

Date of appointment	Contraception used	Pregnancy test result	Doctor's Signature
		<input type="checkbox"/> Positive <input type="checkbox"/> Negative Date:	
		<input type="checkbox"/> Positive <input type="checkbox"/> Negative Date:	
		<input type="checkbox"/> Positive <input type="checkbox"/> Negative Date:	

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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 Teri Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000 E: postlicensing.medicinesauthority@gov.mt

By reporting side effects you can help provide more information on the safety of this medicine.

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

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

Bailleul
LABORATOIRES
Version approved in 09/2024



Contracné
Isotretinoin

**PATIENT
REMINDER
CARD**

Doctor's name:

Telephone:

CONTRACNE must not be taken during pregnancy.

CONTRACNE can seriously harm an unborn baby if a pregnant woman takes it.

If you become pregnant or think you might be pregnant, stop taking CONTRACNE immediately and contact your doctor.

Read the package leaflet carefully before you start treatment.

If you have any questions or concerns about taking CONTRACNE, talk to your doctor or pharmacist.

WHAT YOU HAVE TO DO IF YOU COULD BECOME PREGNANT:

- You must use at least 1 highly effective method of contraception (such as an intra-uterine device or an implant) or correctly use 2 effective methods of birth control that work in different ways (such as an oral contraceptive together with a condom) before, during and for 1 month after stopping treatment.

- You must not become pregnant while taking CONTRACNE, or for 1 month after stopping treatment.

- You must attend regular follow-up visits and have regular pregnancy testing:

- Before you start treatment, you will have to have a pregnancy test, which must be negative.

- To make sure you are not pregnant during treatment, you should have regular pregnancy tests, ideally every month. You should also have a final pregnancy test 1 month after stopping treatment.

REMINDER FOR MEN AND WOMEN

This medication has been prescribed to you only, **do not share it with anybody and return any unused capsules back to the pharmacy.**

APPOINTMENT TABLE

Please use this table to record the dates of your appointments with your doctor:

Date of appointment	Contraception used	Pregnancy test result	Doctor's Signature
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