE, treatment should be stopped immediately and the woman should be promptly referred to the prescribing doctor.

If you are aware that a female patient has become pregnant within one month of stopping CONTRACNE she should be referred to her prescribing doctor.

As pharmacist, you should only dispense CONTRACNE after checking the following information:

For women of child-bearing potential:	
In order to support regular follow up, including pregnancy testing and monitoring, the prescription for CONTRACNE should ideally be limited to a 30-day supply.	
All patients should be instructed:	
Never to give the CONTRACNE to another person.	
To return any unused capsules to their pharmacist at the end of treatment.	
Not to donate blood during CONTRACNE therapy and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to; P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 E: postlicensing.medicinesauthority@gov.mt

As an alternative, Pharmacists can report suspected adverse reactions associated with CONTRACNE at the respective Local Pharmacovigilance units:

MAH	Local representative	Product name	Email	Phone
Laboratoires Bailleul S.A.	Metropolis Pharma	Contracne 10 mg, soft capsule Contracne 20 mg, soft capsule	vigilances@bailleul.com	*Office hours* +356 2143 3330 *Out of office hours* +356 9942 6611

Bailleul LABORATOIRES

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