



**Tasnim**  
Pharmaceutical Co.

ERX : 61796

**Tasnim**   
Pharmaceutical Co.

**Normskin<sup>®</sup>**  
Isotretinoin

Each capsule contains:  
**Isotretinoin 20 mg**

 30 Capsules

Marketing authorization holder:  
**Tasnim Pharmaceutical Co.**  
Tehran - Iran



ERX :

**Tasnim**   
Pharmaceutical Co.

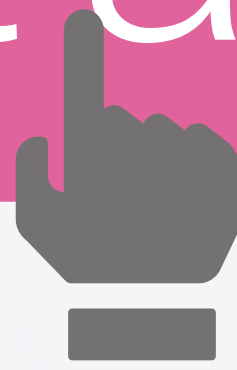
**Normskin<sup>®</sup>**  
Isotretinoin

Each Capsule contains:  
**Isotretinoin 10 mg**

 30 Capsules



**Start**



Click Here To Start

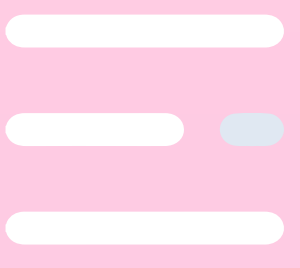
**CONTACT US**

**GUIDE**

If you can't use the buttons, you can scroll down to the bottom of document to view the guide.

Copyright © 2022 **Tasnim** - All Rights Reserved.

Designed & Executed by **ClickBan Co.**



# Menu

SELECT AN OPTION TO CONTINUE;



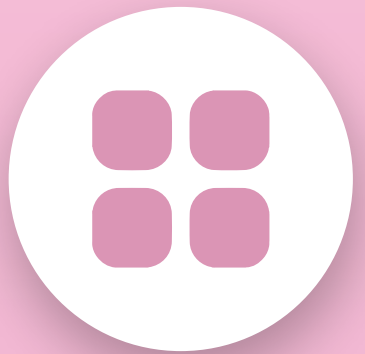
Home



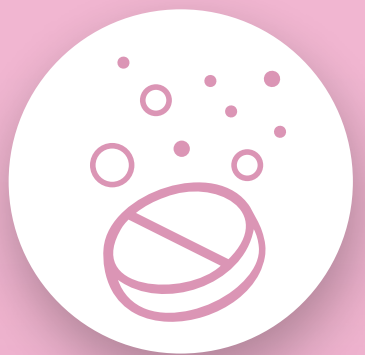
About Normskin



Details



Category & Indication



Mechanism Of Action



Adverse Effects



Articles



Contact Tasnim



Guide

Normskin<sup>®</sup>  
Smart Catalog





# Home

## Normskin®

ERX (Normskin 20 mg) : 61796

ERX (Normskin 10 mg) :

Drug Brand

Normskin

Generic Name

Isotretinoin

Drug form

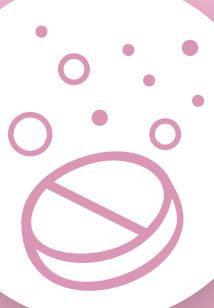
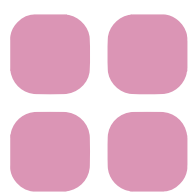
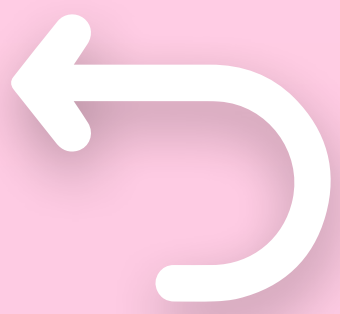
20 mg, 10 mg

Package

30 soft gelatin capsules  
in 3 blister pack in 1 box

[Start Exploring](#)

Problem with buttons? [View Guide](#)



# What is Normskin<sup>®</sup>?

- Normskin<sup>®</sup> (isotertinoin) is a vitamin A derivate. It is the most effective treatment for acute and cystic acne Treatment of severe forms of acne such as nodular or conglobate acne at risk of permanent scarring, resistant to standard therapy with systemic antibacterial and topical therapy.

1

2

>





# What is Normskin<sup>®</sup>?

- It is may be used in order to treatment of some type of skin cancer. The absorption will increase if used with food.it is also reducing the sebum gland and sebum production, decrease the keratinization a skin inflammation.



