CURACNE® 10, 20, 40mg

Isotretinoin

PHARMACIST CHECKLIST

GUIDANCE FOR DISPENSING CURACNÉ

Risk reduction activities are approved by the Saudi Food and Drug Authority - SFDA

The potential for pregnancy must be assessed for all female patients delivered CURACNÉ

A woman has a potential for pregnancy if one of the following applies:
Is a sexually mature woman who:

1) has not had a hysterectomy or bilateral oophorectomy
2) is not in a natural postmenopause for a minimum of 24 consecutive months (i.e., menstruated at a certain point in the last 24 consecutive months).

Is the patient a woman of childbearing potential? Yes/No

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

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

The first prescription for CURACNÉ can only be given after the patient has had one negative medically supervised pregnancy test. This is to make sure she is not already pregnant before starting treatment.

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

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

For women of child-bearing potential:	
If you are aware that a female patient has become pregnant within one month of stopping CURACNÉ she should be referred to her prescribing doctor. The treatment must be stopped, and the patient should be referred to an expert physician specialised or experienced in teratology for advice.	
The patient understands that CURACNÉ belongs to a class of drugs (retinoids) known to cause severe birth defects and that they must not get pregnant whilst taking it. CURACNÉ also increases the risk of miscarriage when taken during pregnancy.	
Patient understands the need for and agrees to pregnancy testing before, during and after treatment.	
Patient understands the need to do a pregnancy test 1 month after stopping treatment because the drug stays in the body for 1 month after the last dose and can damage an unborn baby if pregnancy occurs.	
In order to support regular follow up, including pregnancy testing and monitoring, the prescription for CURACNÉ should ideally be limited to a -30day supply.	
The patient understands that she must consistently and correctly use at least 1 highly effective method of contraception (i.e. a user-independent form such as an intra-uterine device or implant) or 2 complementary methods of birth control (i.e. user-dependent forms such as oral contraceptive and barrier method) before and during treatment.	
The patient understands that the risk persists even after the medication is stopped and that she must not get pregnant within 1 month after stopping treatment	
The patient has received advice on contraception which is appropriate for her and has committed to using it throughout the risk period. She is aware of the risk of contraceptive failure.	
The patient understands that if a pregnancy has occurred during treatment with CURACNÉ, treatment should be stopped immediately and she should be promptly referred to the prescribing doctor.	
The patient understands that if pregnancy occurs within one month of stopping CURACNÉ she should be referred to her prescribing doctor. The treatment must be stopped, and the patient should be referred to an expert physician specialised or experienced in teratology for advice.	
All patients should be instructed:	
Never to give the CURACNÉ to another person.	
To return any unused capsules to their pharmacist at the end of treatment.	
Not to donate blood during CURACNÉ therapy and for one month after discontinuation due to the potential risk to the foetus of a pregnant transfusion recipient.	
The patient received the Patient Reminder Card from her dermatologist and has been encouraged to read it and the package information leaflet thoroughly before and during treatment with CURACNÉ.	

You can report any safety concern with CURACNÉ by contacting PV_middleeast@pierre-fabre.com

You can also report any suspected adverse reaction to the National Pharmacovigilance and Drug Safety Centre (NPC):

- Fax: +966-11-205-7662
- Toll free phone: 8002490000
- E-mail: npc.drug@sfda.gov.sa
- Website: www.sfda.gov.sa/npc

For extra copies please contact PV_middleeast@pierre-fabre.com

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