CURACNÉ® Gé* 5, 10, 20 mg
CURACNÉ® 40 mg
Isotretinoin

Severe acne (such as nodular acne, acne conglobata or acne likely to result in permanent scarring) unresponsive to appropriate conventional treatment with systemic antibiotics and topical therapy

TERRES DE SAD 06/2015 - 362319 - Export use only.

*Belongs to the class of generic medicinal products.
Excipient with a known effect: soya oil.

This medicine is teratogenic. As part of the pregnancy prevention programme, effective contraception is compulsory.

Pierre Fabre
DERMATOLOGIE

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Isotretinoin

Pharmacist's Guide

to dispensing oral Isotretinoin

This document is part of the risk minimisation plan implemented for oral Isotretinoin.

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DERMATOLOGIE

PHARMACIST'S GUIDE CONTENTS

PHARMACIST'S GUIDE
to dispensing oral Isotretinoin

Important Notes:

• This guide summarizes the most important safety information about the risks of teratogenicity, occurrence of psychiatric disorders, lipid disorders, transaminases increased and hepatitis.

• The information in this brochure has been reviewed and approved by the Saudi Food and Drug Authority.

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 and a full understanding of the risks of isotretinoin therapy and monitoring requirements.

Oral Isotretinoin should only be prescribed in severe forms of acne (i.e nodular and conglobata or acne at risk of permanent scarring), resistant to adequate courses of standard therapy with systemic antibacterial and topical therapy.

TERATOGENICITY AND DRUG EXPOSURE DURING PREGNANCY

Your role is essential in ensuring the patient's compliance to the PPP before delivering the drug.

☑ Conditions for dispensing oral Isotretinoin

You have to verify the negative result of pregnancy test before each isotretinoin delivery.

If you are aware that a pregnancy occurred in a woman treated with oral Isotretinoin treatment must be stopped immediately and the patient should be referred to a physician specialized or experienced in teratology for evaluation and advice.

Oral Isotretinoin is a teratogenic drug. Exposure to oral Isotretinoin during pregnancy is associated with a high risk of major fetal malformations. Oral Isotretinoin can only be prescribed to women of childbearing potential under strict measures supported by the Marketing Authorization Holder's (MAH's) Pregnancy Prevention Programme (PPP).

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to dispensing oral Isotretinoin

☑ Female patients

- Prescriptions of oral Isotretinoin in women of child-bearing potential are valid for **4 weeks and are not renewable**. Continuation of treatment therefore requires a new prescription.
- In women of child-bearing potential, **oral Isotretinoin should be dispensed no later than 7 days after the prescription.**
- Oral isotretinoin can only be dispensed in women of child-bearing age after checking the following information:

For the 1st prescription :

- Evaluation of the patient's good level of understanding of the risks in case of pregnancy
- Implementation of **two methods of effective contraception** for at least one month.
- Verify the negative result of the pregnancy test (plasma hCG)
- The women brochure should include the consent form signed by the patient.

For the monthly renewal :

- Evaluation of the patient's good level of understanding of the risks in case of pregnancy.
- Continuation of an effective method of contraception.
- Verify the negative result of the pregnancy test (plasma hCG).

Do not proceed to the renewal if those conditions are not followed.

☑ All patients

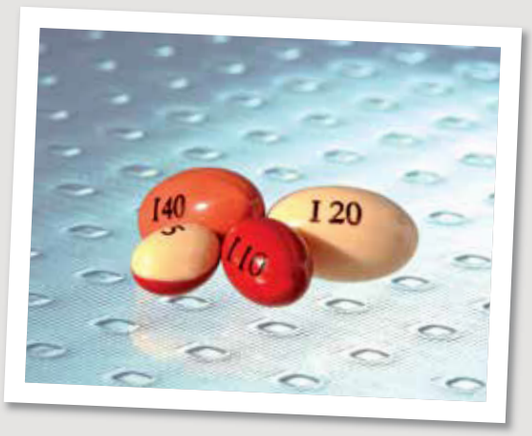
- Patients should be instructed to never give oral Isotretinoin to another person.
- Patients should return any unused capsule to their pharmacist at the end of treatment.
- All patients should be told not to donate blood during therapy and during the month following discontinuation of oral Isotretinoin because of the potential risk of malformation for the foetus of a pregnant transfusion recipient.

Pharmacovigilance department is at your disposal for any information or precise question concerning this Guide for dispensing oral Isotretinoin

PSYCHIATRIC DISORDERS : DEPRESSION, SUICIDE, SUICIDE ATTEMPT, SUICIDE IDEATION

The patient is suffering from severe acne, which is known to be possibly a disfiguring disease and that may alter the self esteem; consequently you must be vigilant towards mood disorders.

Moreover depression, depression aggravated, anxiety, aggressive tendencies, mood alteration, psychotic symptoms and very rarely, suicidal ideations, suicide attempts and suicide were reported in patients treated with oral Isotretinoin soft capsules.



Recognizing psychiatric disorders in adolescents and young adults, include sad mood, hopelessness, feelings of guilt, worthlessness or helplessness, loss of pleasure or interest in activities, fatigue, difficulty concentrating, change in sleep pattern, change in weight or appetite, suicidal thoughts or attempts, restlessness, irritability, acting on dangerous impulses, and persistent physical symptoms unresponsive to treatment.

In case your patient or his/her carer, mentions to you symptoms that could be evocative of depressive disorders, do not hesitate to refer your patient to the prescriber.

LIPID METABOLISM DISORDERS POSSIBLY LEADING TO ACUTE PANCREATITIS, TRANSAMINASES INCREASED AND HEPATITIS.

Oral Isotretinoin treatment alters the plasma lipid levels but the mechanisms and the effects on the metabolism of triglyceride-rich lipoproteins such as chylomicrons and very-low-density lipoproteins remain unclear. The treatment can also alter the transaminases levels, and may cause hepatitis.

Serum lipids and transaminases (fasting values) tests should be performed by the patient before treatment, 1 month after the start of treatment, and subsequently at 3 monthly intervals unless more frequent monitoring is clinically indicated.

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We remind you that any side effects should be reported to:

National Pharmacovigilance and Drug Safety Center (NPC)
Email: npc.drug@sfda.gov.sa
Toll Free Number: 19999
Fax: +966 11 2057662
Website: https://ade.sfda.gov.sa/

Or

Pierre Fabre Middle East
Dubai, UAE
Email: PV_MiddleEast@pierre-fabre.com
Mobile in KSA: 00966 505 404 345
Mobile in UAE: 00971 525 878 223

CHECK LIST OF IMPORTANT ITEMS

Check the following points:	1st dispensing	renewal
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 and a full understanding of the risks of isotretinoin therapy and monitoring requirements	X	
The women brochure should include the completed signed consent form.	X	
Implementation of two methods of effective contraception for at least one month	X	
Continuation of an effective contraception		X
Pregnancy test has to be done in the 3 days preceding the prescription and negative result.	X	X
The dispensing must be done 7 days after the prescription of Isotretinoin at the latest	X	X
You should verify the return of any unused capsules at the end of treatment		X