# Details

Dosage & Administration

Interactions

Breast feeding & pregnancy

View Pictures

More information





## Dosage & Administration

- Oral: Administer standard formulation with a meal  
According to the manufacturer's labeling, capsules should be swallowed whole with a full glass of liquid; do not chew or suck on the capsule

1

2

3

4

>



## Dosage & Administration

- Initial: Oral: 0.5 mg/kg/day in 2 divided doses for 4 weeks, then increase dose to 1 mg/kg/day in 2 divided doses (AAD [Zaenglein 2016]; AAP [Eichenfield 2013]); for severe extensive cases (involving trunk, nuchal region, lower back, buttocks, thighs) may require higher doses up to 2 mg/kg/day in 2 divided doses (manufacturer labeling).

&lt;

1

2

3

4

&gt;





## Dosage & Administration

- Duration of therapy: Typically 15 to 20 weeks depending upon daily dose; a target cumulative dose range of 120 to 150 mg/kg has been recommended based on observed lower relapse rates with courses  $\geq 120$  mg/kg and the plateau effect observed with higher cumulative total doses of  $> 150$  mg/kg (AAD [Zaenglein 2016]).

&lt;

1

2

3

4

&gt;



## Dosage & Administration

- Repeat course: In older adolescents who have completed skeletal growth, a second course of isotretinoin may be repeated after a period of  $\geq 2$  months off therapy for persistent or recurring severe nodular acne; for younger patients who have not completed skeletal growth, the optimal interval before retreatment has not been defined.





# Interactions

- Food Interactions:  
Standard formulation isotretinoin bioavailability increased if taken with food or milk.
- Drug Interactions:  
Note: Interacting drugs may not be individually listed below if they are part of a group interaction (eg, individual drugs within “CYP3A4 Inducers [Strong]” are NOT listed). For a complete list of drug interactions by individual drug name and detailed management recommendations, use the Lexicomp drug interactions program by clicking on the “Launch drug interactions program” link above.

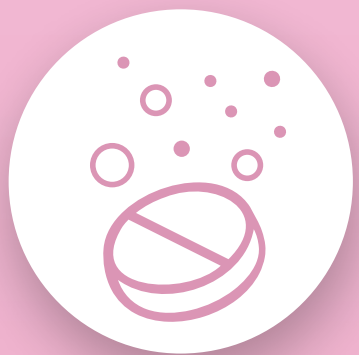
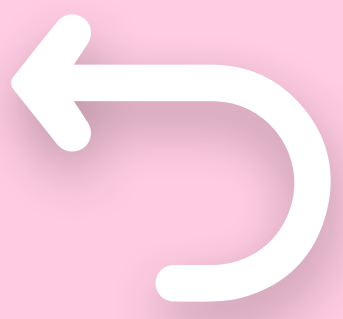
# Interactions

- Alcohol (Ethyl): May enhance the adverse/toxic effect of Isotretinoin (Systemic). Specifically, the risk for elevated triglyceride concentrations may be increased. Risk C: Monitor therapy
- Aminolevulinic Acid (Systemic): Photosensitizing Agents may enhance the photosensitizing effect of Aminolevulinic Acid (Systemic). Risk X: Avoid combination

&lt;

2

&gt;





# Interactions

- Aminolevulinic Acid (Topical): Photosensitizing Agents may enhance the photosensitizing effect of Aminolevulinic Acid (Topical). Risk C: Monitor therapy
- Methoxsalen (Systemic): Photosensitizing Agents may enhance the photosensitizing effect of Methoxsalen (Systemic). Risk C: Monitor therapy

# Interactions

- Mipomersen: Isotretinoin (Systemic) may enhance the hepatotoxic effect of Mipomersen. Risk C: Monitor therapy
- Multivitamins/Fluoride (with ADE): May enhance the adverse/toxic effect of Retinoic Acid Derivatives. Risk X: Avoid combination



# Interactions

- Multivitamins/Minerals (with ADEK, Folate, Iron): May enhance the adverse/toxic effect of Retinoic Acid Derivatives. Risk X: Avoid combination
- Multivitamins/Minerals (with AE, No Iron): May enhance the adverse/toxic effect of Retinoic Acid Derivatives. Risk X: Avoid combination

&lt;

5

&gt;



# Interactions

- Porfimer: Photosensitizing Agents may enhance the photosensitizing effect of Porfimer. Risk C: Monitor therapy
- Vitamin A: May enhance the adverse/toxic effect of Retinoic Acid Derivatives. Risk X: Avoid combination.



# Interactions

- Tetracyclines: May enhance the adverse/toxic effect of Retinoic Acid Derivatives. The development of pseudotumor cerebri is of particular concern. Risk X: Avoid combination
- Verteporfin: Photosensitizing Agents may enhance the photosensitizing effect of Verteporfin. Risk C: Monitor therapy

&lt;

7

&gt;



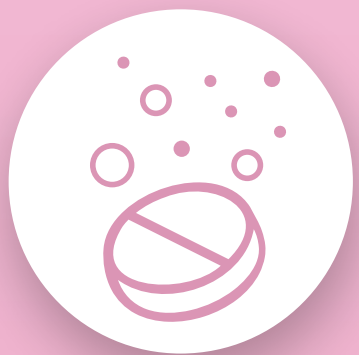
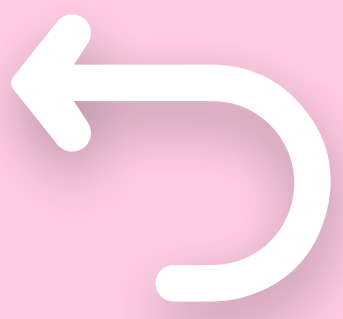
# Interactions

- Progestins (Contraceptive): Retinoic Acid Derivatives may diminish the therapeutic effect of Progestins (Contraceptive). Retinoic Acid Derivatives may decrease the serum concentration of Progestins (Contraceptive). Management: Two forms of effective contraception should be used in patients receiving retinoic acid derivatives. Microdosed progesterone-only preparations (ie, minipills that do not contain estrogen) are considered an inadequate method of contraception. Risk D: Consider therapy modification

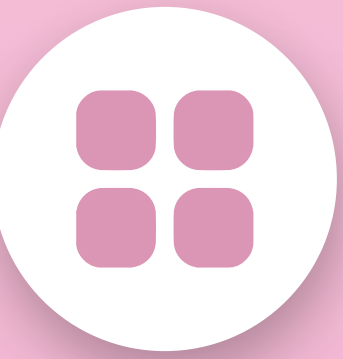
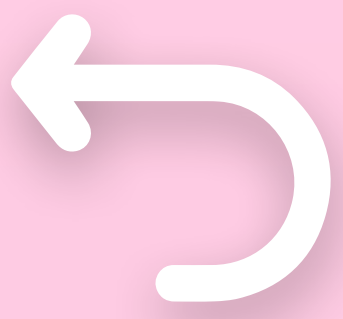


# Breast Feeding & Pregnancy

- FDA Pregnancy Category X -  
Not for use in pregnancy.



# Pictures





# More Information

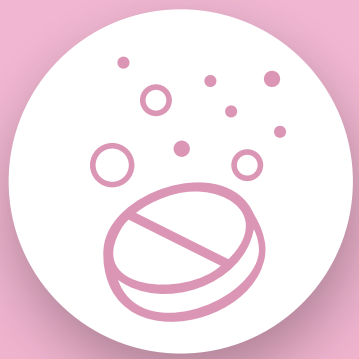
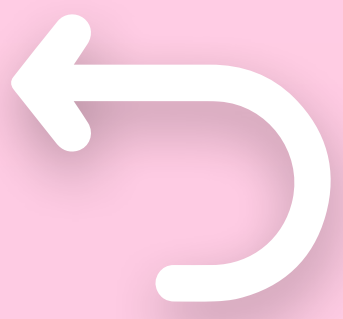
Warning & Precautions

Comparative Dissolution profile of  
Normskin<sup>®</sup> 20 mg VS Accutane<sup>®</sup>  
20 mg

Comparative Dissolution profile of  
Normskin<sup>®</sup> 10 mg VS Accutane<sup>®</sup>  
10 mg

Normskin<sup>®</sup> benefit

Normskin<sup>®</sup> dosing by body weight for  
severe Recalcitrant Nodular Acne



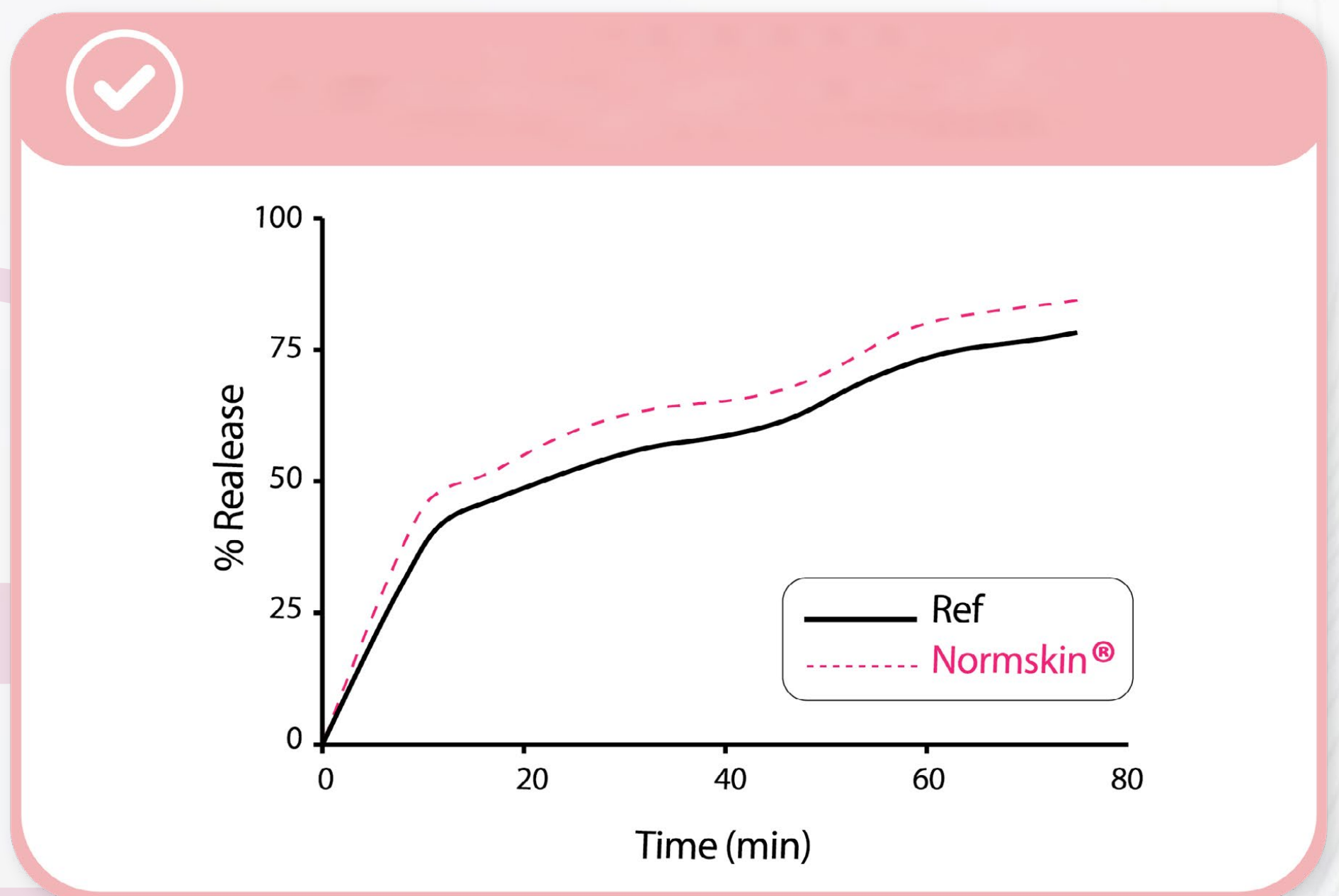
## Warning & Precautions

- Isotretinoin and its metabolites can be detected in fetal tissue following maternal use during pregnancy (Benifla 1995; Kraft 1989).
- [US Boxed Warning]: Isotretinoin must not be used by patients who are pregnant. There is an extremely high risk that life-threatening birth defects can result if pregnancy occurs while taking isotretinoin in any amount, even for short periods of time

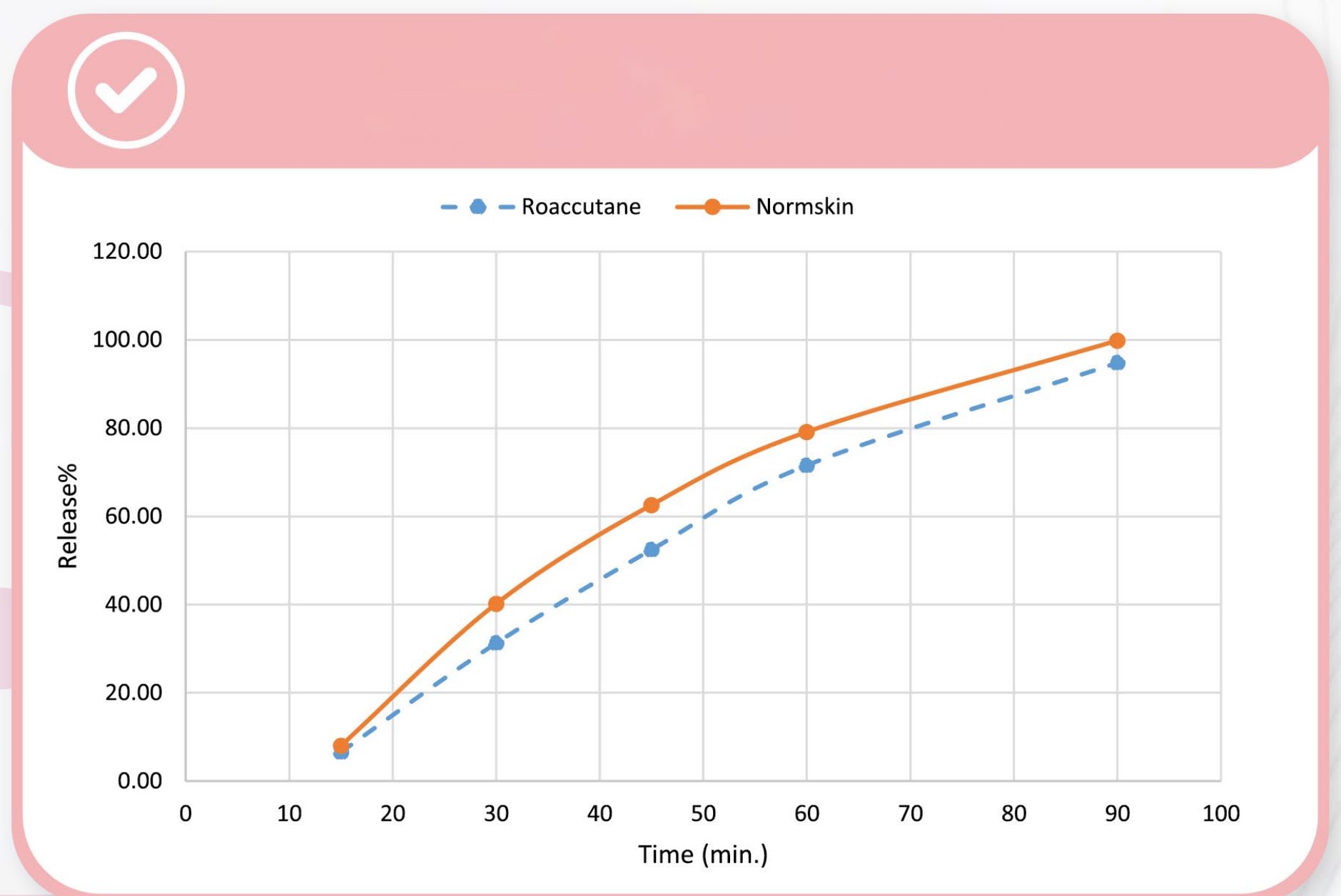




# Comparative Dissolution profile of Normskin<sup>®</sup> 20 mg VS Accutane<sup>®</sup> 20 mg

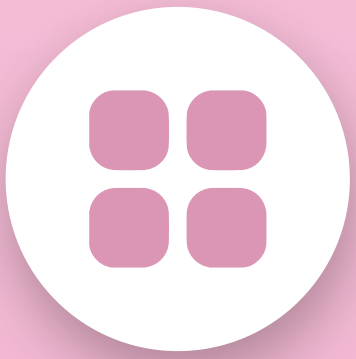
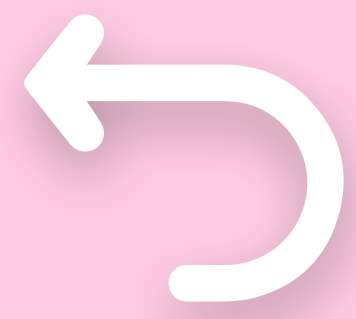
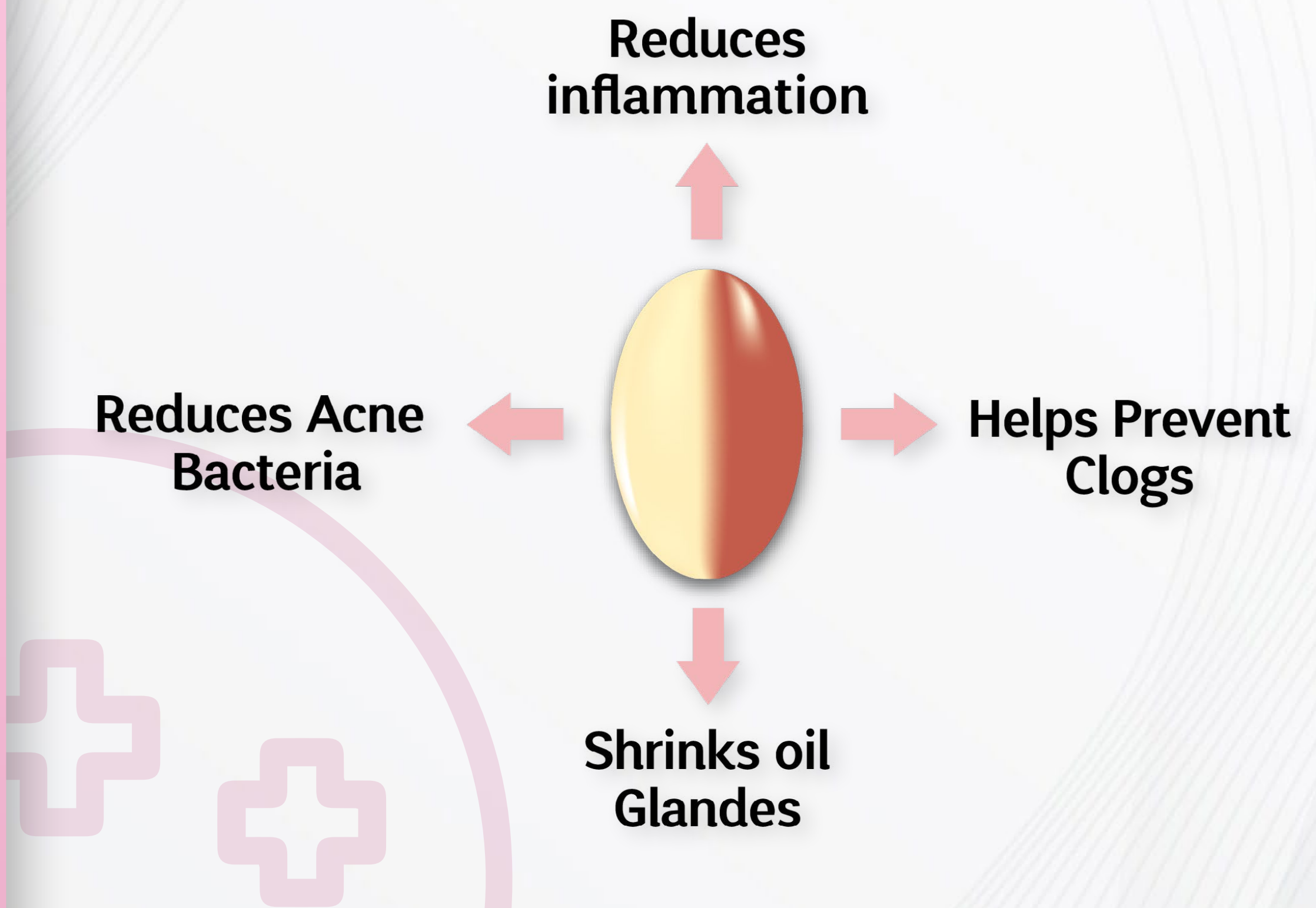


# Comparative Dissolution profile of Normskin<sup>®</sup> 10 mg VS Accutane<sup>®</sup> 10 mg





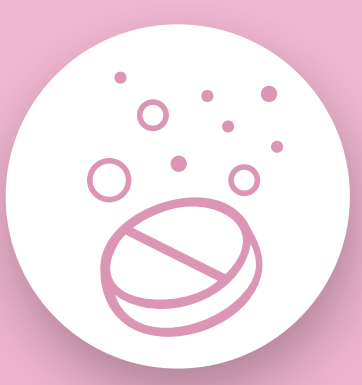
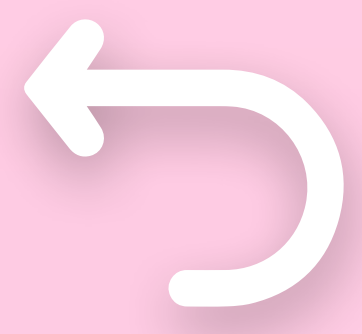
# Normskin® benefit





# Normskin<sup>®</sup> dosing by body weight for severe Recalcitrant Nodular Acne

body weight		Total mg/day		
kilograms	pounds	0.5mg/kg	1 mg/kg	2mg/kg
40	88	20	40	80
50	110	25	50	100
60	132	30	60	120
70	154	35	70	140
80	176	40	80	160
90	198	45	90	180
100	220	50	100	200





# Category & Indication

- Acne Products; Antineoplastic Agent, Retinoic Acid Derivative
- Indications; Acne vulgaris, severe: Treatment of severe recalcitrant nodular acne unresponsive to conventional therapy (including systemic antibiotics).

1

2

>



# Category & Indication

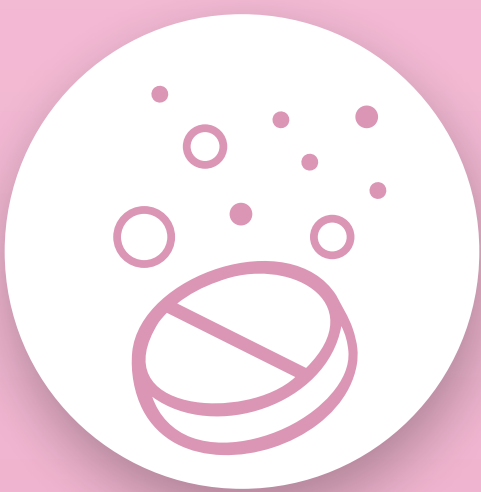
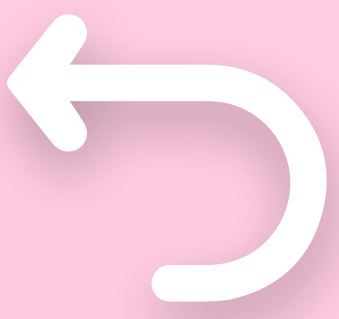
- Use: Off-Label: Adult: Acne vulgaris, moderate; Cutaneous T-cell lymphomas; Squamous cell skin cancer (prevention in high-risk patients)





# Mechanism Of Action

Isotretinoin is an orally administered systemic retinoid. At a pharmacologic strength of 0.5 to 1.0 mg/kg per day, isotretinoin is an effective acne therapy. While the exact mechanism of action is unknown, isotretinoin inhibits sebaceous gland function and keratinization at pharmacologic doses. The drug has been observed to reduce both the sebaceous gland size and sebum production.



# Adverse Effects

- Bone and growth effects  
Data are conflicting, but decreased bone mineral density (Ref), osteopenia, osteoporosis, bone fracture, and delayed healing of bone fractures have been reported (Ref). Premature epiphyseal closure has been reported (Ref).
- Ocular effects  
Visual disturbance, night blindness, dry eye syndrome, eye irritation, and conjunctivitis have been reported in 10% to 70% of patients.



# Adverse Effects

- Hepatic effects  
Clinical hepatitis and mild to moderate increased liver enzymes have been reported in ~15% of patients receiving isotretinoin. Reversibility back to baseline has been demonstrated within 4 weeks of discontinuation.
- Pseudotumor cerebri  
Rare and reversible pseudo tumor cerebri (idiopathic intracranial hypertension) has been documented in case reports and in large scale adverse drug reporting systems.

&lt;

2

&gt;



# Adverse Effects

- Hypertriglyceridemia and pancreatitis  
Increased serum triglycerides occur in ~5% to 25% of patients receiving isotretinoin. Rare and potentially fatal acute pancreatitis may occur in patients with normal or elevated triglyceride levels. Case reports in adolescents and adults have demonstrated reversibility upon discontinuation.



# Adverse Effects

- Musculoskeletal effects  
Common and potentially fatal musculoskeletal symptoms (arthralgia, myalgia, and rhabdomyolysis) have been reported in pediatric and adult patients; generally, symptoms were mild to moderate but occasionally required discontinuation of therapy.

# Adverse Effects

- Psychiatric effects  
While data are conflicting, isotretinoin may cause depression, psychosis, mood disturbance, and rarely, suicidal ideation, suicidal tendencies, death by suicide, aggressive behavior, and/or violent behavior. Symptoms often resolve with therapy discontinuation.

&lt;

5

&gt;





# Adverse Effects

- Cutaneous/hypersensitivity reactions

Cutaneous adverse reactions associated with isotretinoin range from mucocutaneous effects such as cheilitis, xeroderma, dry eye syndrome, conjunctivitis, blepharitis, and episcleritis (Ref) to cases of erythema nodosum, pityriasis rosea-like eruptions, pyogenic granuloma, acne fulminans, skin photosensitivity, and pyoderma gangrenosum.

# Adverse Effects

- Hypersensitivity reactions have also been reported, including immediate (anaphylaxis, angioedema) and delayed reactions (Stevens-Johnson syndrome [SJS], toxic epidermal necrolysis, erythema multiforme-like drug eruption, acute generalized exanthematous pustulosis [AGEP], allergic vasculitis, and allergic myocardial infarction). Inflammatory sacroiliitis has also been described with isotretinoin, in association with a HLA-B27 negative antigen.



# Articles

Leaflet



Guidelines of care for the management of acne vulgaris



Efficacy and Adverse Events of Oral Isotretinoin for Acne: A Systematic Review



Efficacy and safety of systemic isotretinoin treatment for moderate to severe acne



Isotretinoin treatment for acne and risk of depression: A systematic review and meta-analysis



Oral isotretinoin for acne: a complete overview



# Contact Us



+98 21 88 17 4810



tasnimpharmaceutical



tasnimpharma.com



info@tasnimpharma.com



NO. 3 , 14th East Alley ,  
Beyhaghi Blvd. , Argentina Sq. ,  
Tehran , Iran

TAP FOR DIRECTIONS 



# GUIDE

If you have confliotions while interacting with this catalog, this guide will help you.

If you are using iPhone, Mac OS or Windows, you probably won't have any problem with the buttons.

But if you are using an Android device, you must have [Google Drive](#) installed and updated.

In the next steps you'll see the frequently used buttons that are important.

SKIP

NEXT STEP

Problem with buttons? [View Guide](#)





Here you can see the navigation bar which is fixed on left in the document.

# Normskin®

ERX (Normskin 20 mg) : 61796

ERX (Normskin 10 mg) :

Drug Brand | Normskin

You can tap on each of these icons to navigate to its page.

Generic Name | Isotretinoin

Drug form | 20 mg, 10 mg

Package | 30 soft gelatin capsules in 3 blister pack in 1 box

SKIP

NEXT STEP

Problem with buttons? [View Guide](#)





Tap this icon to go back to previous page or menu.

# Normskin®

ERX (Normskin 20 mg) : 61796

ERX (Normskin 10 mg) :

Drug Brand

Normskin

GO BACK TO THE CATALOG

Drug form

20 mg, 10 mg

Tap this icon to go to the next page.

Package

soft gelatin capsules  
in 3 blister pack in 1 box

Start Exploring

Problem with buttons? [View Guide](#)

